



This prospectus (this **Prospectus**) relates to the initial offering (the **Offering**) by Hyloris Pharmaceuticals SA (the **Issuer**, and together with its subsidiaries, **Hyloris** or the **Company**), a public limited liability company organized under the laws of Belgium ("*société anonyme*" / "*naamloze vennootschap*"), registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0674.494.151, and with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium), of up to 5,000,000 new shares, without nominal value, of the Issuer, within a price range between EUR 10.00 and EUR 11.50 per new share (the **Price Range**). The Offer Price (as defined below) may be set within the Price Range or below the lower end of the Price Range, but will not exceed the higher end of the Price Range.

**An investment in the Offered Shares involves significant risks and uncertainties. Prospective investors must read this entire Prospectus, and, in particular, should read Section 2 (Risk Factors) for a discussion of certain factors that should be considered in connection with an investment in the Offered Shares, including the risks relating to the fact that (i) Hyloris has a limited operating history and has not yet generated any substantial revenues. Hyloris has incurred operating losses, negative operating cash flows and an accumulated deficit since inception resulting in a negative equity at the date of this Prospectus and Hyloris may not be able to achieve or subsequently maintain profitability. Hyloris is executing its strategy in accordance with its business model, the viability of which has not been demonstrated, (ii) Hyloris' performance depends primarily on the success of its product candidates, a majority of which are in the early reformulation development stage and have not yet received FDA approval of the 505(b)(2) application or ANDA or the other approvals required before they may be commercially launched, (iii) even if Hyloris receives regulatory approval for any of its product candidates, it may be unable to launch the product successfully and the revenue that Hyloris generates from sales of such product, if any, may be limited, (iv) Hyloris has entered into arrangements with related parties and these arrangements present potential conflicts of interest, (v) certain of Hyloris' directors and members of Hyloris' executive management hold directorships or shareholdings in other pharmaceutical companies, which could create potential conflicts of interest, and (vi) after closing of the Offering, certain significant shareholders of the Issuer may have different interests from the Issuer and/or from the minority shareholders and may be able to control the Issuer, including the outcome of shareholder votes. Every decision to invest in the Offered Shares must be based on all information provided in this Prospectus. Potential investors must be able to bear the economic risk of an investment in the Offered Shares and to undergo a full or partial loss of their investment.**

**This Prospectus is valid until 15 June 2021. Any significant new factor, material mistake or material inaccuracy relating to the information included in this Prospectus which may affect the assessment of the Shares and arises or is noted between the date of approval of this Prospectus and the time of closing of the Offering Period (as defined hereafter) or the Listing Date (as defined hereafter), whichever occurs later, must be mentioned in a supplement to this Prospectus. The obligation to supplement a prospectus in the event of significant new factors, material mistakes or material inaccuracies does not apply when a prospectus is no longer valid.**

The aggregate number of new shares offered in the Offering may be increased by up to 15% of the aggregate number of new shares initially offered to a number of 5,750,000 new shares (the **Increase Option**, and the new shares initially offered and the shares offered as a result of the possible exercise of the Increase Option are collectively being referred to as the **New Shares**, and each existing or future new share representing the Issuer's share capital, as a **Share**). Any decision to exercise the Increase Option will be communicated, at the latest, on the date of the announcement of the Offer Price (as defined below).

In connection with the Offering, KBC Securities NV/SA will, on behalf of the Underwriters (as defined herein), act as stabilization manager (the **Stabilization Manager**). In order to facilitate stabilization by the Stabilization Manager, if any, the Stabilization Manager will be able to over-allot Shares in the Offering (the **Additional Shares**, together with the New Shares, the **Offered Shares**). To enable the Stabilization Manager to cover the placement of Additional Shares in the Offering, if any, or short positions created by such over-allotment, it is expected that the Stabilization Manager will be granted a warrant to subscribe for additional new Shares in a number equal to up to 15% of the number of New Shares subscribed for in the Offering (i.e., including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offer Price (as defined below) (the **Over-allotment Option**). The Over-allotment Option will be exercisable for a period of 30 calendar days following the Listing Date (as defined below). The Stabilization Manager, acting on behalf of the Underwriters, may engage in transactions that stabilize, maintain or otherwise affect the price of the Shares during a period of 30 calendar days following the Listing Date (the **Stabilization Period**). These activities may support the market price of the Shares at a level higher than that which might otherwise prevail.

The Offering consists of: (i) an offer to the public (as defined in Article 2(d) of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC (the **Prospectus Regulation**)) in Belgium; (ii) a private placement in the European Economic Area (the **EEA**) (other than in Belgium) pursuant to applicable exemptions under the Prospectus Regulation, including but not limited to "qualified investors" within the meaning of Article 2(e) of the Prospectus Regulation; (iii) a private placement in the United States to persons who are reasonably believed to be "qualified institutional buyers" (**QIBs**) as defined in Rule 144A (**Rule 144A**) under the U.S. Securities Act of 1933, as amended (the **U.S. Securities Act**), in reliance on Rule 144A; and (iv) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world. All aforementioned "qualified investors" and QIBs are collectively being referred to as **Institutional Investors**. The Offering outside the United States will be made in compliance with Regulation S under the U.S. Securities Act (**Regulation S**).

No minimum amount is set for the Offering. A number of investors (including members of the Board of Directors and the Executive Management) (the **Participating Investors**), have (in the aggregate) (i) subscribed for 303 automatically convertible bonds, with a principal amount per unit of EUR 50,000, for a total aggregate amount of EUR 15,150,000, at a yearly interest rate of 6.00% (the **Convertible Bonds**); and (ii) committed themselves vis-à-vis the Issuer to irrevocably and conditional only on completion of the Offering, subscribe for New Shares in the Offering for a total amount of EUR 22,725,000 (the **Pre-commitments**). The Convertible Bonds have been issued in two tranches, on 31 March 2020 and on 30 April 2020 respectively. In the event the Offering is oversubscribed, a maximum of one third of the Pre-commitments of each individual Participating Investor (i.e., EUR 7,575,000 in the aggregate) can be reduced in line with the allocation principles that apply in the context of the Offering, whereas a minimum of two thirds of the Pre-commitments of each individual Participating Investor (i.e., EUR 15,150,000 in the aggregate) will not be reduced but will be allocated entirely to the relevant Participating Investor. See Section 14.3 (Pre-commitments) for further information. As there is no minimum amount of the Offering, if not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited to the net proceeds from the Pre-commitments.

The completion of the Offering will result in the automatic conversion of all outstanding Convertible Bonds (for their full outstanding principal amount, increased, if requested by the Issuer (which it intends to do), by all or part of any unpaid interests due) in new Shares, at the Offer Price less a discount of 30%. The Issuer believes this discount is justified in the light of the risk assumed by the Participating Investors by making the Pre-commitments. See Section 13.6 (Convertible Bonds) for further information.

The Shares have not been and will not be registered under the U.S. Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act. Prospective purchasers are hereby notified that sellers of the Shares may be relying on the exemption from the provisions of Section 5 of the U.S. Securities Act provided by Rule 144A. For a description of certain restrictions on transfer of the Shares, see Section 16 (Transfer restrictions).

This Prospectus does not constitute, and neither the Issuer nor the Underwriters are making, an offer to sell the Offered Shares or soliciting an offer to purchase any of the Offered Shares to any person in any jurisdiction where such an offer or solicitation is not permitted. The Offered Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other Offering related documents may be distributed or sent to any person or into any jurisdiction, except in circumstances that will result in the compliance with all applicable laws and regulations. Persons into whose possession this Prospectus may come are required to inform themselves about, and to observe all, such restrictions. Neither the Issuer nor the Underwriters accept any responsibility for any violation by any person, whether or not it is a prospective purchaser of Offered Shares, of any such restriction.

The offering period will begin at 9:00 (CEST) on 17 June 2020 and is expected to end no later than 13:00 (CEST) on 26 June 2020, subject to early closing or extension, provided that the offering period will in any event be open for at least six business days (the **Offering Period**). However, in accordance with the possibility provided for in art. 3, § 2 of the Royal Decree of May 17, 2007 on primary market practices, the Issuer expects the Offering Period for the Retail Investors to end on 25 June 2020 at 16:00 (CEST), *i.e.*, the day before the end of the institutional bookbuilding period, due to the timing and logistical constraints associated with the centralization of the subscriptions placed by retail investors with the Underwriters and with other financial institutions. Any extension or early closing of the Offering Period will be announced by means of a press release by the Issuer, and the respective dates for pricing, allocation, publication of the Offer Price and the results of the Offering, "as-if-and-when-issued-and/or-delivered" trading and closing of the Offering will in such case be adjusted accordingly.

The price per Offered Share (the **Offer Price**) will be determined during the Offering Period through a book-building process in which only Institutional Investors may participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time. See Section 14.5 (Offer Price) for further information.

The Offer Price, the number of Offered Shares placed in the Offering and the allocation of Offered Shares to Retail Investors (as defined in Section 14.8.1 (Retail Investors)) is expected to be made public on or about 26 June 2020 and in any event no later than the first business day after the end of the Offering Period. The Offer Price will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, and of costs, if any, charged by financial intermediaries for the submission of applications.

Prior to the Offering, there has been no public market for the Shares. An application has been made to admit all of the Issuer's (i) existing Shares, (ii) the newly issued Offered Shares, (iii) the new Shares that will be issued upon conversion of the Convertible Bonds, (iv) the new Shares (if any) that will be issued pursuant to the exercise of the Over-allotment Option and (v) the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, to trading on the regulated market of Euronext Brussels under the symbol "HYL", and will be allocated the ISIN code BE0974363955. Trading on the regulated market of Euronext Brussels is expected to commence, (i) for the existing Shares and the newly issued Offered Shares: on an "if-and-when-issued-and/or-delivered" basis, on or about 29 June 2020 (the **Listing Date**), provided that this may be accelerated in the event of early closing or postponed in case of extension, and will start at the latest on the Closing Date, when the Offered Shares are delivered to investors, (ii) for the new Shares that will be issued upon conversion of the Convertible Bonds: on the Closing Date, (iii) for the new Shares (if any) that will be issued pursuant to the exercise of the Over-allotment Option: on or about the date of their issuance and (iv) for the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants and the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021: on or about the date of their issuance.

All Offered Shares will be delivered in dematerialized (book-entry) form only, and will be credited on or around the Closing Date to investors' securities accounts via Euroclear Belgium, and will be registered by one or more registrations in the share register of the Issuer in the name of Euroclear Belgium. By way of exception to the foregoing, the New Shares that will be issued to Participating Investors pursuant to the Pre-commitments (except if the Participating Investor that has an existing client relationship and securities account with KBC Bank NV/SA or CBC Banque SA/NV or Van Lanschot Kempen Wealth Management N.V. and has opted to have such New Shares delivered in dematerialized (book-entry) form and credited on such securities account), will be delivered in registered form on or about their issuance. It is expected that the Offered Shares will be delivered to the investors on or about 30 June 2020, against payment therefore in immediately available funds on or about 30 June 2020, provided that this may be accelerated in the event of early closing or postponed in case of extension (the **Closing Date**). See Section 14 (Information on the Offering).

This document constitutes an offer (in relation to the Offered Shares) and listing (in relation to (i) the existing Shares, (ii) the newly issued Offered Shares, (iii) the new Shares that will be issued upon conversion of the Convertible Bonds, (iv) the new Shares (if any) that will be issued pursuant to the exercise of the Over-allotment Option and (v) the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021) prospectus for purposes of Article 3(1), respectively 3(3) of the Prospectus Regulation and has been prepared in accordance with the Prospectus Regulation. In particular, this Prospectus has been drawn up in accordance with Annex 1 and Annex 11 of the Commission Delegated Regulation (EU) No 2019/980 of 14 March 2019 supplementing Regulation (EU) 2017/1129 of the European Parliament and of the Council as regards the format, content, scrutiny and approval of the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Regulation (EC) No 809/2004 (the **Delegated Regulation 2019/980**) and the key financial information contained in the summary of this Prospectus (the **Summary**) was prepared in accordance with Annex 1 to Commission Delegated Regulation (EU) 2019/979 of 14 March 2019 supplementing Regulation (EU) 2017/1129 of the European Parliament and of the Council with regard to regulatory technical standards on key financial information in the summary of a prospectus, the publication and classification of prospectuses, advertisements for securities, supplements to a prospectus, and the notification portal, and repealing Delegated Regulation (EU) No 382/2014 and Commission Delegated Regulation (EU) No 2016/301 (the **Delegated Regulation 2019/979**) and together with the Delegated Regulation 2019/980 the **Delegated Regulations**). In accordance with Article 20 of the Prospectus Regulation, the English language version of this Prospectus (including the Summary) was approved by the Belgian Financial Services and Markets Authority (the **FSMA**) on 16 June 2020, as competent authority under the Prospectus Regulation. The FSMA only approves this Prospectus (including the Summary) as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval should not be considered as an endorsement of the Issuer or the quality of the Offered Shares that are the subject of this Prospectus. Investors should make their own assessment as to the suitability of investing in the Offered Shares.

This Prospectus and the Summary may be distributed separately. This Prospectus was drafted in English and translated into French. The Summary was drafted in English and translated into French and Dutch. The Issuer is responsible for the consistency of the French translation of this Prospectus and the French and Dutch translations of the Summary with the approved English versions thereof. Without prejudice to the responsibility of the Issuer for the translation of this Prospectus and the Summary, if there is an inconsistency between the different language versions, the language version approved by the FSMA (being the English version) shall prevail. If there is an inconsistency between this Prospectus and the Summary, this Prospectus shall prevail over the Summary.

This Prospectus and the Summary shall be made available to investors free of charge as of 17 June 2020 (before opening of the markets) at the registered office of the Issuer (Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium)). This Prospectus and the Summary shall also be made available free of charge to investors at (i) KBC Bank NV/SA, CBC Banque SA/NV, Bolero and KBC Securities NV/SA, upon request by phone 078 152 153 (KBC Bank NV/SA & CBC Banque SA/NV) and 0800 628 16 (Bolero Orderdesk) and on its websites [www.kbc.be/hyloris](http://www.kbc.be/hyloris), [www.bolero.be/nl/hyloris](http://www.bolero.be/nl/hyloris) and [www.kbcsecurities.com](http://www.kbcsecurities.com) This Prospectus can also be consulted as of 17 June 2020 (before opening of the market) on the website of the Issuer ([www.hyloris.com](http://www.hyloris.com)), whereby the access on the aforementioned websites is each time subject to the usual limitations.

**Joint Global Coordinators & Joint Bookrunners**



16 June 2020

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**Hyloris Pharmaceuticals SA**  
Public limited liability company organized under the laws of Belgium  
with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium)  
registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0674.494.151  
(the **Issuer**, and together with its subsidiaries **Hyloris** or the **Company**)

**SUMMARY OF THE PROSPECTUS DATED 16 JUNE 2020 REGARDING THE (I) INITIAL PUBLIC OFFERING IN BELGIUM; (II) PRIVATE PLACEMENT WITHIN THE EUROPEAN ECONOMIC AREA (OTHER THAN BELGIUM) PURSUANT TO APPLICABLE EXEMPTIONS UNDER THE PROSPECTUS REGULATION; (III) PRIVATE PLACEMENT IN THE UNITED STATES TO PERSONS WHO ARE REASONABLY BELIEVED TO BE “QUALIFIED INSTITUTIONAL BUYERS” (QIBS) AS DEFINED IN RULE 144A UNDER THE U.S. SECURITIES ACT, IN RELIANCE ON RULE 144A; AND (IV) PRIVATE PLACEMENTS TO CERTAIN QUALIFIED AND/OR INSTITUTIONAL INVESTORS UNDER APPLICABLE LAWS OF THE RELEVANT JURISDICTION IN THE REST OF THE WORLD, OF UP TO 5,000,000 NEW SHARES, WITHOUT NOMINAL VALUE, OF THE ISSUER, WITHIN A PRICE RANGE BETWEEN EUR 10.00 AND EUR 11.50 PER NEW SHARE**

**APPLICATION FOR ADMISSION TO TRADING OF ALL SHARES IN THE ISSUER ON THE REGULATED MARKET OF EURONEXT BRUSSELS**

**A. INTRODUCTION AND WARNINGS**

**1. INTRODUCTION**

Name and international securities identification number	Share HYL, with ISIN code BE0974363955.
Identity and contact details of the Issuer	Hyloris Pharmaceuticals SA, a public limited liability company organized under the laws of Belgium (“société anonyme” / “naamloze vennootschap”) with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium), registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0674.494.151 and with 875500LZIWS7QE0173 as Legal Entity Identifier (LEI). The Issuer’s telephone number is: +32 (0)4 346 02 07.
Competent authority	Belgian Financial Services and Markets Authority (FSMA), Congressstraat 12-14, 1000 Brussels. Its telephone number is +32 (0)2 220 52 11.
Date of approval of the Prospectus	In accordance with Article 20 of the Prospectus Regulation, the English language version of the Prospectus (including this Summary) was approved by the FSMA on 16 June 2020, as competent authority under the Prospectus Regulation.

Unless determined otherwise in this Summary, the terms used herein that are written with a capital, have the same meaning as defined in the Prospectus.

**2. WARNINGS**

This summary should be read as an introduction to the Prospectus. Any decision to invest in the Offered Shares should be based on a consideration of the Prospectus as a whole by the investor. The investor could lose all or part of the invested capital. Where a claim relating to the information is brought before a court, the plaintiff investor might, under the national legislation of the member states of the EU, have to bear the costs of translating this Prospectus before the legal proceedings are initiated.

Civil liability attaches only to those persons who have tabled this Summary including any translation thereof, but only where this Summary is misleading, inaccurate or inconsistent when read together with the other parts of the Prospectus, or where it does not provide, when read together with the other parts of the Prospectus, key information in order to aid investors when considering whether to invest in the Offered Shares.

**B. KEY INFORMATION ON THE ISSUER**

**1. WHO IS THE ISSUER OF THE OFFERED SHARES**

**Identification** – The Issuer was incorporated as a limited liability company (“société à responsabilité limitée”) organized under the laws of the Grand Duchy of Luxembourg with the name “EVERBRIGHT s.à r.l.” and registered in the Luxembourg Business Register (“Registre de Commerce et des Sociétés de Luxembourg”) under number B 149.546. Since 31 March 2017, Hyloris Pharmaceuticals SA, is a public limited liability company organized under the laws of Belgium (“société anonyme” / “naamloze vennootschap”) with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium), registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0674.494.151 and with 875500LZIWS7QE0173 as Legal Entity Identifier (LEI).

**Principal activities** – Hyloris is an early-stage innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. The Company develops proprietary products it believes offer significant advantages compared to currently available alternatives, with the aim of addressing the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders in the healthcare system. Hyloris’ development strategy focuses on the FDA’s 505(b)(2) regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule has already been established. As compared to traditional New Drug Applications (NDAs) using the FDA’s 505(b)(1) regulatory pathway, the 505(b)(2) regulatory pathway can reduce the clinical burden required to bring a product to the market, significantly shortening the development timelines and reduce costs and risks. Hyloris’ portfolio has a particular focus on IV cardiovascular products, but it also contains other reformulation products and established market products.

The Company is continuously evaluating new development candidates to add to its portfolio, both internally and externally. Hyloris intends to primarily focus on the U.S. market for the commercialization of its product candidates. The high user awareness of the reference listed drugs in the United States and the intended added value to the U.S. healthcare system are expected to facilitate a fast market adoption of Hyloris’ products in the United States. To date, Hyloris’ operations have consisted primarily of the identification of product candidates to build its pipeline and the formulation, testing and development of its existing portfolio. As of the date of this Summary, Hyloris has established a diversified portfolio of two early stage commercial products and 12 product candidates in various stages of development (which has been initiated prior to 2020 for all product candidates).

**Major shareholders** – At the date of this Summary, the following parties are the shareholders of the Issuer that hold 3% or more of the total currently outstanding Shares in the Issuer (i.e., 17,801,768 Shares):

Principal shareholders	Shares owned before the closing of the Offering		Warrants <sup>(1)</sup> owned before the closing of the Offering		Convertible Bonds <sup>(2)</sup> owned before the closing of the Offering		Options on 198,948 existing Shares owned before the closing of the Offering	
	Number (#)	Pct. (%) <sup>(3)</sup>	Number (#)	Pct. (%) <sup>(4)</sup>	Principal amount (€)	Pct. (%) <sup>(5)</sup>	Number (#)	Pct. (%) <sup>(6)</sup>
Mr. Stijn Van Rompay (CEO) <sup>(7)</sup>	6,438,064	36.17%	920,096 <sup>(8)</sup>	60.02%	€ 1,000,000	6.60%	132,619 <sup>(9)</sup>	0.74%
Mr. Thomas Jacobsen (Executive director) <sup>(10)</sup>	3,437,760	19.31%	163,512 <sup>(11)</sup>	10.67%	-	-	66,329 <sup>(12)</sup>	0.37%
Mr. Nick Reunbrouck (brother in-law of Mr. Stijn Van Rompay)	1,610,184	9.05%	-	-	-	-	-	-
Mr. Pieter Van Rompay (brother of Mr. Stijn Van Rompay)	915,000	5.14%	60,244 <sup>(13)</sup>	3.93%	-	-	-	-

- Notes**
- (1) Transaction Warrants and ESOP Warrants, in terms of the number of new Shares issued upon their exercise. Each Transaction Warrant entitles its holder to subscribe for 4 new Shares at a subscription price per new Share of EUR 2.3597, and each ESOP Warrant entitles its holder to subscribe for one new Share at a subscription price per new Share of EUR 5.3375.
- (2) See below for more information on the Convertible Bonds.
- (3) Percentage of all existing Shares before the closing of the Offering on a non-diluted basis, i.e., 17,801,768 Shares.
- (4) Percentage of Shares to be issued upon exercise of all outstanding Transaction Warrants and ESOP Warrants (taken together) before the closing of the Offering.
- (5) Percentage of the aggregate principal amount of all Convertible Bonds before the closing of the Offering.
- (6) Percentage of all existing Shares before the closing of the Offering on a non-diluted basis
- (7) Acting through SVR Management BV. All securities listed are held by Mr. Stijn Van Rompay.
- (8) Shares to be issued upon exercise of 68,000 ESOP Warrants (which will start have fully vested as of 1 January 2024) and 213,024 Transaction Warrants.
- (9) Pursuant to the Call Option.
- (10) Acting through Jacobsen Management BV. All securities listed are held by Mr. Thomas Jacobsen.
- (11) Which are all new Shares to be issued upon exercise of Transaction Warrants.
- (12) Pursuant to the Call Option.
- (13) Which are all new Shares to be issued upon exercise of Transaction Warrants

As of the date of this Summary, the Issuer is not being controlled in the sense of Article 1:14 CCA.

A number of investors (including members of the Board of Directors and the Executive Management) (the **Participating Investors**), have committed themselves vis-à-vis the Issuer to irrevocably and conditionally only on completion of the Offering, subscribe for New Shares in the Offering for a total aggregate amount of EUR 22,725,000 (the **Pre-commitments**). These Participating Investors have also subscribed (in the aggregate) for 303 automatically convertible bonds, with a principal amount per unit of EUR 50,000, for a total aggregate amount of EUR 15,150,000, at a yearly interest rate of 6.00% (the **Convertible Bonds**). The completion of the Offering will result in the automatic conversion of all outstanding Convertible Bonds (for their full outstanding principal amount, increased, if requested by the Issuer (which it intends to do), by all or part of any unpaid interests due) in new Shares, at the Offer Price less a discount of 30%. The Issuer believes this discount is justified in the light of the risk assumed by the Participating Investors by making the Pre-commitments.

The table below gives an overview of the individual amounts of the Pre-commitments of each Participating Investor:

Participating Investor	Amount Pre-commitment (€)	New Shares pursuant to the Pre-commitment <sup>(1)</sup>	# Convertible Bonds	Total Principal Amount of Convertible Bonds (€)	New Shares following conversion <sup>(2)</sup>
Scorpiaux SRL	6,000,000	558,139	80 <sup>(3)</sup>	4,000,000	539,600
NOSHAQ SA	2,400,000	223,255	32 <sup>(4)</sup>	1,600,000	214,784
Saffelberg Investments SA	2,400,000	223,255	32 <sup>(3)</sup>	1,600,000	215,840
Jean-Claude Marian	1,500,000	139,534	20 <sup>(3)</sup>	1,000,000	134,900
Nomalinvest SA	1,500,000	139,534	20 <sup>(4)</sup>	1,000,000	134,240
Dirk Van Praag	1,500,000	139,534	20 <sup>(3)</sup>	1,000,000	134,900
Stijn Van Rompay	1,500,000	139,534	20 <sup>(4)</sup>	1,000,000	134,240
TrustCapital SA	1,125,000	104,651	15 <sup>(4)</sup>	750,000	100,680
GIPAR SA	600,000	55,813	8 <sup>(3)</sup>	400,000	53,960
Atlantis Invest SRL	450,000	41,860	6 <sup>(3)</sup>	300,000	40,470
Thojo BM	450,000	41,860	6 <sup>(3)</sup>	300,000	40,470
Arno Verhoeven	450,000	41,860	6 <sup>(3)</sup>	300,000	40,470
Marc Corluy	300,000	27,906	4 <sup>(3)</sup>	200,000	26,980
Koen Matthijs	300,000	27,906	4 <sup>(3)</sup>	200,000	26,980
Dirk Vandeputte	300,000	27,906	4 <sup>(3)</sup>	200,000	26,980
Peter Hellings	225,000	20,930	3 <sup>(3)</sup>	150,000	20,235
Ludo and Ria Schellens-Brullemans	225,000	20,930	3 <sup>(3)</sup>	150,000	20,235
Pierre-Yves André	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Johan De Meester	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Joris De Meester	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Fiduciam	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Bart Roscam	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Sediaal SA	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Koenraad Van der Elst	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Stefan Vandeputte	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Serge Vermeersch	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
Inge Weyns-Verlinden	150,000	13,953	2 <sup>(3)</sup>	100,000	13,490
<b>Total</b>	<b>22,725,000</b>	<b>2,113,937</b>	<b>303</b>	<b>15,150,000</b>	<b>2,040,864</b>

- Notes:**
- (1) Assuming the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75, the conversion takes place immediately after closing of the Offering and that the principal amount, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date, (included), is converted.
- (2) Assuming full allocation of the Pre-commitment and assuming the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75.
- (3) Convertible Bonds issued in principle on 31 March 2020 and subscribed for on 31 March 2020, bearing interest as of 31 March 2020 (included).
- (4) Convertible Bonds issued in principle on 31 March 2020 and subscribed for on 30 April 2020, bearing interest as of 30 April 2020 (included).

**Board of Directors** – The Board of Directors of the Issuer consists of seven members: (i) Mr. Stefan Yee (non-executive director and chairperson), (ii) Mr. Stijn Van Rompay (CEO, acting through SVR Management BV), (iii) Mr. Thomas Jacobsen (executive director, acting through Jacobsen Management BV), (iv) Mr. Leon Van Rompay (non-executive director, acting through Van Rompay Management NV), (v) Mr. Marc Foidart (independent director, acting through Noshag Partners SCRL), (vi) Ms. Carolyn Myers (independent director), and (vii) James Gale (independent director).

**Statutory auditor** – KPMG Réviseurs d'Entreprises SCRL, with registered office at Luchthaven Brussel Nationaal 1K, 1930 Zaventem (Brussels), has been appointed as Statutory Auditor of the Issuer on 31 December 2019 for a period of three years. The mandate will expire at the end of the general meeting called to approve the accounts for the 2021 financial year. KPMG Réviseurs d'Entreprises SCRL has designated Mr. Olivier Declercq (IRE No. A02076), "réviseur d'entreprises", as permanent representative. KPMG Réviseurs d'Entreprise SCRL is a member of the Belgian Institute of Certified Auditors ("Institut des Réviseurs d'Entreprises" / "Instituut van de Bedrijfsrevisoren") (membership number B00001).

## 2. WHAT IS THE KEY FINANCIAL INFORMATION REGARDING THE ISSUER?

### Selected financial information

The following tables set out the selected key consolidated historical financial information of Hyloris as at the dates and for the periods indicated. Unless indicated

otherwise, the figures set forth in the below table are in EUR thousands.

	31/12/2019	31/12/2018	31/12/2017	31/03/2020	31/03/2019
<b>Income Statement</b>					
Total revenue	91	91	213	63	40
Gross profit	111	26	135	44	18
Research and Development expenses	(4,577)	(4,870)	(2,313)	(784)	(443)
General and administrative expenses	(808)	(622)	(1,657)	(523)	(136)
Operating loss	(5,274)	(5,469)	(3,866)	(1,264)	(561)
Financial income/(expenses)	(508)	(590)	83	(316)	(124)
Loss for the period	(5,768)	(6,039)	(3,717)	(1,580)	(685)
Earning per share	(1.49)	(1.71)	(1.27)	(0.36)	(0.16)
<b>Balance Sheet</b>					
Intangible assets	2,138	3,949	3,825	2,374	N/A
Cash and cash equivalent	205	2,687	271	11,213	N/A
Total Assets	5,983	7,948	4,365	20,493	N/A
Total Equity	(10,188)	(4,462)	(4,286)	(8,425)	N/A
Non-current liabilities	22	9,309	6,781	10,682	N/A
Current liabilities	16,149	3,101	1,870	18,235	N/A
Total Equity and Liabilities	5,983	7,948	4,365	20,493	N/A
Net Financial Debt	12,991	6,674	6,530	15,624	N/A
<b>Cash Flow Statement</b>					
Net cash generated from operating activities	(4,562)	(5,368)	(1,616)	(2,444)	(675)
Net cash generated from investing activities	(1,228)	19	(2,736)	(240)	(32)
Net cash generated from financing activities	3,308	7,765	4,398	13,691	533

**Other financial information** – No pro forma financial information is provided in the Prospectus. There are no qualifications to the audit report on the historical financial information.

### 3. WHAT ARE THE KEY RISKS THAT ARE SPECIFIC TO THE ISSUER?

#### **Risks related to Hyloris' business activities and industry:**

- *Hyloris has a limited operating history, and has not yet generated any substantial revenues. Hyloris has incurred operating losses, negative operating cash flows and an accumulated deficit since inception resulting in a negative equity at the date of the Summary and Hyloris may not be able to achieve or subsequently maintain profitability. Hyloris is executing its strategy in accordance with its business model, the viability of which has not been demonstrated.*
- *Hyloris' performance depends primarily on the success of its product candidates, a majority of which are in the early reformulation development stage and have not yet received FDA approval of the 505(b)(2) application or ANDA or the other approvals required before they may be commercially launched.*
- *Even if Hyloris receives regulatory approval for any of its product candidates, it may be unable to launch the product successfully and the revenue that Hyloris generates from sales of such product, if any, may be limited.*
- *Hyloris has entered into arrangements with related parties and these arrangements present potential conflicts of interest.*
- *Certain of Hyloris' directors and members of Hyloris' Executive Management hold directorships or shareholdings in other pharmaceutical companies, which could create potential conflicts of interest.*
- *Hyloris may be unable to successfully manage its growth.*
- *Despite receiving regulatory approval for a product candidate, competitors may receive regulatory approval for a product that is identical or substantially the same as one of Hyloris' product candidates, which may prevent Hyloris from commercializing its product candidates in accordance with its business plan or result in significant delays in doing so.*
- *Because the sector of the pharmaceutical market that Hyloris is targeting is open to greater competition than the market for new drug formulations and new pharmaceutical products, Hyloris' business is dependent on the continuous generation of new ideas and the development of new product candidates.*
- *Hyloris relies and expects to continue to rely in large part on the know-how of its development partners and, in particular, the know-how of its development partner with respect to its IV Cardiovascular Portfolio and it also relies on the know-how of its partners for the development and expansion of its portfolio.*
- *The occurrence of a pandemic, epidemic or other health crisis, including the recent outbreak of COVID-19, could have a negative impact on Hyloris' product development activities, including its access to APIs, the conduct of its clinical trials and its ability to source required funding, which could delay or prevent it from executing its strategy as planned.*
- *Hyloris currently has no sales and marketing function and it will be required to develop one in order to execute its strategy with respect to its IV Cardiovascular Portfolio in the United States and to secure suitable sales and marketing partners for its other products. If Hyloris is unable to do so, it may not successfully commercialize any of its product candidates.*
- *Hyloris will be completely dependent on third parties to supply APIs and manufacture its products, and commercialization of Hyloris' product candidates could be delayed, halted or made less profitable if those third parties fail to obtain and maintain the required approvals from the FDA or comparable foreign regulatory authorities, or otherwise fail to provide Hyloris with sufficient quantities of its products.*

### C. KEY INFORMATION ON THE SECURITIES

#### 1. WHAT ARE THE MAIN FEATURES OF THE SECURITIES

An application has been made to admit (i) all of the Issuer's existing Shares, (ii) the newly issued Offered Shares, (iii) the new Shares that will be issued upon conversion of the Convertible Bonds, (iv) the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment

Option, and (v) the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, to trading on the regulated market of Euronext Brussels under the symbol "HYL", and will be allocated the ISIN code BE0974363955.

**Rights attached to the Shares** – All New Shares, as well as the new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants, will be issued in euro, in accordance with Belgian law and will be ordinary shares representing the capital, of the same class as the existing Shares, fully paid up, with voting rights and without nominal value. They will have the same rights as the existing Shares. All Offered Shares, as well as the new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the ESOP Warrants, will be profit sharing as from any distribution in respect of which the relevant ex-dividend date falls after the date of their issuance. The new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants will entitle their holder to the dividend distributed in the financial year during which the relevant Transaction Warrants are exercised, even if the dividend was declared or has been paid prior to the issuance of such new Shares.

**Seniority** – All Shares represent an equal part of the Issuer's share capital and have the same rank in the event of insolvency of the Issuer.

**Restrictions on the free transferability of the Shares** – Subject to the general restrictions relating to the Offering and the distribution of the Prospectus (including this Summary) and the specific lock-up restrictions to which the Issuer, the Issuer's existing shareholders, the Issuer's current warrant holders, and the Participating Investors, have committed themselves in the context of the Offering, there is no restriction on the free transferability of the Shares, other than those applicable by operation of law.

**Dividend policy** – The Issuer has not declared or paid dividends on its Shares in the past. In the future, the Issuer's dividend policy will be determined and may change from time to time by determination of the Issuer's Board of Directors. Any declaration of dividends will be based upon the Issuer's earnings, financial condition, capital requirements and other factors considered important by the Board of Directors. Belgian law and the Issuer's Articles of Association do not require the Issuer to declare dividends. Currently, the Board of Directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future. As a consequence of all of these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future nor, if they are paid, as to their amount.

## 2. WHERE WILL THE SECURITIES BE TRADED?

An application has been made to admit (i) all of the Issuer's existing Shares, (ii) the newly issued Offered Shares, (iii) the new Shares that will be issued upon conversion of the Convertible Bonds, (iv) the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and (v) the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, on the regulated market of Euronext Brussels under the symbol "HYL", and will be allocated the ISIN code BE0974363955. Trading on the regulated market of Euronext Brussels is expected to commence, (i) for the existing Shares and the newly issued Offered Shares: on an "if-and-when-issued-and/or-delivered" basis, on or about 29 June 2020 (the **Listing Date**), provided that this may be accelerated in the event of early closing or postponed in case of extension, and will start at the latest on the Closing Date, when the New Shares are delivered to investors, (ii) for the new Shares that will be issued upon conversion of the Convertible Bonds: on the Closing Date, (iii) for the new Shares (if any) that will be issued pursuant to the exercise of the Over-allotment Option: on or about the date of their issuance, and (iv) for the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021: on or about the date of their issuance.

## 3. WHAT ARE THE KEY RISKS THAT ARE SPECIFIC TO THE SECURITIES?

- **After closing of the Offering, certain significant shareholders of the Issuer may have different interests from the Issuer and/or from the minority shareholders and may be able to control the Issuer, including the outcome of shareholder votes.**

- **There has been no prior public market for the Shares and an active market for the Shares may not develop, which may cause the Shares to trade at a discount to the Offer Price and make it difficult to sell the Shares.**

- **The fact that no minimum amount is set for the Offering may affect Hyloris' investment plan and the liquidity of the Shares.**

## D. KEY INFORMATION ON THE OFFER OF SECURITIES TO THE PUBLIC AND THE ADMISSION TO TRADING ON A REGULATED MARKET

### 1. UNDER WHICH CONDITIONS AND TIMETABLE CAN I INVEST IN THIS SECURITY?

**General conditions** – Through the Offering, the Issuer intends to issue up to 5,000,000 new shares, without nominal value, within a price range between EUR 10.00 and EUR 11.50 per new share (the **Price Range**). The Offer Price may be set within the Price Range or below the lower end of the Price Range but will not exceed the higher end of the Price Range. The Price Range has been determined by the Issuer after consultation with the Underwriters, taking into account market conditions and factors including but not limited to: (i) the condition of the financial markets; (ii) the Issuer's financial position; (iii) qualitative assessment of the demand for the Offered Shares; and (iv) all other factors deemed relevant. The Issuer reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit and/or a decrease of the upper limit, or if the Price Range is narrowed to a single price, the change will be published in the financial press and by means of a press release, through electronic information services such as Reuters or Bloomberg. However, Investors who have submitted subscription orders will not be individually notified of any such Price Range narrowing. A change to the Price Range by a decrease of the lower limit of the Price Range will also be published in the financial press and by means of a press release, through electronic information services, as well as in a supplement to this Prospectus. The relevant financial intermediary shall contact investors on the day when a supplement is published.

The 5,000,000 initially offered new shares in the Offering may be increased by up to 15% of the aggregate number of new shares initially offered to a number of 5,750,000 new shares (the **Increase Option**, and the new shares initially offered and the shares offered as a result of the possible exercise of the Increase Option are collectively being referred to as the **New Shares**, and each existing or future new share representing the Issuer's share capital as a **Share**). Any decision to exercise the Increase Option will be communicated, at the latest, on the date of the announcement of the Offer Price.

In connection with the Offering, KBC Securities NV/SA will, on behalf of the Underwriters (as defined herein), act as stabilization manager (the **Stabilization Manager**). In order to facilitate stabilization by the Stabilization Manager, if any, the Stabilization Manager will be able to over-allot Shares in the Offering (the **Additional Shares**, together with the New Shares, the **Offered Shares**). To enable the Stabilization Manager to cover the placement of Additional Shares in the Offering, if any, or short positions created by such over-allotment, it is expected that the Stabilization Manager will be granted a warrant to subscribe for additional new Shares in a number equal to up to 15% of the number of New Shares subscribed for in the Offering (i.e., including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offer Price (as defined below) (the **Over-allotment Option**). The Over-allotment Option will be exercisable for a period of 30 calendar days following the Listing Date (as defined below). The Stabilization Manager, acting on behalf of the Underwriters, may engage in transactions that stabilize, maintain or otherwise affect the price of the Shares during a period of 30 calendar days following the Listing Date (the **Stabilization Period**). These activities may support the market price of the Shares at a level higher than that which might otherwise prevail.

The offering period will begin at 9:00 (CEST) on 17 June 2020 and is expected to end no later than 13:00 (CEST) on 26 June 2020, subject to early closing or extension, provided that the offering period will in any event be open for at least six business days (the **Offering Period**). However, in accordance with the

possibility provided for in art. 3, § 2 of the Royal Decree of May 17, 2007 on primary market practices, the Issuer expects the Offering Period for the Retail Investors to end on 25 June 2020 at 16:00 (CEST), i.e., the day before the end of the institutional bookbuilding period, due to the timing and logistical constraints associated with the centralization of the subscriptions placed by retail investors with the Underwriters and with other financial institutions. Any extension or early closing of the Offering Period will be announced by means of a press release by the Issuer, and the respective dates for pricing, allocation, publication of the Offer Price and the results of the Offering, “as-if-and-when-issued-and/or-delivered” trading and closing of the Offering will in such case be adjusted accordingly.

The Offering consists of: (i) an offer to the public (as defined in Article 2(d) of Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC (the **Prospectus Regulation**)) in Belgium; (ii) a private placement in the European Economic Area (the EEA)(other than in Belgium) pursuant to applicable exemptions under the Prospectus Regulation, including but not limited to “qualified investors” within the meaning of Article 2(e) of the Prospectus Regulation; (iii) a private placement in the United States to persons who are reasonably believed to be “qualified institutional buyers” (**QIBs**) as defined in Rule 144A (**Rule 144A**) under the U.S. Securities Act of 1933, as amended (the **U.S. Securities Act**), in reliance on Rule 144A; and (iv) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world. All aforementioned “qualified investors” and QIBs are collectively being referred to as **Institutional Investors**. The Offering outside the United States will be made in compliance with Regulation S under the U.S. Securities Act (**Regulation S**).

No minimum amount is set for the Offering. As there is no minimum amount set for the Offering, if not all of the Offered Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited to the net proceeds from the Pre-commitments.

The Shares have not been and will not be registered under the U.S. Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act. Prospective purchasers are hereby notified that sellers of the Shares may be relying on the exemption from the provisions of Section 5 of the U.S. Securities Act provided by Rule 144A.

The **Offer Price** will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, if applicable, and costs, if any, charged by financial intermediaries for the submission of applications, and will apply to all investors, whether Retail Investors (as defined below) or Institutional Investors. The Offer Price will be determined within the Price Range on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time.

Certain key dates in connection with the Offering are summarized in the following table. The Issuer can adjust the dates and times of the capital increase and the periods indicated in the below Timetable and in the Prospectus (including this Summary). In that case, the Issuer will inform Euronext Brussels and the investors thereof through a press release and on the website of the Issuer. Insofar as legally required, the Issuer will furthermore publish a supplement to the Prospectus.

17 June 2020, at 9:00 (CEST)	Expected start of the Offering Period
25 June 2020, at 16:00 (CEST)	Expected end of the Offering Period for Retail Investors
26 June 2020, at 13:00 (CEST)	Expected end of the Offering Period for Institutional Investors <sup>(1)</sup>
26 June 2020	Expected publication of the Offer Price and results of the Offering and communication of allocations
29 June 2020	Expected Listing Date (listing and start of “if-and-when-issued-and/or-delivered” trading)
30 June 2020	Expected Closing Date (payment, settlement and delivery of the Offered Shares)
29 July 2020	Expected last possible exercise date of the Over-allotment Option <sup>(2)</sup>

**Notes**  
(1) In the event of an early closing or extension of the Offering Period, these dates will be amended and published in the same manner as the announcement of the start of the Offering Period. If the Offering Period is extended with more than five business days, this will also be published in a supplement to the Prospectus.  
(2) To enable the Stabilization Manager, acting on behalf of the Underwriters, to cover over-allotments or short positions, if any, resulting from the over-allotment, if any.

**Plan of distribution** – Subscription orders by Retail Investors (as defined below) may be submitted through Bolero, the online investment platform of KBC Bank NV/SA and CBC Banque SA/NV, at the counters of KBC Bank NV/SA, CBC Banque SA/NV in Belgium and at the counters of Van Lanschot Kempen Wealth Management N.V., Belgian branch, at no cost to the investor or alternatively through other than the aforementioned intermediaries. Applications are not binding upon the Issuer or the Underwriters as long as they have not been accepted in accordance with the allocation rules described below. Investors wishing to place purchase orders for the Offered Shares through intermediaries other than Bolero, KBC Bank NV/SA in Belgium, CBC Banque SA/NV in Belgium, or Van Lanschot Kempen Wealth Management N.V., Belgian branch, should request details of the costs which these intermediaries may charge, and which they will have to pay themselves. To be valid, the subscription orders must be submitted no later than 25 June 2020 at 16:00 (CEST), unless the Offering Period is closed earlier or extended, in which case the subscription orders must be submitted no later than 16:00 (CEST) at such earlier or extended closing date of the Offering Period.

A **Retail Investor** shall mean an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation. Retail Investors must indicate in their subscription orders the number of Offered Shares they are committing to subscribe for. Every order must be expressed in number of Offered Shares with no indication of price and shall be deemed placed at the Offer Price. Only one application per Retail Investor will be accepted. If the Underwriters determine, or have reason to believe, that a single Retail Investor has submitted several subscription orders, through one or more intermediaries, they may disregard such subscription orders. There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below. KBC Securities NV/SA will act as centralization agent for subscription orders by Retail Investors. Retail Investors can only acquire the Offered Shares at the Offer Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to the Prospectus in accordance with the Prospectus Regulation, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement in accordance with the Prospectus Regulation. The relevant financial intermediary shall contact investors on the day when a supplement is published.

Institutional Investors must indicate in their subscription orders the number of Offered Shares or an amount they are committing to subscribe for, and the prices at which they are making such subscription orders during the book-building period. There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below. Only Institutional Investors can participate in the book-building process during the Offering Period.

The exact number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Issuer after consultation with the Underwriters on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors as set forth below. In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. However, the proportion of Offered Shares allocated to Retail Investors may be increased or decreased if subscription orders received from them exceed, respectively, do not reach 10% of the Offered Shares effectively allocated.

In the event of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective and

quantitative allocation criteria, whereby all Retail Investors will be treated equally. The criteria to be used for allocation are the preferential treatment of applications submitted by Retail Investors at the counters of KBC Bank NV/SA and CBC Banque SA/NV and through Bolero (the online investment platform of KBC SecuritiesBank NV/SA and CBC Banque SA/NV) in Belgium, and at the counters of Van Lanschot Kempen Wealth Management N.V., Belgian branch, and the number of Offered Shares for which applications are submitted by Retail Investors. Furthermore, in the event the Offering is oversubscribed, a maximum of one third of the Pre-commitment of each individual Participating Investor (i.e., EUR 7,575,000 in the aggregate) can be reduced in line with the allocation principles that apply in the context of the Offering, whereas a minimum of two thirds of the Pre-commitment of each individual Participating Investor (i.e., EUR 15,150,000 in the aggregate) will not be reduced but will be allocated entirely to the relevant Participating Investor.

In the event of an over-allotment, the Underwriters will use reasonable efforts to deliver the New Shares to individual persons residing in Belgium and to investors subject to Belgian income tax on legal entities ("*impôt des personnes morales*" / "*rechtspersonenbelasting*"), in this order of priority. No tax on stock exchange transactions is due on the subscription for newly issued Shares, but such tax could be due on the subscription for existing Shares.

The Offer Price must be paid by the investors in full, in euro, together with any applicable stock exchange taxes and costs. No tax on stock exchange transactions is due on the subscription for newly issued Shares. All Offered Shares will be delivered in dematerialized (book-entry) form only, and will be credited on or around the Closing Date to investors' securities accounts via Euroclear Belgium, and will be registered by one or more registrations in the share register of the Issuer in the name of Euroclear Belgium. By way of exception to the foregoing, the New Shares that will be issued to Participating Investors pursuant to the Pre-commitments (except if the Participating Investor that has an existing client relationship and securities account with KBC Bank NV/SA or CBC Banque SA/NV or Van Lanschot Kempen Wealth Management N.V. and has opted to have such New Shares delivered in dematerialized (book-entry) form and credited on such securities account), will be delivered in registered form on or about their issuance. The new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, will also be delivered in registered form on or about their issuance.

**Admission to trading** – Prior to the Offering, there has been no public market for the Shares. An application has been made to admit (i) all of the Issuer's existing Shares, (ii) the newly issued Offered Shares, (iii) the new Shares that will be issued upon conversion of the Convertible Bonds, (iv) the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and (v) the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, to trading on the regulated market of Euronext Brussels under the symbol "HYL", and will be allocated the ISIN code BE0974363955. Trading on the regulated market of Euronext Brussels is expected to commence, (i) for the existing Shares and the newly issued Offered Shares: on an "if-and-when-issued-and/or-delivered" basis, on or about 29 June 2020 (the Listing Date), provided that this may be accelerated in the event of early closing or postponed in case of extension, and will start at the latest on the Closing Date, when the New Shares are delivered to investors, (ii) for the new Shares that will be issued upon conversion of the Convertible Bonds: on the Closing Date, (iii) for the new Shares (if any) that will be issued pursuant to the exercise of the Over-allotment Option: on or about the date of their issuance, and (iv) for the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021: on or about the date of their issuance.

**Dilution** – The existing shareholders of the Issuer will explicitly and irrevocably waive their statutory preferential subscription right in the context of the Offering. Existing shareholders of the Issuer that do not participate in the Offering, will undergo a future dilution of voting rights and dividend rights. An existing shareholder that owned 1% of the share capital of the Issuer prior to the Offering, does not subscribe for the Offering and assuming placement of the maximum number of new Shares (including the exercise in full of the Increase Option and the Over-allotment Option), will, after their issuance, but without taking into account the automatic conversion of the Convertible Bonds in new Shares immediately after the closing of the Offering, hold 0.73% of the share capital of the Issuer.<sup>1</sup> Assuming the Offer Price is at the midpoint of the Price Range, such existing shareholder will, taking into account the automatic conversion of the Convertible Bonds (for their full outstanding principal amount, increased, if requested by the Issuer (which it intends to do), by all or part of any unpaid interests due) in new Shares immediately after the closing of the Offering, hold 0,67% of the share capital of the Issuer.<sup>2</sup>

**Costs in relation to the Offering** – Assuming that the Offer Price is at the midpoint of the Price Range, and that the Offering is completely subscribed for, the gross proceeds from the Offering will amount to EUR 53,750,000 (assuming that only the 5,000,000 initially offered New Shares are issued), EUR 61,812,500 (assuming that the Increase Option is exercised in full) and EUR 71,084,375 (assuming that the Stabilization Manager decides to fully exercise its Over-allotment Option). The fees and commissions payable to the Underwriters by the Issuer are then expected to respectively amount to maximum EUR 2.5 million, EUR 2.9 million and EUR 3.4 million. In addition, the aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of the Prospectus (including this Summary) and Offering related documents, and expenses incurred by the Underwriters (which are estimated at EUR 0.05 million)) and the remuneration of the FSMA (which are estimated at EUR 0.02 million) and Euronext Brussels, is expected to amount to approximately EUR 1.4 million.

## 2. WHY IS THIS PROSPECTUS BEING PRODUCED?

**Use and estimated net amount of the proceeds** – The principal purpose of the Offering is to obtain additional capital to support the execution of Hyloris' strategy, which is based on the following three pillars: (i) building a diversified and growing portfolio of proprietary products through the development and licensing of product candidates that address underserved medical needs utilizing the capital and time efficient 505(b)(2) regulatory pathway, (ii) utilizing a flexible go-to-market strategy with a focus on the U.S. market, and (iii) generating diversified revenue streams with the IV Cardiovascular Portfolio as the foundation for long-term growth. In particular, the Issuer intends to use the net proceeds of the Offering as follows:

- EUR 22.725 million is expected to be allocated to the development (up to and including the approval by the regulatory authority) of the existing portfolio of product candidates, whereby the amount will differ per product candidate based on the current phase of development;
- EUR 11 million is expected to be allocated to the establishment of a commercial infrastructure in the United States for the commercialization of its IV Cardiovascular Portfolio (except for Sotalol IV<sup>3</sup>);
- To fund the expansion of the pipeline, both internally and through business development opportunities, and
- For general corporate purposes.

Through the Offering, the Company also aims to increase its visibility, diversify its shareholder base and accelerate company growth via different capital sources.

The Issuer cannot predict with certainty all of the particular uses for the proceeds from the Offering, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Issuer's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its further development of its pipeline; regulatory or competitive developments; the net proceeds actually raised in the Offering; the amounts received by way

<sup>1</sup> This calculation is based on the number of existing Shares (i.e., 17,801,768) and the placement of the maximum amount of Offered Shares (i.e., 6,612,500).

<sup>2</sup> This calculation is based on the number of existing Shares (i.e., 17,801,768), the placement of the maximum amount of Offered Shares (i.e., 6,612,500) and the issuance of 2,040,864 new Shares pursuant to the conversion of the Convertible Bonds.

<sup>3</sup> Sotalol IV was licensed to a U.S. based partner before Hyloris started the development of its other IV Cardiovascular Portfolio product candidates and therefore had not yet defined its strategy to establish its own commercial team in the United States for its IV Cardiovascular Portfolio

of revenues and the Issuer's operating costs and expenditures. As such, the Issuer's management assumes certain flexibility in applying the net proceeds from the Offering and may change the allocation of these proceeds as a result of these and other contingencies. Pending the use of the proceeds from the Offering, the Issuer intends to invest the net proceeds in interest bearing, cash and cash equivalents instruments or short-term certificates of deposit.

Furthermore, as no minimum amount is set with respect to the Offering (see "General conditions" under Section D.1 of this Summary and "Risks related to the Offering" Section C.3 of this Summary), the Issuer has the right to proceed with a capital increase in a reduced amount, corresponding to a number of new Shares lower than the 5,000,000 initially offered New Shares (*i.e.*, excluding the exercise, in part or in full, of the Increase Option) in the Offering, it being understood that, in a worst case scenario, the net proceeds of the Offering would be equal to the net proceeds from the Pre-commitments of the Participating Investors. In the event that the net proceeds from the Offering are limited to the net proceeds from the Pre-commitments of the Participating Investors (*i.e.*, EUR 19,810,173), Hyloris would use these proceeds, together with the net proceeds from the Convertible Bonds (*i.e.*, EUR 7,650,000<sup>4</sup>), for the further development and finalization of its current product candidate portfolio. The establishment of a commercial team in the United States, the expansion of the product candidate pipeline and the potential development opportunities would potentially be delayed until additional financing were to become available. In the event that the Issuer proceeds with the capital increase in a reduced amount, it may be required to raise additional capital in order to meet the funding requirements for the establishment of a commercial team in the United States, the expansion of the product candidate pipeline and the pursuit of potential development opportunities. Such additional funding could be a combination of external financing and further shareholders' financing, and, the final amount raised would determine the pace of expansion of the current product candidate portfolio.

**Underwriting Agreement** – The Underwriters and the Issuer have committed themselves in good faith to negotiate an agreement (the **Underwriting Agreement**) that will contain the contractual arrangements between them in relation to the Offering. In line with normal market practice, such an agreement is only entered into upon the determination of the Offer Price, which is expected to take place on or about 26 June 2020. Therefore, at present, the Underwriters and the Issuer have no obligation to enter into such an agreement, to subscribe for the Offered Shares or to issue the New Shares. In the event such an agreement is entered into between the Underwriters and the Issuer, it is expected that it will, in addition to a number of other elements, contain the following principles: (i) Subject to the terms and conditions to be set forth in the Underwriting Agreement, the Underwriters will each severally but not jointly agree to subscribe and procure payment for 50% of the total number of New Shares (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) less those New Shares subscribed for by the Participating Investors pursuant to the Pre-commitments (the "**Underwritten Shares**"), in their own name but for the account of the relevant subscribers in the Offering to whom those Underwritten Shares have been allocated; (ii) The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the Underwriting Agreement (and then only in accordance with the terms and subject to the conditions set forth therein); (iii) Immediately after receipt of the Underwritten Shares, the Underwriters will deliver such Underwritten Shares to the relevant subscribers in the Offering and the Underwriters shall guarantee to the Issuer the payment of the Offer Price; (iv) In the Underwriting Agreement, the Issuer will make certain customary representations and warranties and the Issuer will agree to indemnify each of the Underwriters against certain liabilities in connection with the Offering, including liability under the U.S. Securities Act; (v) The Underwriting Agreement will provide that each Underwriter shall have the right to terminate the Underwriting Agreement before the realisation of the capital increase in relation to the Offering, upon the occurrence of certain events such as (a) a matter having arisen requiring under Belgian law the publication of a supplement to the Prospectus; (b) there having been a breach of any of the representations and warranties made by the Issuer; (c) the Issuer not having complied with the covenants and undertakings set out in the Underwriting Agreement; (iv) there having been or it being likely that there will be a material adverse effect; (d) any of the conditions precedent not having been satisfied, such as the delivery of the launch and closing documents; (e) the application for trading being withdrawn or refused by Euronext Brussels; or (f) a force majeure event having occurred. Following termination of the Underwriting Agreement by an Underwriter, subject to the terms and conditions of the Underwriting Agreement, the other Underwriter will be authorised but not obliged to further proceed with the Offering and the performance of the Underwriting Agreement without the involvement of the Underwriter who terminated the Underwriting Agreement. In the event that the Underwriting Agreement is not executed or is executed but subsequently terminated, a supplement to this Prospectus shall be published. After publication of the supplement, the subscriptions for the Offered Shares will automatically be cancelled and withdrawn, and subscribers will not have any claim to delivery of the Offered Shares or to any compensation.

**Most material conflicts of interest pertaining to the offer or the admission to trading** – KBC Securities NV/SA, having its registered office at Havenlaan 2, 1080 Brussels, Belgium (KBC Securities) and Van Lanschot Kempen Wealth Management N.V., having its office at Beethovenstraat 300, 1077 WZ Amsterdam, the Netherlands (Kempen & Co) act as Joint Global Coordinators and Joint Bookrunners (together the **Underwriters**) in the context of the Offering, and are expected to, subject to certain conditions, enter into an "Underwriting Agreement" with the Issuer. In connection with the Offering, each of the Underwriters and any of their respective affiliates (see above), acting as an investor for its own account, may take up Offered Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Shares or related investments and may offer or sell such Shares or other investments otherwise than in connection with the Offering. Accordingly, references in this Summary to Shares being offered or placed should be read as including any offering or placement of Offered Shares to any of the Underwriters or any of their respective affiliates acting in such capacity. None of the Underwriters intends to disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligation to do so. In addition, certain of the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Underwriters (or their affiliates) may from time to time acquire, hold or dispose of Shares. As of the date of this Summary, the Underwriters have only signed an agreement with the Company to assist them with this Offering without having any other relationships with the Company. Certain of the Underwriters and/or their respective affiliates may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Issuer or any parties related to it, in respect of which they may in the future receive, customary fees and commissions. As a result of these transactions, these parties may have interests that may not be aligned or could possibly conflict with the interests of investors. The Adjustment Warrants and Anti-dilution Warrants will be waived and cancelled if (i) the Offer Price is not lower than EUR 6.769525, (ii) subscription orders for an amount of at least EUR 40 million have been received no later than 30 June 2020 and (iii) the Shares of the Company are admitted to trading on the regulated market of Euronext Brussels on an "if-and-when-issued-and/or-delivered" basis within 3 business days following the closing of the Offering Period. Therefore, the existing shareholders of Hyloris that do not hold Anti-dilution Warrants and/or Adjustment Warrants have an interest in the closing of the Offering Period on or prior to 30 June 2020 and the admission of the Shares of the Company to trading on the regulated market of Euronext Brussels on an "if-and-when-issued-and/or-delivered" basis within 3 business days following the closing of the Offering Period, as they otherwise could face dilution of their shareholding in the Issuer upon the exercise of these warrants. From the Listing Date, the financial service for the Shares will be provided by KBC Bank NV/SA, who will act as listing and paying agent of the Issuer. Should the Issuer alter its policy in this respect, this will be announced in accordance with applicable law.

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<sup>4</sup> This is the aggregate nominal amount of the Convertible Bonds (EUR 15,150,000) minus the repaid part of the shareholder loans after the reporting period (*i.e.*, 7.5 million, see Note 19 to the condensed consolidated financial statements).

## 2 RISK FACTORS

*Hyloris is subject to a number of risks. If one or more of the following risks were to arise, Hyloris' may be unable to execute its strategy and implement its business plan which may prevent it from developing its product portfolio, bringing products to market and commercializing those products in a way that results in positive operational and financial results. As a result, the price of the Shares could be materially and adversely affected and investors could lose all or part of their investment. An investment in the Offered Shares is only suitable for investors who are able to assess the risks of such investment and who have adequate means to absorb any losses that may result from such investment.*

*The description of risks set out below does not purport to be exhaustive. Additional risks and uncertainties that, as of the date of this Prospectus, are unknown to, cannot be foreseen by, or are not considered significant by Hyloris may also exist.*

*In addition to the other information set out in this Prospectus, the risks described below should be carefully considered by prospective investors prior to making any investment decision relating to the Offered Shares. Investors should carefully read the entire Prospectus and form their own opinions about, and make their own decisions on, the merits and risks of investing in the Offered Shares in light of their personal circumstances. In addition, investors should consult their financial, legal and tax advisors for a careful assessment of the risks associated with investing in the Offered Shares.*

*The risk factors presented herein have been divided into categories based on their nature. Within each category, the risk factors estimated to be the most material on the basis of an overall evaluation of the criteria set out in the Prospectus Regulation and according to the assessment made by Hyloris about the materiality of the risk are presented first. Additionally, the order of the categories does not represent any evaluation of the materiality of categories themselves or of the relative materiality of the risk factors within any particular category when compared to the risk factors in another category. Quantitative information, where available and appropriate, has been included to demonstrate the materiality of the risk. Where quantitative information is not available, or where it is not appropriate to include such information, a qualitative description of the potential negative impact of the risk has been included on a scale of low, medium or high.*

### 2.1 RISKS RELATED TO HYLORIS' BUSINESS ACTIVITIES AND INDUSTRY

#### 2.1.1 RISKS RELATED TO IDEA GENERATION AND PRODUCT DEVELOPMENT

##### **2.1.1.1 HYLORIS' PERFORMANCE DEPENDS PRIMARILY ON THE SUCCESS OF ITS PRODUCT CANDIDATES, A MAJORITY OF WHICH ARE IN THE EARLY REFORMULATION DEVELOPMENT STAGE AND HAVE NOT YET RECEIVED FDA APPROVAL OF THE 505(B)(2) APPLICATION OR ANDA OR THE OTHER APPROVALS REQUIRED BEFORE THEY MAY BE COMMERCIALY LAUNCHED.**

Hyloris has two early stage commercial products and twelve product candidates in various stages of development. Hyloris intends to initiate four or more new product candidates per year starting from 2021. A majority of Hyloris' existing product candidates are in the early reformulation development stage and are therefore particularly subject to the risks set out in this risk factor.

Hyloris acquired the rights to one of its two early stage commercial products, Sotalol IV, which had already been approved by the FDA for sale in the United States and which recently received FDA approval for a label extension (filed by Hyloris' marketing partner, AltaThera). It also acquired the rights to Maxigesic® IV, which has been approved for sale in Australia, New Zealand and the United Arab Emirates. Hyloris will not, however, receive any part of the profits generated by Maxigesic® IV from

Australia and New Zealand (see also Section 8.12.6.2 (AFT Pharmaceuticals – Development collaboration agreement)).

Of its twelve product candidates under development, Hyloris has so far submitted (through its commercial partner) an abbreviated new drug application (**ANDA**) for HY-EMP-016), and expects to submit a 505(b)(2) application for Tranexamic Acid RTU in the early second half of 2020, to the FDA. Hyloris' ten remaining product candidates (including those in its IV Cardiovascular Portfolio) are still in the early stages of reformulation development and there can be no assurance that Hyloris will be able to successfully complete the development of these product candidates or any new product candidates it initiates in the future.

Hyloris' business model focuses on making use of the time and capital efficient 505(b)(2) regulatory pathway (which is expected to result in shorter development timelines and reduced development costs as compared to traditional new drug applications) for a substantial majority of its existing product candidates and Hyloris expects to continue making use of the 505(b)(2) regulatory pathway going forward. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. For a further explanation of the 505(b)(2) regulatory pathway and the differences from the traditional regulatory pathway, see Section 8.9 (Overview of the 505(b)(2) Regulatory Pathway) and Section 8.6.3 (Focus on time and capital efficient 505(b)(2) regulatory pathway significantly lowers the risks and costs compared to traditional new drug applications).

Among other regulatory requirements, Hyloris will not be permitted to market its product candidates in the United States until it receives approval of a 505(b)(2) application, or ANDA, from the U.S. Food and Drug Administration (the **FDA**), or in other countries, until it receives the requisite approval from the regulatory agencies in those countries. The research, testing, manufacturing, labelling, packaging, storage, approval, sale, marketing, advertising and promotion, pricing, export, import and distribution of pharmaceutical products are also subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries.

The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that Hyloris' data is insufficient for approval and require additional clinical trials, or preclinical, bioequivalence or other studies. The issuance of regulatory approval is uncertain and subject to a number of risks, including, but not limited to, the failure of a clinical trial for any reason, the failure of Hyloris to successfully formulate the product candidate or the determination of the FDA that Hyloris has not provided acceptable data, or, in the instance that a bioequivalence study is required, has not provided sufficient evidence of such bioequivalence in order "to bridge" the relevant product candidates to the innovator drug. Additionally, Hyloris' product candidates may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude it from obtaining regulatory approval or prevent or limit commercial use with respect to one or all intended indications.

If at any stage in the process it becomes clear that Hyloris will not be able to proceed with a proposed development candidate utilizing the 505(b)(2) regulatory pathway as anticipated, Hyloris would need to reevaluate its plans to include such development candidate in its product candidate portfolio and may

have to amend or abandon such plans. In such cases, Hyloris may have already expended significant resources on a product candidate's reformulation or development or related regulatory user fees. Development costs vary between product candidates but are expected to range between EUR 2.0 million to a maximum of EUR 7.0 per million per product candidate. The total amount of development costs expended and potentially lost as a result of a decision not to proceed with the development of a product candidate for any reason would vary depending on the particular product candidate and the stage of development at which such a decision is made. To date, Hyloris has taken the decision to abandon two of its product candidates, and on one of these occasions it resulted in Hyloris recording an impairment charge. Because Hyloris ultimately decided to focus on its other product candidates as these showed higher potential, Hyloris, in 2019, made the decision to put the development of its product candidate HY-REF-028, on which it had already spent EUR 2.8 million to develop, on hold, it being understood that Hyloris may restart the project at a later date. For 2019, in accordance with IFRS requirements, Hyloris recorded in its financial statements an impairment charge of EUR 3.2 million related to this decision, which represented the EUR 2.8 million in development costs as well as the capitalization of the borrowing costs used to purchase the asset.

Failure to obtain regulatory approval for product candidates for the foregoing, or any other reasons, may prevent Hyloris from commercializing its product candidates and ultimately Hyloris' ability to generate revenue would be materially impaired. In particular, failure to obtain regulatory approval for Maxigesic® IV (outside those countries where it is already approved), Tranexamic Acid RTU and HY-EMP-016 may prevent Hyloris from becoming profitable in the short term, and failure to obtain regulatory approval for its intravenous (IV) Cardiovascular portfolio (including Dofetilide IV, Metolazone IV, HY-CVS-073 or HY-CVS-074), HY-REF-004, HY-REF-029 and any additional new product candidates may prevent Hyloris' potential to grow in the long term.

Hyloris believes that the potential negative impact of this risk is high.

**2.1.1.2 BECAUSE THE SECTOR OF THE PHARMACEUTICAL MARKET THAT HYLORIS IS TARGETING IS OPEN TO GREATER COMPETITION THAN THE MARKET FOR NEW DRUG FORMULATIONS AND NEW PHARMACEUTICAL PRODUCTS, HYLORIS' BUSINESS IS DEPENDENT ON THE CONTINUOUS GENERATION OF NEW IDEAS AND THE DEVELOPMENT OF NEW PRODUCT CANDIDATES.**

Because Hyloris develops new products by reformulating well-known pharmaceuticals, developing proprietary products it believes offer advantages compared to currently available alternatives, its ability to maintain revenues from its product portfolio may be limited by the fact that this particular sector of the pharmaceutical market is open to greater competition than the market for new drug formulations and new pharmaceutical products. Pharmaceutical products developed by reformulating existing drugs, in particular developed and approved through the 505(b)(2) regulatory pathway, enjoy fewer protections from competition and those protections extend for shorter durations than the market protections available to new drugs.

As a result, Hyloris' success over time will depend on its ability to continuously add new products to its product portfolio, which in turn will require the generation of new ideas for products to add to its product development portfolio and the successful development of those products. Additionally, Hyloris' business model relies on the development and sustainment of a diversified product portfolio which will generate

revenue streams across multiple products in multiple pharmaceutical categories. Consequently, Hyloris is continuously evaluating multiple ideas in various therapeutic areas in order to maintain a consistent pipeline of product candidates and aims to initiate four or more new product candidates per year starting from 2021.

The new product ideas that Hyloris generates must be suitable for approval utilizing the 505(b)(2) regulatory pathway as use of that regulatory approval process is a central element of Hyloris' business model. Additionally, Hyloris faces, and expects to continue to face, competition from pharmaceutical companies based in the U.S. and pharmaceutical companies that have developed and own the intellectual property rights to approved drugs, who may be in a better position to reformulate or repurpose their own established pharmaceutical products and therefore may have a competitive advantage over Hyloris.

In order to successfully and continuously generate new ideas, Hyloris in part relies and will continue to rely on a limited number of existing and possibly new business partners, and therefore Hyloris is dependent on the willingness of those partners to transfer intellectual property and other necessary proprietary rights to Hyloris on terms that make the development of the relevant new product candidate financially and economically viable. There can be no assurance that Hyloris will secure such rights on acceptable terms or at all. If Hyloris is unable to continuously generate new product ideas or is unable to continuously convert new product ideas into new product candidates and ultimately add new products for its portfolio, its revenues may be materially and negatively impacted and it may be unable to grow in accordance with its business plan.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.1.3 HYLORIS RELIES AND EXPECTS TO CONTINUE TO RELY IN LARGE PART ON THE KNOW-HOW OF ITS DEVELOPMENT PARTNERS AND, IN PARTICULAR, THE KNOW-HOW OF ITS DEVELOPMENT PARTNER WITH RESPECT TO ITS IV CARDIOVASCULAR PORTFOLIO AND IT ALSO RELIES ON THE KNOW-HOW OF ITS PARTNERS FOR THE DEVELOPMENT AND EXPANSION OF ITS PORTFOLIO.**

Even though Hyloris' Executive Management has expertise in many aspects of pharmaceutical development, Hyloris' ability to successfully develop its portfolio relies in large part upon the know-how of its development partners, and specifically, Academic Pharmaceuticals and Alter Pharma. Hyloris currently relies on Academic Pharmaceuticals for five of its 14 product candidates (Sotalol IV, Dofetilide IV, HY-CVS-073, HY-CVS-074 and Metolazone IV) and it relies on Alter Pharma for three of its 14 product candidates (Maxigesic IV, Fusidic Acid Cream and HY-REF-038), representing 36% and 21% of its product candidate portfolio, respectively (expressed as a percentage of the total number of 14 products and product candidates). The development work for Sotalol IV and Maxigesic® IV, for which Hyloris relied on these partners, is already complete.

Hyloris has entered into a partnership with Academic Pharmaceuticals, a company located in the United States, which in turn is largely dependent on a single cardiovascular expert, its chief executive officer, for the product candidates in, and development of, its IV Cardiovascular Portfolio, which is of particular strategic importance to Hyloris. Based on Hyloris' existing product candidate pipeline and its current business plan (including the assumptions included therein), as from 2025, sales in IV Cardiovascular

are expected to represent the main driver of overall sales growth with more than 70% of Hyloris revenues by 2027. As a result, Hyloris' relationship with Academic Pharmaceuticals and their role in developing the IV Cardiovascular Portfolio is particularly important to the successful execution of Hyloris' business plan.

Though Hyloris is anticipating and planning for the retirement of this cardiovascular expert in the medium-term, as he is currently within the range of the typical retirement age, if Hyloris were to unexpectedly lose its partnership with Academic Pharmaceutical or any of its other partners, such as Alter Pharma, for any reason, identifying, vetting and recruiting suitable replacement partners with similar expertise, and negotiating the terms of any such relationship, would be time consuming, could result in substantial costs and could divert Hyloris' efforts and attention from other aspects of Hyloris' business. The unexpected loss of the services of any development partner, and, in particular, the loss of services of Academic Pharmaceuticals' chief executive officer, could have a material adverse effect on the expected timing and costs associated with the development of Hyloris' product portfolio, and specifically its IV Cardiovascular Portfolio.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.1.4 CITIZENS' PETITIONS, PATENT INFRINGEMENT LAWSUITS AND OTHER CLAIMS, WHICH ARE ROUTINELY BROUGHT AGAINST 505(B)(2) AND ANDA APPLICANTS, COULD BE BROUGHT AGAINST HYLORIS AND COULD DELAY OR PREVENT THE REGULATORY REVIEW OR APPROVAL OF ITS PRODUCT CANDIDATES OR COULD PREVENT HYLORIS FROM LAUNCHING ITS PRODUCT CANDIDATES AS PLANNED.**

Companies, and in particular companies that produce or market branded reference pharmaceuticals, routinely bring litigation against 505(b)(2) and ANDA applicants seeking regulatory approval to manufacture and market reformulated and generic forms of their products which they may claim are still subject to patent protection. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against a 505(b)(2) or ANDA applicant. Likewise, pharmaceutical companies may bring patent infringement suits against companies that are currently marketing and selling their approved products, whether generic or reformulated.

Hyloris' competitors may file citizens' petitions with the FDA in an attempt to persuade the FDA that Hyloris' product candidates, or the clinical studies that support their approval, contain deficiencies. Such actions by competitors could delay or even prevent the FDA from approving any 505(b)(2) application or ANDA submitted by Hyloris or cause Hyloris to delay or abandon the launch of a product candidate.

Hyloris may also face situations where a competitor has patents covering the active ingredient, product formulation or an approved use of the pharmaceutical in respect of which Hyloris seeks to file a 505(b)(2) application or ANDA. Such drugs and their patent information would be listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the **Orange Book**). If there are patents listed in the Orange Book for a product that Hyloris seeks to market prior to the expiration of its relevant patents, Hyloris must include a "Paragraph IV" certification in its 505(b)(2) or ANDA application, challenging the validity or enforceability of the listed patent or patents, or claim that the listed patent or patents will not be infringed by the manufacture, use or sale of the proposed drug. Notice of the "Paragraph IV" certification must be given to the patent owner and the original NDA holder

and if, within 45 days of receiving notice, either the patent owner or original NDA holder sues the applicant for patent infringement, approval of the 505(b)(2) application or ANDA is stayed for 30 months (during which approval will not be granted) unless such period is shortened by the expiration of the patents, the settlement of the lawsuit, or a court decision in the infringement case that is favorable to the applicant.

Moreover, the FDA has adopted an interpretation of the U.S. Federal Food, Drug and Cosmetic Act's (the **FDCA**) marketing exclusivity provisions whereby the approval of a Hyloris 505(b)(2) application may be blocked by exclusivity awarded to a previously-approved pharmaceutical product that shares certain innovative features with Hyloris' product candidates, even if Hyloris' 505(b)(2) application does not reference the previously-approved pharmaceutical product as a pharmaceutical listed in the Orange Book or rely upon any of its safety or efficacy data.

Hyloris has plans to submit one of its 505(b)(2) applications (which will include a "Paragraph IV" certification) for FDA approval before a competing patent expires, and Hyloris is otherwise not aware of any possible patent infringement as of the date of this Prospectus. However, although Hyloris has processes in place and takes significant steps to fully ascertain the regulatory and intellectual property status of existing and reference products as part of its development process, not all of the relevant information is publicly available and therefore there can be no assurance that Hyloris' product candidates do not infringe other parties' patents or other proprietary rights and competitors or other parties may bring patent infringement or other claims against Hyloris, which could result in litigation (see also Risk Factor 2.1.2.6, which covers the risks related to intellectual property more extensively) and result in the delay or refusal of the regulatory review or approval of its product candidates or cause Hyloris to delay or abandon the launch of its product candidates.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.1.5 ANY TERMINATION OR SUSPENSION OF, OR DELAYS IN THE COMMENCEMENT OR COMPLETION OF, ANY NECESSARY CLINICAL TRIALS IN RESPECT OF ANY OF HYLORIS' PRODUCT CANDIDATES, INCLUDING AS A RESULT OF HYLORIS' RELIANCE ON THIRD PARTIES TO CONDUCT SUCH CLINICAL TRIALS, COULD RESULT IN INCREASED COSTS TO HYLORIS, DELAY OR LIMIT ITS ABILITY TO GENERATE REVENUE AND ADVERSELY AFFECT HYLORIS' COMMERCIAL PROSPECTS.**

Although the 505(b)(2) regulatory pathway enjoys reduced clinical trial requirements compared to the 505(b)(1) regulatory pathway, Hyloris must successfully complete clinical trials for certain of its product candidates before it can apply for marketing approval. Clinical activities typically represent approximately 9% of Hyloris' total development costs, and any delay, failure, termination or suspension of any necessary clinical trials or other development activities in respect of any of its product candidates could result in increased costs to and capital requirements of Hyloris, delay, limit or prevent its ability to generate revenue and adversely affect Hyloris' commercial prospects. Even if Hyloris completes its clinical trials, there can be no assurance that it will receive marketing approval for the relevant product candidate and Hyloris may be required to conduct additional clinical trials before the FDA or comparable foreign regulatory authorities approve Hyloris' application or post-approval Phase 4 clinical trials could be required.

The commencement and completion of clinical studies can be delayed or unsuccessful for a number of reasons, including but not limited to the following:

- the FDA, comparable foreign regulatory authorities or institutional review boards (or **IRBs**), may disagree with the design or implementation of one of Hyloris' clinical trials and could suspend, terminate, refuse to approve or withdraw its approval of the trial;
- inspections of Hyloris' clinical study sites could result in the discovery of regulatory violations that require corrective action, potentially resulting in the suspension or termination of one or more sites, the imposition of a clinical hold on the entire study, or the prohibition of the use of some or all of the data in support of the relevant marketing applications;
- the data collected from Hyloris' clinical trials may not be sufficient to support the submission of a 505(b)(2) application or other application to obtain regulatory approval in the United States or elsewhere or the results of Hyloris' clinical trials may not be satisfactory or may not meet the level of statistical significance (i.e. the results do not achieve statistical conditions to be considered successful) or clinical significance (i.e. the effectiveness of the treatment is not sufficient to be considered successful) required by the FDA or other regulatory agencies for marketing approval;
- the trial could fail for any reason, including that the dosing of Hyloris' product candidates is not at an optimal level;
- patients in Hyloris' clinical trials may suffer adverse effects for reasons that may or may not be related to the product candidates;
- the occurrence of a pandemic or other public health crisis, such as COVID-19, may impact the ability to recruit patients and otherwise disrupt normal functioning of the healthcare system which could impair the ability to conduct clinical trials as planned; and
- subjects for clinical testing failing to enroll or remain in clinical trials at the rate Hyloris was expecting.

Because activities in hospitals in the United States have been severely restricted as those facilities focus on dealing with COVID-19 cases and restrict non-essential medical procedures, the recruitment of patients for participation in clinical trials for Maxigesic® IV in the United States has not been possible and the recruitment program has been temporarily suspended. Likewise, the commencement of clinical trials in respect of HY-REF-004 has been similarly delayed. Currently, Hyloris has suspended the execution of these clinical trials for an expected period of a maximum of three months and intends to resume these clinical activities as soon as conditions allow. Although the precise timing of such resumption cannot be predicted, Hyloris expects the commercial launch of these products to be delayed by between three and six months as a result of the delays to the clinical trials and these delays have been accounted for in Hyloris' product development timelines. The delays to the clinical trials and the resulting delays to commercial launch are likely to result in a commensurate delay in the generation of revenues from these products, but are not expected to have a material impact on development costs.

Other than these COVID-19 delays, Hyloris has not experienced any other delays or suspensions of its clinical trials.

Although Hyloris designs the clinical trials for its product candidates in consultation with contract research organizations (**CROs**), the conduct of such clinical trials is always expected to be outsourced to such CRO's. As such, Hyloris expects to rely entirely on its CROs to conduct and manage its clinical programs, including the execution of any required clinical studies for its product candidates. As a result, many important aspects of Hyloris' pharmaceutical development programs would be outside of its direct control. Reliance on CROs and clinical sites will not relieve Hyloris of its regulatory responsibilities, and Hyloris will remain responsible for ensuring that each of the studies is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. If Hyloris, its CROs or clinical sites fail to comply with these applicable requirements or standards, the clinical data generated in clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Hyloris to repeat, extend the duration of, or increase the size of its clinical trials before approving its marketing applications and Hyloris may incur liability as a result of any such non-compliance. Further if a CRO or clinical site needs to be replaced, Hyloris may need to expend significant time and resources to find a suitable replacement and may not be able to enter into arrangements with alternative CROs or clinical sites at all. If any of these risks were to occur, Hyloris' development program may be materially and irreversibly harmed.

If Hyloris experiences delays in completion of the clinical studies required in relation to any of its product candidates including as a result of its reliance on CROs to conduct such clinical trials, its commercial prospects may be materially harmed and Hyloris' ability to generate product revenues may be delayed. Any delays in completing the required clinical trials, including the delays that have been caused by the COVID-19 pandemic, may increase costs, slow down the development and approval process and jeopardize Hyloris' ability to commence product sales and generate revenues.

Hyloris believes that the potential negative impact of this risk is medium.

## **2.1.2 RISKS RELATED TO MANUFACTURING AND COMMERCIALIZATION**

### **2.1.2.1 EVEN IF HYLORIS RECEIVES REGULATORY APPROVAL FOR ANY OF ITS PRODUCT CANDIDATES, IT MAY BE UNABLE TO LAUNCH THE PRODUCT SUCCESSFULLY AND THE REVENUE THAT HYLORIS GENERATES FROM SALES OF SUCH PRODUCT, IF ANY, MAY BE LIMITED.**

If approved for marketing, the commercial success of Hyloris' product candidates will depend upon each product's acceptance by the medical community, including physicians, patients and healthcare payors. The degree of market acceptance for any of Hyloris' product candidates will depend on a number of factors, including:

- the relative efficacy, safety, convenience, dosing burden, ease of administration and the extent of adverse side effects experienced of the product;
- the willingness of physicians to prescribe the product candidates, hospitals to integrate their use, and the target patient population to try new therapies;

- the introduction of any new products that may in the future become available targeting indications for which Hyloris' product candidates may be approved;
- procedures or therapies that may reduce the incidences of any of the indications in which Hyloris' product candidates may show utility;
- pricing, cost-effectiveness and insurance reimbursement policies with respect to the product; and
- the effectiveness of Hyloris' or any future collaborators' sales and marketing efforts.

Any of these factors could render a product candidate obsolete, non-competitive or less attractive at any point before or after the product's launch, including before Hyloris can successfully launch the product or recover the costs associated with its development and commercialization.

If Hyloris is unable to compete effectively, or if its product candidates face competition sooner than expected, Hyloris' market share and revenues will be materially negatively impacted. For example, with respect to many of its product candidates, Hyloris intends to bring a product to market to address a medical need for which there are already alternative products available in the market. Although Hyloris believes its 505(b)(2) product candidates could offer advantages compared to the currently available alternatives, Hyloris will initially face direct competition from those alternatives, which are already available and known to the market. These competitors may have an advantage over Hyloris due to their greater size, financial or other resources and institutional experience, including greater experience and expertise in obtaining and maintaining regulatory approvals, securing distribution relationships and marketing approved drugs and may be in a better position to reformulate or repurpose their own established pharmaceuticals. Hyloris' efforts to educate the medical community and third-party payors on the benefits of its product candidates (for which it expects to rely on the expertise of its staff with regard to its portfolio, the know-how of its current and future partners and the experience of the personnel Hyloris intends to hire to comprise its U.S. sales force) may require significant resources and may never be successful.

In addition, even if Hyloris obtains regulatory approvals, the timing or scope of any approvals may prohibit or reduce its ability to launch its product candidates successfully. For example, if the approval process takes longer than expected, Hyloris may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. If any of Hyloris' product candidates are approved, but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors, and/or patients or if, following approval, any Phase 4 clinical trials or other post-market surveillance are required, produce negative findings or are overly costly or time-consuming, Hyloris may not generate sufficient revenue and it may not be able to achieve or sustain profitability.

Hyloris may also rely on the trademarks it may develop to distinguish its products from the products of its competitors. Third parties may oppose Hyloris' trademark applications or otherwise challenge Hyloris' use of the trademarks. In the event that the trademarks Hyloris uses are successfully challenged, Hyloris could be forced to rebrand its products, which could result in loss of brand recognition and could require Hyloris to devote resources to advertising and marketing new brands. Further, Hyloris cannot provide

assurance that competitors will not infringe the trademarks it uses or that it will have adequate resources to enforce these trademarks.

If Hyloris is unable to generate adequate market acceptance of its product candidates or if third parties are able to use Hyloris' proprietary information in a way that impairs Hyloris' relative competitive advantage, or if its product candidates face competition sooner than expected, Hyloris' market share and revenues will be materially negatively impacted. If any of these risks occur during the initial execution of Hyloris' business plan and, in particular, with respect to any of the first four products in Hyloris' pipeline (Sotalol IV, Maxigesic® IV, HY-EMP-016 and Tranexamic RTU), or if any of these risks occur with respect to any of the products candidates in Hyloris' IV Cardiovascular Portfolio, on which Hyloris' short to medium-term future success is particularly dependent, Hyloris may not generate sufficient revenue and it may not be able to achieve or sustain profitability.

Hyloris believes that the potential negative impact of this risk is high.

**2.1.2.2 DESPITE RECEIVING REGULATORY APPROVAL FOR A PRODUCT CANDIDATE, COMPETITORS MAY RECEIVE REGULATORY APPROVAL FOR A PRODUCT THAT IS IDENTICAL OR SUBSTANTIALLY THE SAME AS ONE OF HYLORIS' PRODUCT CANDIDATES, WHICH MAY PREVENT HYLORIS FROM COMMERCIALIZING ITS PRODUCT CANDIDATES IN ACCORDANCE WITH ITS BUSINESS PLAN OR RESULT IN SIGNIFICANT DELAYS IN DOING SO.**

If one of Hyloris' product candidates is approved through the 505(b)(2) regulatory pathway, one or more competitors could file ANDAs for generic versions of that product candidate. This risk is even greater for products approved through the 505(b)(2) regulatory pathway as compared to those approved under the traditional NDA pathway due to the fact that the exclusivity periods for products approved through the 505(b)(2) regulatory pathway are typically shorter than for those approved through the traditional NDA pathway. Of Hyloris' current product candidate portfolio, two products, Maxigesic® IV and HY-REF-004, are eligible to receive such market exclusivity; however, Hyloris does not expect to rely on such market exclusivity for either product. For further detail regarding the exclusivity periods possible under the 505(b)(2) regulatory pathway, see Section 8.9.5 (Patents and market exclusivity).

If there are patents listed for the product candidate in the Orange Book by Hyloris, a competitor's 505(b)(2) or ANDA applications would be required to include a "Paragraph IV" certification as to each listed patent indicating whether the applicant does or does not intend to challenge any existing patent or patents. Hyloris cannot predict which, if any, of the patents it may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether Hyloris would sue on any such patents, or the outcome of any such suit. If any of Hyloris' owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a "Paragraph IV" certification and subsequent litigation, the period which Hyloris does not face competition from generics will be reduced and Hyloris' revenues with respect to that product may be less than expected and Hyloris may not realize commercial success with respect to that product after having already invested significant time and expense in its development.

Regulators in any applicable jurisdiction, including in the United States, may at any time approve one or more products that is a new or improved version of the originally approved pharmaceutical product and

such products may be identical or similar to, or directly compete with one of Hyloris' products that have also received regulatory approval. Regulators may also approve one or more products that are identical or similar to or directly compete with one of Hyloris' product candidates before Hyloris receives its own regulatory approval for such product candidate, which may delay or prevent Hyloris from receiving approval of its own product candidate. In such circumstances, a competing product may be granted a period of exclusivity, which would have a material negative impact on Hyloris' ability to launch or commercialize its product. Hyloris believes the risk of competing developments is particularly high for products in its Other Reformulation Portfolio. For example, oral liquid versions of pharmaceutical capsules such as atomoxetine are currently being developed by a number of companies and so this risk applies in particular to that product candidate, however, Hyloris believes the risk applies generally to all of Hyloris' product candidates.

Though Hyloris has not made the decision to do so to date and though this would only apply with respect to a generic product, there may be situations in the future where Hyloris uses its business judgment and decides to market and sell its approved products, notwithstanding the fact that allegations of patent infringement have not been finally resolved by the courts, which is commonly known as an "at-risk launch." The risk involved in doing so can be substantial because the remedies for infringement available to the owner of a patent may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be multiplied up to three times.

If products that will compete with Hyloris' product candidates are simultaneously approved, or if competing products are approved before Hyloris' version of the product is approved, it could delay or prevent Hyloris from registering, launching or commercializing the relevant product candidate in accordance with its plans. It could also lead to litigation or disputes which may result in unforeseen costs and delays in the commercialization of the relevant product and could ultimately prevent Hyloris from successfully launching the relevant product or executing its commercialization strategy in accordance with its business plan.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.2.3 THE OCCURRENCE OF A PANDEMIC, EPIDEMIC OR OTHER HEALTH CRISIS, INCLUDING THE RECENT OUTBREAK OF COVID-19, COULD HAVE A NEGATIVE IMPACT ON HYLORIS' PRODUCT DEVELOPMENT ACTIVITIES, INCLUDING ITS ACCESS TO APIs, THE CONDUCT OF ITS CLINICAL TRIALS AND ITS ABILITY TO SOURCE REQUIRED FUNDING, WHICH COULD DELAY OR PREVENT IT FROM EXECUTING ITS STRATEGY AS PLANNED.**

Hyloris' business and the business of its development partners could be materially adversely affected by the effects of pandemics, epidemics or other health crises, including the recent outbreak of COVID-19. On 11 March 2020, the World Health Organization declared COVID-19 a global pandemic, which resulted in the implementation of travel and other restrictions across the world to reduce the spread of the disease. As a result of these developments, Hyloris has implemented work-from-home policies for all of its employees. The effects of local lockdown orders, government-imposed quarantines, travel restrictions, port closures, business closures and work-from-home policies have restricted Hyloris' access to active pharmaceutical ingredients (APIs), delayed two clinical programs (Maxigesic® IV and

HY-REF-004) and may negatively impact its productivity, delay additional clinical programs, disrupt product development or approval timelines, decrease the availability of funding and otherwise have a material adverse effect on Hyloris' business. Hyloris believes that the overall impact of COVID-19 on its business and operations has so far been minimal; however, the ongoing magnitude of such impact will depend, in part, on the length and severity of the restrictions and other limitations on Hyloris' ability to conduct its product development activities.

COVID-19 related measures may also impact third parties with whom Hyloris conducts business, including CROs, contract development organizations (**CDOs**), contract development and manufacturing organizations (**CDMOs**), contract manufacturing organizations (**CMOs**), API suppliers and others. These measures may cause a disruption in the supply chain which could result in a material adverse effect on the availability and cost of APIs and other raw materials necessary for the manufacture of its products and the development of its product candidates. To date, supply chain disruptions resulting from the COVID-19 situation have impacted two of Hyloris' products. The APIs used in the manufacture of Metolazone IV are sourced from a provider in India, where a nationwide lockdown is in effect, and APIs for Atomoxetine Oral Liquid are sourced from providers based in China, where nationwide lockdowns have only recently been relaxed, and India. The shipment of goods from India to the United States is currently only possible between a limited number of airports and Indian customs processes are experiencing significant delays due to a backlog of shipments. As a result, Hyloris has experienced delays in obtaining certain amounts of API required for the production of Metolazone IV and although a first batch of the API required for the production of Atomoxetine Oral Liquid has been received by Hyloris' CDO, there can be no assurance that such delays will not persist or worsen or that the APIs required will be available in sufficient amounts, in the timeframes required, or at all.

In addition, Hyloris' ongoing and upcoming clinical trials have been and may continue to be affected by the recent COVID-19 outbreak. Site initiation and patient enrolment have been delayed due to prioritization of hospital resources toward the COVID-19 outbreak and the suspension of many non-critical surgeries, which is where many trial participants are sourced. Further, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be delayed or disrupted, which would adversely impact Hyloris' clinical trials. Activities in hospitals in the United States have been severely restricted as those facilities focus on dealing with COVID-19 cases and restrict non-essential medical procedures. As a result, the recruitment of patients for participation in clinical trials for Maxigesic<sup>®</sup> IV in the United States, has not been possible and the recruitment program has for now been suspended. Likewise, the commencement of clinical trials in respect of HY-REF-004 has been similarly delayed. Currently, Hyloris has suspended the execution of these clinical trials for an expected period of a maximum of three months and intends to resume these clinical activities as soon as conditions allow, however, the timing of such resumption cannot be predicted.

Furthermore, the effects of local lockdown orders, government-imposed quarantines, travel restrictions, business closures and work-from-home policies have resulted in a disruption in the product development of Tranexamic Acid RTU, leading Hyloris to reschedule its anticipated FDA filing date for that product candidate by approximately four months.

The spread of COVID-19 has caused a broad economic impact globally. While the ultimate overall economic impact caused by the COVID-19 pandemic may be difficult to assess or predict, it is currently resulting in significant disruption to the global financial markets. Although the COVID-19 pandemic did not prevent Hyloris from completing its private placement of Convertible Bonds in April 2020, if the resulting disruptions are sustained or recurrent, could make it more difficult for Hyloris to access capital, which could in the future negatively affect its ability to execute its strategy of developing the products in its existing pipeline as well as introducing and developing new product candidates and consequently ever becoming profitable.

The ultimate impact of the COVID-19 outbreak or a similar health pandemic or epidemic is highly uncertain and subject to rapid change. Although Hyloris is monitoring developments relating to the COVID-19 situation closely, the impact of COVID-19 on Hyloris' business is uncertain at this time and will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions taken to contain it or address its impact, among other things. Therefore, Hyloris does not yet know the full extent of the impact on its business (including its supply chains, its clinical trials and its access to the capital required to execute its business strategy); however, Hyloris believes the extent of that impact will likely increase to the extent that COVID-19 continues to affect the global economy in general for a sustained period of time.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.2.4 HYLORIS CURRENTLY HAS NO SALES AND MARKETING FUNCTION AND IT WILL BE REQUIRED TO DEVELOP ONE IN ORDER TO EXECUTE ITS STRATEGY WITH RESPECT TO ITS IV CARDIOVASCULAR PORTFOLIO IN THE UNITED STATES AND TO SECURE SUITABLE SALES AND MARKETING PARTNERS FOR ITS OTHER PRODUCTS. IF HYLORIS IS UNABLE TO DO SO, IT MAY NOT SUCCESSFULLY COMMERCIALIZE ANY OF ITS PRODUCT CANDIDATES.**

Hyloris has no internal sales and marketing capability and Hyloris' Executive Management do not have specific experience in marketing pharmaceutical products in the United States. Hyloris currently plans to establish a U.S. based sales and marketing function and establish a focused direct sales team in the United States targeting cardiologists in U.S. hospitals in order to commercialize its IV Cardiovascular Portfolio in the United States. Hyloris expects this team to eventually include a total of approximately 70 employees, including approximately 50 sales representatives, compared to the 9.90 full-time equivalent employees of Hyloris as of 31 March 2020. Factors that may inhibit Hyloris' efforts to commercialize successfully its IV Cardiovascular Portfolio in the United States by establishing an internal sales and marketing function include:

- an inability to recruit and retain adequate numbers of effective sales and marketing personnel or medical science liaisons in the United States;
- an inability of U.S. sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any of Hyloris' product candidates;

- the lack of complementary products to be offered by U.S. sales personnel, which may put Hyloris at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing function.

In addition, Hyloris will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel and experienced medical science liaisons.

Except in respect of its IV Cardiovascular Portfolio, Hyloris has entered or plans to enter into licensing agreements with commercial partners for distribution of its products. If Hyloris enters into such relationships, it may have limited or no control over the sales, marketing and distribution activities of these third parties. Hyloris' future revenues may depend heavily on the success of the efforts of these third parties

Hyloris may not be able to successfully build such a sales and marketing function in a timely manner or, to the extent necessary, to enter into collaboration or licensing agreements with third parties on acceptable terms or at all. If Hyloris is not successful in entering into appropriate collaboration or licensing arrangements, or in recruiting sufficient sales and marketing personnel or generally in building a sales and marketing team, it will have difficulty successfully commercializing its product candidates.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.2.5 HYLORIS WILL BE COMPLETELY DEPENDENT ON THIRD PARTIES TO SUPPLY APIS AND MANUFACTURE ITS PRODUCTS, AND COMMERCIALIZATION OF HYLORIS' PRODUCT CANDIDATES COULD BE DELAYED, HALTED OR MADE LESS PROFITABLE IF THOSE THIRD PARTIES FAIL TO OBTAIN AND MAINTAIN THE REQUIRED APPROVALS FROM THE FDA OR COMPARABLE FOREIGN REGULATORY AUTHORITIES, OR OTHERWISE FAIL TO PROVIDE HYLORIS WITH SUFFICIENT QUANTITIES OF ITS PRODUCTS.**

Hyloris does not currently have, nor does it plan to acquire, the capability or infrastructure to produce API. In addition, Hyloris does not have the capability to manufacture any of its product candidates as a finished pharmaceutical product for development or commercial distribution. As a result, Hyloris is and will be obligated to rely on API suppliers and CMOs in order to develop its product candidates and to produce its products once they are approved for commercialization. While Hyloris has entered into certain agreements with API suppliers and CMOs for clinical and commercial supply with respect to some of its product candidates, there can be no assurance Hyloris will be able to maintain those relationships or engage additional API suppliers and CMOs as necessary for clinical or commercial supply of any of its product candidates on favorable terms or at all.

Hyloris' API suppliers and CMOs and the facilities they use must be approved by the FDA or comparable foreign regulatory authorities and will be subject to ongoing periodic unannounced inspections by such authorities for compliance with applicable regulatory requirements covering all aspects of the manufacturing, testing, quality control and record keeping process. Though Hyloris has strict selection

criteria for its API suppliers and CMOs and closely monitors them, Hyloris will not have full control over their achieving the required approvals and maintaining compliance with these ongoing requirements. Reliance on API suppliers and CMOs will not relieve Hyloris of its regulatory responsibilities, and Hyloris will be responsible for ensuring that all aspects of the manufacture of its products are conducted in accordance with all applicable legal, regulatory and scientific standards. If the FDA or a comparable foreign regulatory authority does not approve the CMO's facilities for the development and manufacture of Hyloris' product candidates or if any such approval is withdrawn in the future, Hyloris may need to find an alternative CMO, which would significantly impact its ability to develop or market its product candidates. Failure by any of Hyloris' API suppliers and CMOs to comply with applicable regulations could result in sanctions being imposed on Hyloris, including fines, injunctions, civil penalties, failure to grant approval to market any of its product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could prevent Hyloris' from developing or marketing any of its product candidates and significantly and adversely affect Hyloris' ability to execute its strategy and implement its business plan.

If, for any reason, Hyloris' API suppliers and CMOs are unable to perform as required, Hyloris may have to expend significant resources in identifying satisfactory alternative partners or may not be able to secure suitable alternative partnerships. As a result, Hyloris could experience significant interruptions in the delivery of its products or may not be able to generate or sustain sufficient inventory levels, resulting in lost sales. Because of the significant regulatory requirements that Hyloris would need to satisfy in order to qualify a new API supplier or CMP, transferring the supply of APIs or the manufacture of any of its product candidates to one or more alternative suppliers or manufacturers would be very burdensome, take a significant amount of time, require the expenditure of a significant amount of management resources and could lead to significant interruptions in supply and in turn lost sales or could require Hyloris to remove a product from the market entirely, including recalling products already sold.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.2.6 INTELLECTUAL PROPERTY RIGHTS ARE DIFFICULT AND COSTLY TO OBTAIN, MAINTAIN AND PROTECT AND HYLORIS MAY NOT BE ABLE TO FULLY ENSURE THE PROTECTION OF ITS RIGHTS, WHICH MAY ADVERSELY IMPACT HYLORIS' FINANCIAL PERFORMANCE AND PROSPECTS.**

Hyloris' commercial success will depend, in part, on obtaining and maintaining patent protection for its product candidates, successfully defending those patents against third-party challenges, including challenges to the validity of its patents before the U.S. Patent and Trademark Office (**U.S. PTO**), and successfully enforcing those patents against third-party competitors.

The degree of future protection for Hyloris' proprietary rights is uncertain, in part because the patent positions of pharmaceutical companies involve complex legal, scientific and factual questions for which important legal principles remain unresolved and current legal means afford only limited protection and may not adequately protect Hyloris' rights, permit Hyloris to gain or keep its competitive advantage, or provide Hyloris with any competitive advantage at all. For example, others may file, and in the future are likely to file, patent applications covering products and technologies that are similar, identical to or competitive with Hyloris' product candidates. In these circumstances, Hyloris may need to defend or assert its rights under its patents, including by filing lawsuits alleging patent infringement which would

require Hyloris to engage in litigation or other proceedings and may divert Executive Management's attention from other aspects of Hyloris' business, which could be particularly burdensome for Hyloris as compared to its larger and more established competitors. Hyloris may not prevail in any lawsuits that it initiates, and the damages or other remedies awarded, if any, may not be commercially meaningful.

If Hyloris or one of its licensing partners initiated legal proceedings against a third party to enforce a patent covering one of its product candidates, the defendant could counterclaim that the patent covering the product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Third parties may also raise claims before administrative bodies in the United States or abroad, even outside the context of litigation. The outcome of any such proceedings is unpredictable and could result in the revocation or amendment of Hyloris' patents or Hyloris' licensors' patents in such a way that they no longer cover product candidates. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, Hyloris would lose at least part, and perhaps all, of the patent protection on the relevant product candidate. Such a loss of patent protection may result in the introduction of competing products which could reduce Hyloris' relevant market share and revenues which would have a material adverse impact on Hyloris' financial results. Further, even if Hyloris has valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve its business objectives.

In addition, depending on decisions by the U.S. Congress, the federal courts, the U.S. PTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents approval could change in unpredictable ways that would weaken Hyloris' ability to obtain new patents, enforce its existing in-licensed patents or patents that it might obtain in the future.

In addition, patent protection requires compliance with certain requirements on an ongoing basis in order to remain effective. Non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If Hyloris or its licensors that control the prosecution and maintenance of Hyloris' licensed patents fail to maintain the patents and patent applications covering Hyloris' product candidates, Hyloris' competitors may enter the market, which could have a material adverse effect on Hyloris' market share and sales.

In the future, Hyloris may rely on know-how and trade secrets to protect technology, especially in cases when Hyloris believes patent protection is not appropriate or obtainable. However, know-how and trade secrets are difficult to protect. While Hyloris intends to require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, Hyloris may not be able to adequately protect its trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which Hyloris may have rights. If Hyloris cannot maintain the confidentiality of its proprietary technology and other confidential information, Hyloris' ability to receive patent protection and protect valuable information owned by Hyloris may be jeopardized. Enforcing a claim that a third-party entity illegally obtained and is using any of Hyloris' trade secrets is expensive and time consuming, and the outcome is unpredictable.

In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, Hyloris' competitors may independently develop equivalent knowledge, methods and know-how.

Hyloris believes that the potential negative impact of this risk is low.

**2.1.2.7 THE PATENTS AND THE PATENT APPLICATIONS COVERING HYLORIS' PRODUCTS AND PRODUCT CANDIDATES APPROVED OR EXPECTED TO BE APPROVED THROUGH THE 505(B)(2) REGULATORY PATHWAY ARE AND WILL BE LIMITED TO SPECIFIC FORMULATIONS, METHODS OF USE AND PROCESSES AND HYLORIS' MARKET OPPORTUNITY WITH RESPECT TO ITS PRODUCT CANDIDATES MAY BE LIMITED BY A LACK OF PATENT PROTECTION FOR THE ACTIVE INGREDIENTS AND BY COMPETITION FROM OTHER FORMULATIONS AND DELIVERY METHODS THAT MAY BE DEVELOPED BY COMPETITORS.**

For Hyloris' products approved or product candidates expected to be approved through the 505(b)(2) regulatory pathway, Hyloris has obtained, is seeking to obtain, or plans to obtain patent protection, including through patents covering specific formulations, methods of use and processes; however, Hyloris will not have patent protection for the active ingredients in its product candidates or products. The type of patent protection obtained by Hyloris does not prevent its competitors from developing products using the same active ingredients, and, as a result, other 505(b)(2) products or generic products that do not infringe Hyloris' issued patents covering formulations, methods of use and processes are, or may be, available while Hyloris is marketing its products. Competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredients as Hyloris' product candidates so long as the competitors do not infringe any patents that Hyloris has developed for its products, subject to any regulatory exclusivity to which Hyloris' products may be entitled. The commercial potential of Hyloris' products and product candidates approved or expected to be approved through the 505(b)(2) regulatory pathway could be significantly harmed if competitors are able to develop and commercialize alternative formulations of Hyloris' product candidates that do not infringe the issued patents covering Hyloris' products.

Hyloris believes that the potential negative impact of this risk is low.

**2.1.3 RISKS RELATED TO MANAGEMENT AND PERSONNEL**

**2.1.3.1 HYLORIS MAY BE UNABLE TO SUCCESSFULLY MANAGE ITS GROWTH.**

During the next few years, Hyloris expects to expand its operations significantly as it continues to seek regulatory approvals for and commercialize the product candidates in its existing pipeline and as it introduces new product candidates into its pipeline for development and commercialization. Growth may place a significant strain on Hyloris' Executive Management, operating and financial systems and administrative resources. Growth may cause Hyloris' operating costs to increase faster than planned, and some of Hyloris' internal systems and processes, may need to be enhanced, updated or replaced. If Hyloris cannot effectively manage its expanding operations and costs, it may not be able to grow as quickly or as profitably as expected or at all. For example, Hyloris currently has no sales and marketing function and expects to develop one in order to execute its marketing strategy with respect to its IV Cardiovascular Portfolio in the United States (see Section 8.10.2 (IV Cardiovascular Portfolio)). Building-up such a sales team may place a significant strain on Hyloris' Executive Management and may cause

costs to increase more than anticipated (see also Risk Factor 2.1.3.2, which covers this specific example more extensively).

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.3.2 IN ORDER TO EXECUTE ITS BUSINESS PLAN, HYLORIS WILL NEED TO RETAIN ITS KEY EMPLOYEES AND WILL ALSO BE REQUIRED TO ATTRACT AND RETAIN ADDITIONAL HIGHLY QUALIFIED PERSONNEL AS IT INCREASES THE SIZE OF ITS ORGANIZATION.**

Hyloris' ability to execute its business plan will depend in large part upon its ability to attract and retain highly qualified executives, managers, scientific and medical personnel and, in relation to its anticipated sales and marketing function with respect to its IV Cardiovascular Portfolio in the United States, sales and marketing staff. Although key members of Hyloris' existing staff have entered into employment and consulting agreements which contain standard confidentiality, non-compete and termination provisions, and despite Hyloris' efforts to retain valuable employees, members of Hyloris' team may terminate their employment on short notice. The loss of the services of any of Hyloris' key employees, particularly in light of the relatively small size of the Executive Management team, which as of the date of this Prospectus comprised six individuals, and the overall number of employees in Hyloris, which as of the date of this Prospectus comprised eight additional individuals (for a total of 9.90 full-time equivalents), could have a material adverse effect on Hyloris' ability to effectively manage its business and execute its strategy. In particular, Hyloris believes that the loss of the services of its Chief Executive Officer, who is also a major shareholder, or other members of Hyloris' Executive Management would have a material adverse effect on its business.

In addition, as Hyloris continues to execute its strategy and develop its business, it will need to expand the size of its employee, consultant and contractor base. In the near term, Hyloris is looking to hire approximately four to six additional employees and in the future, Hyloris expects to hire additional personnel as necessary in order to support the development of its product candidate portfolio. Competition for skilled personnel in the pharmaceutical market is intense and competition for highly qualified and experienced employees may limit Hyloris' ability to hire and retain the employees it requires on acceptable terms or at all. Other pharmaceutical companies with which Hyloris competes for qualified personnel may have greater financial and other resources, different risk profiles, and a longer operating history than Hyloris. If Hyloris is unable to continue to attract and retain high-quality personnel, the rate and success at which it can develop and commercialize product candidates would be limited.

Hyloris believes that the potential negative impact of this risk is medium.

**2.1.3.3 HYLORIS IS CURRENTLY IN THE PROCESS OF EXPANDING ITS EXECUTIVE MANAGEMENT BY ADDING ADDITIONAL KEY MEMBERS, INCLUDING A CHIEF SCIENTIFIC OFFICER AND A CHIEF OPERATING OFFICER, AND IT IS ALSO CURRENTLY SEARCHING FOR A PERMANENT CHIEF FINANCIAL OFFICER. UNTIL SUCH TIME AS THOSE POSITIONS ARE FILLED, THE EXISTING EXECUTIVE MANAGEMENT TEAM MAY EXPERIENCE PRESSURE AND CONSTRAINTS ON ITS TIME AND RESOURCES**

As of the date of this Prospectus, the Executive Management Team is comprised of the following members:

Name	Position
Mr. Stijn Van Rompay <sup>(1)</sup>	Chief Executive Officer
Ms. Astrid Heiremans <sup>(2)</sup>	Acting Chief Financial Officer
Mr. Thomas Jacobsen <sup>(3)</sup>	Executive Director <sup>(4)</sup>
Mr. Koenraad Van der Elst <sup>(5)</sup>	Chief Legal Officer
Mr. Edward Maloney <sup>(6)</sup>	Chief Business Development Officer

Notes:

- (1) Acting through SVR Management BV.
- (2) Acting through Finfactory BV.
- (3) Acting through Jacobsen Management BV.
- (4) Responsible for IP, regulatory and commercial partnerships.
- (5) Acting through Herauld BV.
- (6) Acting through Humara Kinetics LLC.

Hyloris expects to strengthen its Executive Management in the near future with a permanent Chief Financial Officer and the addition of a Chief Scientific Officer and a Chief Operating Officer. As of the date of this Prospectus, the Issuer is in advanced talks with potential candidates for the Chief Scientific Officer and Chief Operating Officer positions. The Company is actively looking for a permanent Chief Financial Officer and expects to hire a permanent Chief Financial Officer following the Offering. Until such time, Ms. Astrid Heiremans is the acting Chief Financial Officer of the Company.

Until the new members can be added to its Executive Management, Hyloris will continue to operate with its lean Executive Management. Although Hyloris believes that its existing Executive Management has sufficient experience to meet its current requirements, and it believes that it will be able to execute its plan to grow its Executive Management in the short term in order to support its growth and development strategies, any delay in completing the planned additions to its Executive Management could result in additional pressure and constraints on the time and resources of its existing Executive Management, as they will need to divide their time and attention to manage the respective tasks.

Hyloris believes that the potential negative impact of this risk is low.

#### **2.1.4 RISKS RELATED TO CONFLICTS OF INTEREST**

##### **2.1.4.1 HYLORIS HAS ENTERED INTO ARRANGEMENTS WITH RELATED PARTIES AND THESE ARRANGEMENTS PRESENT POTENTIAL CONFLICTS OF INTEREST.**

As part of the business, Hyloris has entered into several transactions with related parties, namely, the Alter Pharma group<sup>5</sup>. Hyloris' Chief Executive Officer (**CEO**), Mr. Stijn Van Rompay, and board member and Executive Director, Mr. Thomas Jacobsen, are currently the majority shareholders of Hyloris. Immediately prior to the closing of the Offering, Mr. Stijn Van Rompay and Mr. Thomas Jacobsen owned

<sup>5</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

36.2% and 19.3% of the Shares of Hyloris, respectively. Mr. Pieter Van Rompay, sibling of Mr. Stijn Van Rompay, owns 5.1% of the Shares of Hyloris, while Hyloris' Chief Business Development Officer (CBDO) Edward Maloney is also a shareholder (owning less than 3% of the Shares). Mr. Stijn Van Rompay, Mr. Thomas Jacobsen and Mr. Pieter Van Rompay also have material ownership interests in the Alter Pharma group (owning 21.8%, 5% and 6.8%, respectively). In addition, Mr. Stijn Van Rompay and Mr. Thomas Jacobsen each own less than 0.01% of the shares in the Alter Pharma group, indirectly, through civil-law partnership Burgerlijke Maatschap Eden. Burgerlijke Maatschap Eden has a 11.1% ownership interest in the Alter Pharma group. Mr. Stijn Van Rompay is the managing partner of Burgerlijke Maatschap Eden, with the power and duty to, amongst other things, administer the partnership and exercise the rights attached to the shares in the Alter Pharma group held by the partnership, in accordance with the terms and conditions of the partnership agreement. If Mr. Stijn Van Rompay would no longer fulfil this mandate, Mr. Thomas Jacobsen will succeed him as managing partner of the partnership. Mr. Stijn Van Rompany and Mr. Thomas Jacobsen are both members of the Alter Pharma group's board of directors and Mr. Thomas Jacobsen also holds an executive position in the Alter Pharma group.

Hyloris has entered into various agreements with subsidiaries of the Alter Pharma group, including Generic Specialty Pharma, Nordic Specialty Pharma, Stasisport Pharma and Neogen Developments. These include licensing agreements, asset purchase agreements, development agreements and patent and know-how agreements. The products associated with these arrangements are Maxigesic® IV, HY-REF-075, Fusidic Acid Cream, HY-REF-038 and HY-REF-028 (which Hyloris is no longer developing). Under the various transactional agreements between Hyloris and the subsidiaries of the Alter Pharma group, Hyloris is required to pay these entities a combination of licensing fees, milestone payments and royalty payments. The transactional agreements also subject Hyloris to a loss of its rights to the product candidates in the event it breaches any of its representations, warranties or covenants included in the relevant agreements. See Section 12 (Related Party Transactions) for more information on these related party transactions.

Hyloris has also received shareholder loans from related parties. For example, on 28 June 2019, Hyloris entered into a loan agreement with Mr. Stijn Van Rompay pursuant to which Mr. Stijn Van Rompay lent Hyloris USD 2,100,000 and EUR 8,500,000. As of the date of this Prospectus, USD 2,100,000 and EUR 2,719,494.31 in principal are still outstanding under this loan agreement, for which it was specified and agreed on 3 June 2020 that these outstanding amounts will be reimbursed at the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT. For the years ended 31 December 2017, 2018 and 2019, the total amount of services purchased from related parties amounted to EUR 6.6 million, of which EUR 2.8 million relates to the discontinued product HY-REF-028. As of 31 December 2019, trade payables relating to such related party transactions totaled EUR 1.9 million. As of 31 December 2019, the total amount of outstanding loans from related parties was EUR 11.7 million. For further details of the related party transactions into which Hyloris has entered, see Section 12 (Related party transactions), Note 18 to the Interim Financial Information (as defined in Section 5.5 (Presentation of financial and other information)) and Note 27 to the Annual Financial Statements (as defined in Section 5.5 (Presentation of financial and other information)).

While Hyloris believes that the terms of the transactional agreements, including the licensing fees, milestone payments and royalty payments, approximate the terms and payments Hyloris could have obtained in an arms' length transaction with an unaffiliated party, these arrangements may present Mr. Stijn Van Rompay and Mr. Thomas Jacobsen with conflicts of interest which may include the allocation of financial and management resources, the repayment of loans and trade payables and decisions relating to the allocation and pursuit of certain business opportunities. Although Hyloris has mechanisms in place to protect the interests of its shareholders in accordance with Belgian law, including the advice and judgment of the Board of Directors, of which three (out of a total of seven members) are independent and have no interest in these related parties, there can be no assurance that a conflict of interest will not arise or that any such conflict will not adversely impact the interests of Hyloris' shareholders.

Hyloris believes that the potential negative impact of this risk is high.

**2.1.4.2 CERTAIN OF HYLORIS' DIRECTORS AND MEMBERS OF HYLORIS' EXECUTIVE MANAGEMENT HOLD DIRECTORSHIPS OR SHAREHOLDINGS IN OTHER PHARMACEUTICAL COMPANIES, WHICH COULD CREATE POTENTIAL CONFLICTS OF INTEREST.**

As described in Section 10.6.5 (Corporate Opportunities) of this Prospectus, the members of Hyloris' Board of Directors and its Executive Management have been appointed based on their competencies and experience in the pharmaceutical industry and other related areas of expertise. As such, Hyloris' directors and members of Executive Management may hold directorships in other pharmaceutical companies or in companies that control other pharmaceutical companies, or they may otherwise be active in the pharmaceutical industry in their individual capacities. Additionally, members of Hyloris' Executive Management hold shares in other pharmaceutical companies that are active in development activities similar or complementary to those of Hyloris. For example, Mr. Van Rompay, and Mr. Jacobsen have material ownership interests in the Alter Pharma group (owning 21.8% and 5%, respectively), which focuses on the generics market. Mr. Stijn Van Rompany and Mr. Thomas Jacobsen are both members of Alter Pharma Group NV's board of directors, and Mr. Jacobsen also holds an executive position in the Alter Pharma group.

These directorships and shareholdings could create potential conflicts of interests with respect to the allocation of time, resources or business opportunities. For example, if a Hyloris director or member of Executive Management were to become aware of an opportunity with respect to a high-potential product candidate, being a director of or having a significant shareholding in a competing company may obligate or incentivize such director or member of Executive Management to present that opportunity to a competitor of Hyloris rather than to Hyloris. In all cases, however, such directorships and shareholdings are subject to applicable rules with respect to corporate governance. –Those rules will not, however, eliminate the potential for conflicts of interests that may have a negative material impact on Hyloris due to lost opportunity or otherwise. The relationship between these directors and members of Executive Management and the companies which they serve ultimately relies on a degree of trust between the parties and the ability of those individuals to exercise fair and equitable judgment in respect of decisions under which potential conflicts of interest present themselves. As a result, the possibility that conflicts of interest may arise and that the resolution of those conflicts may have a material negative impact on Hyloris cannot be eliminated.

Each member of Executive Management has signed a non-compete agreement with Hyloris. For further information, please see Section 10.5.3.3 (Payments upon Termination). Although Hyloris believes that its strategy is distinct from those of the companies where such conflicts of interest may otherwise arise, and from the business model of the Alter Pharma group in particular, this or any similar situation could potentially lead to a conflict of interest which may favor the rights of majority shareholders over the rights of minority shareholders and may have a negative impact on Hyloris' opportunity to execute its strategy in the most time and cost efficient manner.

Hyloris believes that the potential negative impact of this risk is high.

## **2.2 RISKS RELATED TO HYLORIS' FINANCIAL SITUATION**

### **2.2.1 HYLORIS HAS A LIMITED OPERATING HISTORY AND HAS NOT YET GENERATED ANY SUBSTANTIAL REVENUES. HYLORIS HAS INCURRED OPERATING LOSSES, NEGATIVE OPERATING CASH FLOWS AND AN ACCUMULATED DEFICIT SINCE INCEPTION RESULTING IN A NEGATIVE EQUITY AT THE DATE OF THE PROSPECTUS AND HYLORIS MAY NOT BE ABLE TO ACHIEVE OR SUBSEQUENTLY MAINTAIN PROFITABILITY. HYLORIS IS EXECUTING ITS STRATEGY IN ACCORDANCE WITH ITS BUSINESS MODEL, THE VIABILITY OF WHICH HAS NOT BEEN DEMONSTRATED.**

To date, Hyloris' operations have consisted primarily of the identification of product candidates to build its pipeline and the formulation, testing and development of its existing portfolio. As a result, Hyloris has not yet generated any substantial revenues. As a relatively young business, Hyloris is subject to all the risks inherent in the organization, management recruitment, financing, expenditures, complications and delays of a new business. The viability of Hyloris' business plan has not yet been proven. Hyloris' limited operating history makes it difficult for potential investors to evaluate Hyloris' ability to successfully implement or execute its business plan and achieve profitability. For further details on the risks related to Hyloris' business activities and industry please see the risk factors set out in Section 2.1 above.

From 1 January 2017 to 31 December 2019, Hyloris incurred a net loss of EUR 15.5 million. For the year ended 31 December 2019, Hyloris generated revenue of EUR 91 thousand, incurred a net loss of EUR 5.8 million, and its operations used EUR 4.6 million of cash and cash equivalents. In addition, Hyloris experienced a negative equity of EUR 10.2 million, 4.5 million and 4.3 million as of December 31, 2019, 2018, and 2017, respectively, mainly due to continuous net losses.

As a result of the negative net equity (at non-consolidated level) of the Issuer's subsidiaries, the Issuer's subsidiaries (*i.e.*, Hyloris Developments, RTU Pharma and Dermax) had to comply with the procedure under Article 7:228 CCA, which provides that if, as a result of losses incurred, the ratio of a company's net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the board of directors must convene a general shareholders' meeting within two months as of the date upon which the board of directors discovered or should have discovered this undercapitalisation, to resolve on either the continuation or the dissolution of the company. In addition, pursuant to Article 7:229 CCA, if the amount of the company's net assets is below EUR 61,500 (the minimum amount of share capital of a corporation with limited liability organised under the laws of Belgium ("*naamloze vennootschap*" / "*société anonyme*")), any interested

party is entitled to request the competent court to dissolve the company. The court can order the dissolution of the company or grant a grace period within which the company is to remedy the situation. Notwithstanding the negative net equity, the Issuer (as sole shareholder of its subsidiaries) resolved on 15 June 2020, in accordance with Article 7:228 CCA, to continue the activities of each of the subsidiaries, and not to dissolve them.

Following completion of the Offering, Hyloris expects to incur substantial expenses without generating substantial revenues unless and until it has successfully commercialized its two current products (which are not expected to independently generate substantial revenues), and it is able to obtain regulatory approval and successfully commercialize additional product candidates. Even if Hyloris is able to commercialize its product candidates, there can be no assurance that it will generate significant revenues or achieve profitability.

More precisely, Hyloris expects to have significant research, regulatory and development expenses as it advances its product candidates in the United States and elsewhere. As a result, on the basis of its current business plan (including the assumptions included therein), Hyloris expects to incur substantial expenses without generating substantial revenues unless and until it has successfully commercialized its two current products and Hyloris may continue to experience losses in the future. Hyloris could, by way of a positive and best-case scenario, based on its current product candidate portfolio (and on the hypothesis that its portfolio would remain unchanged) achieve operational profitability (on EBIT level) at the earliest by late 2022. Until such time, in view of increasing costs related to the further development of its current product candidate portfolio that will not be offset by its revenues, Hyloris is expected to continue to incur increasing losses. As a result, there can be no assurance that Hyloris will achieve profitability within the expected time frame, or will ever achieve it. If Hyloris achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable may impair Hyloris' ability to sustain operations and adversely affect its ability to raise capital and to execute its product development strategy. If Hyloris is unable to generate positive cash flow within a reasonable period of time, it may be unable to pursue its business plan or continue operations, in which case potential investors may lose some or all of their investment.

Hyloris believes that the potential negative impact of this risk is high.

**2.2.2 IN THE OPINION OF THE COMPANY, HYLORIS DOES NOT HAVE SUFFICIENT WORKING CAPITAL FOR ITS PRESENT REQUIREMENTS, THAT IS FOR AT LEAST THE NEXT 12 MONTHS FOLLOWING THE DATE OF THIS PROSPECTUS. WHILE IN THE OPINION OF THE COMPANY FOLLOWING THE OFFERING IT WILL HAVE SUFFICIENT WORKING CAPITAL TO DO SO, HYLORIS MAY REQUIRE ADDITIONAL FINANCING IN ORDER TO EXECUTE ITS BUSINESS PLAN AND FUND ITS OPERATIONS, WHICH MAY NOT BE AVAILABLE ON REASONABLE TERMS OR AT ALL.**

In the opinion of the Company, Hyloris currently does not have sufficient working capital for its present requirements, that is for at least the next 12 months following the date of this Prospectus. Based on a working capital assessment, the Company expects that it will have a shortfall of approximately EUR 2 million by the end of the second quarter of 2021. See also Section 6.3 (Working Capital Statement).

Hyloris is undertaking the Offering in order to acquire the additional capital it expects is necessary to realize its business plan. See Section 6.5 (Reasons for the Offering and use of proceeds) for more information on the use of proceeds of the Offering. Assuming the completion of the Offering, the Company is of the opinion that, taking into account the amount of the Pre-commitments (*i.e.*, EUR 22,725,000) together with its available cash and cash equivalents, it will have sufficient working capital to meet its present requirements, that is for a period of at least 12 months following the date of this Prospectus.

Depending on, among other things, the Offer Price and the Offered Shares that will be effectively subscribed for upon completion of the Offering and any unforeseen circumstances (including the potential impact of COVID-19 on the global economy or general financing conditions) that could cause delays in timelines or larger outlays of capital than currently budgeted, Hyloris may, after the Offering, still require additional capital, which it may not be able to secure. In the event Hyloris requires additional capital, it may endeavor to seek additional funds through various financing sources, including the issue of additional equity and debt securities, entering into additional loans, licensing fees for its technology and joint ventures with industry partners. Equity financing may have a dilutive effect on existing shareholders and debt financing would result in increased interest expenses. In any event, there can be no guarantee that such additional funds will be available through these or any other financing sources on commercially reasonable terms, or at all. If such financing is not available on satisfactory terms, Hyloris may be unable to further pursue its business plan and it may be unable to continue operations, in which case potential investors may lose some or all of their investment.

Hyloris believes that the potential negative impact of this risk is medium.

### **2.2.3 CHANGES IN CURRENCY EXCHANGE RATES COULD HAVE A MATERIAL NEGATIVE IMPACT ON THE PROFITABILITY OF HYLORIS.**

Hyloris is exposed to foreign currency risk, mainly relating to the fact that most of its financing has been raised in euro and it records its transactions and prepares its financial statements in euro, but generates substantially all of its revenue, and incurs substantially all of its costs, in U.S. dollars. The relationships between the U.S. dollar and the euro may be volatile and vary based on a number of interrelated factors, including the supply and demand of each currency, political, economic, legal, financial, accounting and tax matters, and other actions beyond Hyloris' control. If the U.S. dollar weakens against the euro, this could lead to exchange rate losses which could negatively impact Hyloris' results when translated into euro for reporting purposes. For details on Hyloris' exposure to exchange differences of its monetary assets and monetary liabilities, please see Note 5.3 to the Annual Financial Statements

Because most of Hyloris' financing has been raised in euro, Executive Management has in the past considered, and in the future may consider, entering into hedging arrangements to cover potential currency exposure and mitigate the financial impact. As of the date of this Prospectus, Hyloris has not entered into any hedging arrangements. If Hyloris does enter into hedging arrangements in the future, there can be no assurance that any such hedging arrangement will be successful.

Hyloris believes that the potential negative impact of this risk is low.

## **2.3 LEGAL AND REGULATORY RISKS**

### **2.3.1 *THIRD-PARTY COVERAGE, REIMBURSEMENT AND HEALTH CARE COST CONTAINMENT INITIATIVES AND TREATMENT GUIDELINES MAY CONSTRAIN HYLORIS' BUSINESS.***

Hyloris' ability to successfully market its product candidates will depend in part on the level of reimbursement that healthcare organizations, including government health administration authorities, private health coverage insurers and other healthcare payors, provide for the cost of Hyloris' products and related treatments. Countries in which any of Hyloris' product candidates will be sold through reimbursement schemes under national health insurance programs frequently require that manufacturers and sellers of pharmaceutical products obtain governmental approval of initial prices and any subsequent price increases. In certain countries, including the United States, government-funded and private medical care plans can exert significant indirect pressure on prices. Increasingly, third-party payors attempt to contain health care costs in ways that are likely to impact Hyloris' business, including:

- failing to approve or challenging the prices charged for health care products;
- introducing importation schemes of products from lower priced jurisdictions;
- limiting both coverage and the amount of reimbursement for new therapeutic products;
- denying or limiting coverage for products that are approved by the regulatory agencies but are considered to be experimental or investigational by third-party payors; and
- refusing to provide coverage when an approved product is used in a way that has not received regulatory marketing approval.

Hyloris may not be able to sell its product candidates profitably if adequate prices are not approved or coverage and reimbursement is unavailable or limited in scope.

Hyloris believes that the potential negative impact of this risk is low.

### **2.3.2 *PRODUCT LIABILITY LAWSUITS MAY RESULT IN SUBSTANTIAL LIABILITIES FOR WHICH HYLORIS MAY NOT HAVE ADEQUATE INSURANCE COVERAGE.***

Hyloris may face product liability lawsuits as a result of the clinical testing of its product candidates and the use of its products following commercialization. Although Hyloris' development strategy focuses on the FDA's 505(b)(2) regulatory pathway for pharmaceuticals where the safety and efficacy of the molecule has been established, it may still face lawsuits related to the development and use of its commercialized products. For example, Hyloris may be sued if any product it develops is alleged to cause injury or illness or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Such product liability claims may include allegations of defects in manufacturing or design, a failure to warn of dangers inherent in the product, negligence, strict liability and breaches of warranty. In the United States, on which Hyloris intends primarily to focus, claims may also be asserted under state consumer protection acts. If Hyloris is unable to successfully defend against any product liability claims brought against it, it may incur substantial liabilities or be required to limit or halt

commercialization of its product candidates. Even successful defense against such claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may, among other things, result in:

- decreased demand for any of Hyloris' products or product candidates;
- injury to Hyloris' reputation;
- withdrawal of clinical trial participants;
- litigation costs;
- diversion of Executive Management's time and resources;
- substantial settlement payments, monetary awards or other damages;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- the inability to commercialize some or all of Hyloris' product candidates; and
- a negative impact on the price of the Shares.

Hyloris carries product liability insurance it considers adequate for its current level of clinical testing and development. However, Hyloris expects to require additional product liability coverage in the future as it continues the development and commercialization of its products and product candidates. An inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of Hyloris' products. Although Hyloris expects to obtain and maintain adequate insurance coverage, any claim that may be brought could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by insurance or that is in excess of the limits of Hyloris' insurance coverage. Hyloris' insurance policies also have various exclusions, and Hyloris may be subject to a product liability claim for which it has no coverage. The reputational and financial impact of any such product liability lawsuit, individually or in the aggregate, could have a material adverse effect on Hyloris' business.

Hyloris believes that the potential negative impact of this risk is low.

**2.3.3 *EVEN IF HYLORIS OBTAINS APPROVAL FOR ANY OF ITS PRODUCT CANDIDATES, IT WILL BE SUBJECT TO ONGOING OBLIGATIONS AND CONTINUED REGULATORY REVIEW, WHICH MAY RESULT IN SIGNIFICANT UNFORESEEN ADDITIONAL EXPENSE. ADDITIONALLY, HYLORIS' PRODUCT CANDIDATES COULD BE SUBJECT TO LABELLING AND OTHER MARKETING RESTRICTIONS AND WITHDRAWAL FROM THE MARKET AND HYLORIS MAY BE SUBJECT TO PENALTIES IF IT FAILS TO COMPLY WITH REGULATORY REQUIREMENTS OR IF IT EXPERIENCES UNANTICIPATED PROBLEMS WITH ITS PRODUCT CANDIDATES.***

Even if Hyloris obtains approval for any of its product candidates for an indication, the FDA or foreign equivalent may still impose significant restrictions on their indicated uses, marketing or conditions of approval and the products will be subject to post-market surveillance to monitor safety and efficacy.

Hyloris' product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labelling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information.

Although not particularly common in relation to the 505(b)(2) regulatory pathway, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy (**REMS**) as part of an NDA or following the approval of an NDA, which may impose further requirements or restrictions on the distribution or use of an approved pharmaceutical, such as limiting prescription rights to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry. REMS are designed to help reduce the occurrence or severity of a particular serious adverse event. The FDA uses the following considerations to determine whether a medication needs a REMS: (i) whether the particular risks associated with the medication, on balance, outweigh its benefits, and (ii) whether additional interventions beyond FDA-approved labeling are necessary to ensure that the drug's benefits outweigh its risks. As of the date of this Prospectus, the FDA has only required a REMS with respect to one of Hyloris' products (Dofetilide IV), and Hyloris believes that the likelihood that the FDA would require a REMS in relation to any of its product candidates in the future is low.

With respect to sales and marketing activities conducted by Hyloris or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries.

In addition, if any of Hyloris' product candidates are approved for a particular indication, Hyloris' product labelling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. Even if Hyloris complies with the marketing requirements for its products, physicians may nevertheless legally prescribe Hyloris' products to their patients in a manner that is inconsistent with the approved label. If Hyloris is found to have promoted such off-label uses, it may become subject to significant liability and government fines.

If Hyloris or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or if Hyloris, its API suppliers or its manufacturers fail to comply with applicable regulatory requirements, Hyloris may be subject to administrative or judicial sanctions.

The occurrence of any event or penalty mentioned above may inhibit Hyloris' ability to continue developing and commercializing one or more of its product candidates, which in turn could prevent such products from generating revenue and/or leave Hyloris unable to recover the related product development costs. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase Hyloris' product liability exposure. The materialization of any of the regulatory risks set out above or the incurrence of any of the additional expenses resulting from such risks may have a material adverse effect on Hyloris' reputation, its ability to successfully commercialize its products in accordance with its plans and on its revenues and profitability.

Hyloris believes that the potential negative impact of this risk is low.

#### **2.3.4 CURRENT AND FUTURE LEGISLATION MAY INCREASE THE DIFFICULTY AND COST FOR HYLORIS TO OBTAIN REQUIRED APPROVALS AND PROFITABLY COMMERCIALIZE ITS PRODUCT CANDIDATES.**

Hyloris operates in a heavily regulated industry where government bodies impose substantial requirements covering virtually all aspects of Hyloris' activities. In the EEA, the United States and certain other countries, there have been, and Hyloris expects that there will continue to be, legislative and regulatory initiatives and, in particular, changes and proposed changes to the healthcare system that could prevent or delay approval of Hyloris' product candidates, restrict or regulate post-approval activities and affect Hyloris' ability to profitably sell its products. Legislative and regulatory proposals have been made, among others, to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. There also have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs, including the cost of pharmaceuticals, and improve the quality of healthcare. These initiatives include, among others, the Affordable Care Act, which was enacted in March 2010 and which has been and continues to be subject to extensive public debate.

Since its enactment, there have been numerous judicial and political challenges to the Affordable Care Act, and Hyloris expects that there will be additional challenges and amendments to the Affordable Care Act in the future. In addition, the U.S. Congress and various state legislatures are also considering a variety of proposals relating to the pharmaceutical industry and healthcare more generally. These proposals include measures which would impact pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing, which could have a material impact on Hyloris' revenues.

Additionally, the policies of the FDA or other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay the development or regulatory approval of Hyloris' product candidates. For example, the administration of President Donald Trump has taken several executive actions, including the issuance of a number of executive orders that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, Hyloris' business may be negatively impacted. In addition, notwithstanding the approval of many products by the FDA pursuant to the 505(b)(2) regulatory pathway, over the last few years some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2) to allow reliance on the FDA's prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any 505(b)(2) application that Hyloris submits and Hyloris' business may be negatively impacted.

Hyloris expects U.S. state and federal healthcare reform measures will be adopted in the future, and such reform measures may significantly alter or replace the existing new drug approval process and

pharmaceutical pricing structure. Any such reform measures could negatively impact Hyloris' ability to successfully and profitably develop and commercialize its product candidates.

Hyloris believes that the potential negative impact of this risk is low.

### **2.3.5 *THIRD PARTIES MAY CLAIM AN OWNERSHIP INTEREST IN HYLORIS' INTELLECTUAL PROPERTY.***

Former employees, collaborators or other third parties may claim an ownership interest in one or more of Hyloris' or Hyloris' licensors' patents or other proprietary or intellectual property rights. For example, Hyloris has entered into certain arrangements with its partners which govern certain of its intellectual property rights. If any dispute were to arise out of these arrangements or if the scope of the intellectual property clauses in such agreements were found to be invalid or insufficient to transfer complete ownership to Hyloris or the grant Hyloris the right to use the relevant intellectual property, the third party may bring legal actions against Hyloris and seek monetary damages and/or enjoin clinical testing, manufacturing and marketing of the affected product or products. If Hyloris becomes involved in any litigation, it could consume a substantial portion of Hyloris' resources and cause a significant diversion of effort by Hyloris' technical and Executive Management. If any of these actions are successful, in addition to any potential liability for damages, Hyloris could be required to obtain a license to continue to manufacture or market the affected product, in which case Hyloris may be required to pay substantial royalties or grant cross-licenses to Hyloris' patents. Hyloris cannot, however, assure that any such license will be available on acceptable terms, if at all. Ultimately, Hyloris could be prevented from commercializing a product candidate, or be forced to cease some aspect of its business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

Hyloris believes that the potential negative impact of this risk is low.

## **2.4 RISKS RELATED TO THE SHARES**

### **2.4.1 *AFTER CLOSING OF THE OFFERING, CERTAIN SIGNIFICANT SHAREHOLDERS OF THE ISSUER MAY HAVE DIFFERENT INTERESTS FROM THE ISSUER AND/OR FROM THE MINORITY SHAREHOLDERS AND MAY BE ABLE TO CONTROL THE ISSUER, INCLUDING THE OUTCOME OF SHAREHOLDER VOTES.***

Following the closing of the Offering and listing of its Shares, the Issuer will have a number of significant shareholders, some of which are also members of the Board of Directors of the Issuer. For an overview of the Issuer's current significant shareholders and their respective shareholding in the Issuer, reference is made to Section 11 (Significant Shareholders). Currently, all of the existing shareholders (and most of the security holders) of the Issuer and the Issuer itself have entered into a shareholders' agreement (the **Shareholders' Agreement**), containing, amongst others, terms regarding Hyloris' business and governance, as well as pre-emptive rights and transfer restrictions regarding the Shares. The Shareholders' Agreement will be terminated effective as of the closing of the Offering save for a post-IPO lock-up arrangement between the current Shareholders as described in Section 15.3.2

(Conventional post-IPO lock-up) of this Prospectus. As of the date of this Prospectus, the Issuer is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described in Section 15.3 (Lock-up)). Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Issuer's other Shares are held, take certain other shareholders' decisions that require at least 50%, 66.67%, 75% or 80% of the votes of the shareholders that are present or represented at General Shareholders' Meetings where such items are submitted to voting by the shareholders. Alternatively, to the extent that these shareholders have insufficient votes to impose certain shareholders' decisions, they could still have the ability to block proposed shareholders' resolutions that require at least 50%, 66.67%, 75% or 80% of the votes of the shareholders that are present or represented at general shareholders' meetings where such decisions are submitted to voting by the shareholders. Furthermore, a shareholder that is also a member of the Board of Directors and/or the Executive Management will, in some instances and in comparison with minority shareholders, have a better understanding of the particulars of the Issuer and its business. Such shareholders could use such knowledge, within the boundaries of applicable law, to their own benefit when submitting or voting on items on the agenda of a General Shareholders' Meeting. Any such voting by such significant shareholders may not be in accordance with the interests of the Issuer or the minority shareholders of the Issuer. Following closing of the Offering, the following members of the Board of Directors and/or the Executive Management will also be shareholders: Mr. Stijn Van Rompay (CEO, acting through SVR Management BV, holding 25.37% of the Shares), Mr. Thomas Jacobsen (executive director, acting through Jacobsen Management BV, holding 12.99% of the Shares), Mr. Edward Maloney (CBDO, acting through Humara Kinetics LLC, 1.62% of the Shares) and Mr. Koenraad Van der Elst (CLO, acting through Herault BV, holding 0.10% of the Shares)<sup>6</sup>.

The Issuer is expected to agree pursuant to the Underwriting Agreement (as defined below) (which is expected to be entered into on or about 26 June 2020) to a standstill on the issuance of new Shares and issuance of new securities that are substantially similar to Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, Shares or any such substantially similar securities, for a period of 360 days following the Listing Date, as described in Section 15.3 (Lock-up). The standstill would not apply to the issue of new Shares upon exercise of existing outstanding warrants (see Section 13.4 (Warrants)), the issue of new Shares pursuant to the conversion of the Convertible Bonds (see Section 13.6 (Convertible Bonds)) or the issue of new Shares pursuant to the exercise of the Over-allotment Option (see Section 13.5.2 (Over-allotment Option)). After such period, or within that period with the Joint Global Coordinator's consent, the Issuer may increase its share capital against cash or contributions in kind to finance any future acquisition or other investment or to strengthen its balance sheet. In addition, after the standstill period, the Issuer may also issue warrants that are exercisable into new Shares, or raise capital through public or private convertible debt or equity securities, or rights to acquire these securities.

The Issuer may, subject to certain conditions, limit or disapply the statutory preferential subscription rights of the existing shareholders otherwise applicable to capital increases through contributions in

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<sup>6</sup> Each time on an undiluted basis, assuming a placement of the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option) and exercise in full by the Stabilization Manager of the Over-allotment Option, that all Pre-commitments are allocated to the Participating Investors in full, and subject to the other assumptions set forth in note (4) to the table set forth in Section 11 (Significant Shareholders).

cash, while no statutory preferential subscription rights apply to capital increases through contributions in kind. Such transactions could therefore dilute the stakes in the Issuer's share capital held by the shareholders at that time and could have a negative impact on the Share price, earnings per Share and net asset value per Share.

Hyloris believes that the potential negative impact of this risk is high.

**2.4.2 IF SECURITIES OR INDUSTRY ANALYSTS DO NOT PUBLISH RESEARCH REPORTS ABOUT HYLORIS, OR IF THEY CHANGE THEIR RECOMMENDATIONS REGARDING THE SHARES IN AN ADVERSE WAY, THE MARKET PRICE OF THE SHARES MAY FALL AND THE TRADING VOLUME MAY DECLINE.**

The trading market for the Shares may be influenced by the research reports that industry or securities analysts publish about Hyloris or its industry.

The fact that fewer analyst reports are being published because of their expensive nature pursuant to MiFID II, combined with the fact that Hyloris will be a recently listed, relatively young and small company, and therefore likely low on the shortlist of analysts, the analyst coverage of Hyloris will be very limited. Therefore, if one or more of the analysts who cover Hyloris or its industry, downgrades its recommendation, the market price of the Shares may fall, or if one or more of the analysts ceases to cover Hyloris or fails to publish research reports about Hyloris on a regular basis, Hyloris may be confronted with a significant loss of visibility in the financial markets, which in turn could cause the market price of the Shares or trading volume to decline.

This decline could be exacerbated due to the Issuer's limited market capitalization.

Hyloris believes that the potential negative impact of this this risk is medium.

**2.4.3 THE MARKET PRICE OF THE SHARES MAY FLUCTUATE WIDELY IN RESPONSE TO VARIOUS FACTORS. INVESTORS MAY NOT BE ABLE TO RESELL THEIR SHARES AT OR ABOVE THE OFFER PRICE AND MAY LOSE ALL OR PART OF THEIR INVESTMENT.**

The Offer Price will be determined by negotiations between the Issuer and representatives of the Joint Global Coordinators and may not be indicative of prices that will prevail in the trading market following the Offering. The price of the Shares may decline following the Offering. Publicly traded securities from time to time experience significant price and volume fluctuations that may be unrelated to the results of operations or the financial condition of the companies that have issued them.

In addition, the market price of the Shares may prove to be highly volatile and may fluctuate significantly in response to a number of factors, including the Company's progress in developing and commercializing its products, which may in turn be affected by the progress of the Company's clinical trials, the market acceptance of its products and the time its products enter the market, and could also cause a potential or perceived loss of consumer confidence in Hyloris' products; the impact of governmental approvals, such as FDA approval, and governmental regulations on the Company's products and industry, including potentially more restrictive or adverse changes in patent law; and changes in general conditions in the economy, such as volatile oil prices, unstable global credit markets and widespread furloughs and layoffs due to COVID-19 (see Risk Factor 2.1.2.3 (The occurrence of a

pandemic, epidemic or other health crisis, including the recent outbreak of COVID-19, could materially affect Hyloris' business and operations, as well as the business and operations of third parties with whom Hyloris conducts business.) for more information on COVID-19), which have increased unemployment rates and could therefore result in decreased consumer spending both generally, and specifically on Hyloris' products;

The market price of the Shares may be adversely affected by these preceding or other factors regardless of Hyloris' actual financial condition and results of operations.

Taking into account the current market conditions and the recent volatility of, and persisting uncertainty in, the financial markets due to COVID-19 and the measures taken in that respect, Hyloris believes that the potential negative impact of this risk is medium.

**2.4.4 FUTURE SALES OF SUBSTANTIAL AMOUNTS OF SHARES, OR THE PERCEPTION THAT SUCH SALES MAY OCCUR, COULD ADVERSELY AFFECT THE MARKET VALUE OF THE SHARES.**

All of the Issuer's existing shareholders as well as all of the Participating Investors have entered into a lock-up arrangement with the Joint Global Coordinators with respect to certain of their Shares and other rights or securities issued by the Issuer for a period of 360 days after the Closing Date, subject to certain exceptions, as described in Section 15.3.1 (Lock-up pursuant to the IPO). Pursuant to this lock-up arrangement, on the Closing Date, all securities in the Issuer held by the existing shareholders and the Participating Investors (including the Shares issued to the Participating Investors pursuant to the conversion of the Convertible Bonds and any Shares that may be issued pursuant to the exercise of the outstanding warrants of the Issuer), will be subject to a lock-up restriction, with the sole exception of any Offered Shares that they subscribe for or in the Offering (including the New Shares that will be issued pursuant to the Pre-commitments). Assuming (i) the placement of the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option) (ii) that the Offer Price is the midpoint of the Price Range, *i.e.*, EUR 10.75, (iii) the exercise in full by the Stabilization Manager of the Over-allotment Option, (iv) that all Pre-commitments are allocated in full to the Participating Investors, (v) that none of the Adjustment Warrants, Anti-dilution Warrants, Transaction Warrants and ESOP Warrants have been exercised and (vi) that the principal amount as per the expected Closing Date, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted, then immediately after the closing of the Offering and the conversion of the Convertible Bonds, 75.01% of the Issuer's then outstanding Shares will be subject to the lock-up arrangement at the Closing Date.

In respect of the period after expiry of this lock-up arrangement, the Issuer and its existing shareholders have, pursuant to the existing Shareholders' Agreement, entered into an additional lock-up arrangement, in respect of the Shares held by the Issuer's existing shareholders prior to the Offering (excluding any of the Offered Shares that may be subscribed for in the Offering, any new Shares resulting from the conversion of the Convertible Bonds and any new Shares resulting from the exercise of Transaction Warrants or ESOP Warrants), as described in Section 15.3.2 (Conventional post-IPO lock-up). Assuming (i) the placement of the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option) (ii) that the Offer Price is the midpoint of the Price Range, *i.e.*, EUR 10.75, (iii) the exercise in full by the Stabilization Manager of the Over-allotment Option, (iv) that all Pre-

commitments are allocated in full to the Participating Investors, (v) that none of the Adjustment Warrants, Anti-dilution Warrants, Transaction Warrants and ESOP Warrants have been exercised, (vi) that the principal amount as per the expected Closing Date, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted, and (vii) no new Shares have been issued between the Closing Date and the effective date of the conventional post-IPO lock-up, then on such effective date, 67.29% of the Issuer's then outstanding Shares will be subject to the lock-up arrangement at the effective date of the conventional post-IPO lock-up. Following the expiration of these respective lock-up provisions, potential future sales of Shares by the relevant existing shareholders or the relevant Share option holders, or the perception that such sales could occur, may adversely affect the market price of the Shares. Subsequent to the expiration of these lock up provisions, the sale of a significant number of Shares by these shareholders on the public markets, especially if sold within a condensed time frame, or the perception that such a sale may occur, may adversely affect the market price of the Shares. In addition, such sales could make it more difficult for the Issuer itself to issue new Shares or to sell existing treasury Shares at a time and a price that it deems appropriate. Hyloris cannot make any predictions as to future sales of the Shares in any amount or the perception that any such sales could have on the market price of the Shares. For an overview of the Issuer's current significant shareholders and their respective shareholding in the Issuer, reference is made to Section 11 (Significant Shareholders).

Hyloris believes that the potential negative impact of this risk is low.

**2.4.5 THE ISSUER HAS NO FIXED DIVIDEND POLICY AND WILL PROBABLY NOT BE IN A CAPACITY TO PAY DIVIDENDS IN THE FORESEEABLE FUTURE.**

The Issuer has not declared or paid dividends on its Shares in the past. In the future, Hyloris' dividend policy will be determined, and may change from time to time, by Hyloris' Board of Directors. Currently, the Board of Directors of the Issuer expects to retain all earnings, if any, generated by Hyloris' operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future. See Section 6.6 (Dividends and dividend policy) for further information on the Issuer's dividends, dividend policy and legal and (contractual) financial constraints in relation thereto. Any declaration of dividends will be based upon the Issuer's earnings, financial condition, capital requirements and other factors considered important by the Issuer's Board of Directors. Belgian law and the Issuer's Articles of Association do not require the Issuer to declare dividends. As a consequence of these factors, there can be no assurance as to whether dividends or similar payments can or will be paid out in the future nor, if they are paid, as to their amount.

While the probability that Hyloris will not distribute dividends in the foreseeable future is high, Hyloris believes that the potential negative impact of this risk is low.

**2.4.6 INVESTORS RESIDENT IN COUNTRIES OTHER THAN BELGIUM MAY NOT BE ABLE TO EXERCISE THEIR STATUTORY PREFERENTIAL SUBSCRIPTION RIGHTS, RESULTING IN A DILUTION OF THEIR STAKE IN THE ISSUER.**

Under Belgian law and the Issuer's constitutional documents, shareholders have a waivable and cancellable statutory preferential subscription right to subscribe pro rata to their existing shareholdings

to the issuance, against a contribution in cash, of new Shares or other securities entitling the holder thereof to new Shares, unless such rights are limited or cancelled by resolution of the Issuer's general shareholders' meeting or, if so authorized by a resolution of such meeting, the Board of Directors. Certain shareholders of the Issuer who do not reside in Belgium, such as those in the United States, Australia, Switzerland, Canada or Japan, may be restricted in their ability to exercise similar such rights as Belgian shareholders. The exercise of statutory preferential subscription rights by certain shareholders not residing in Belgium requires compliance with applicable securities laws in the jurisdictions where the holders of those securities are located, including the U.S. Securities Act, which the Issuer may be unable or unwilling to do. Therefore, because of the Belgian law's entitlement to subscription rights which may not necessarily be applicable for companies domiciled outside of Belgium, foreign shareholders, including U.S. shareholders, investing in Belgian companies such as Hyloris may be unable or not permitted to exercise their statutory preferential subscription rights in the event of a future offering and therefore, such foreign investors may suffer dilution of their shareholdings in contrast to Belgian shareholders who would not suffer such dilution. See also Section 13.7.4.3 (Statutory Preferential Subscription Right).

While the probability that foreign shareholders, including U.S. shareholders, may be unable or not permitted to exercise their statutory preferential subscription rights in the event of a future offering, is high, Hyloris believes that the potential negative impact of this risk is low.

**2.4.7 *THERE IS A RISK THAT HYLORIS COULD BE OR BECOME A "PASSIVE FOREIGN INVESTMENT COMPANY" FOR U.S. FEDERAL INCOME TAX PURPOSES, WHICH COULD RESULT IN ADVERSE U.S. TAX CONSEQUENCES FOR U.S. INVESTORS.***

While Hyloris believes that it currently is not a passive foreign investment company (a **PFIC**), no assurance can be given that it will not be considered a PFIC for the current or any future tax year. The determination of whether Hyloris is a PFIC is made on an annual basis and generally cannot be made until the end of each taxable year. Also, the PFIC determination will depend upon the application of complex U.S. federal income tax rules (which are subject to differing interpretations) concerning the classification of Hyloris' income and assets for this purpose, and the application of these rules to Hyloris is uncertain in some respects. There can be no assurance that the U.S. Internal Revenue Service (the **IRS**) will not take a different position concerning application of the PFIC rules to Hyloris or that any such position would not be sustained by a court. Prospective investors should be aware that Hyloris is not obliged to conduct its business or operations in order to avoid PFIC treatment.

If Hyloris is treated as a PFIC, U.S. Holders (as defined in Section 13.11.3 (Certain U.S. Federal Income Tax Considerations) of this Prospectus) of Shares will be subject to adverse U.S. federal income tax consequences, including taxation of distributions and gains at the highest rate applicable to ordinary income, ineligibility for any preferential tax rates for individuals on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations. Hyloris does not intend to make available to U.S.

Holders the information necessary to make a "qualified electing fund" or "QEF" election. Consequently, it is expected that U.S. Holders will not be able to make a potentially favorable QEF election in the event that Hyloris is a PFIC in the current or any future taxable year. Further, while a U.S. Holder may be able to make a mark-to-market election to include gain on the Shares as ordinary income, the election cannot be made for any of the Issuer's subsidiaries that are also PFICs.

For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event Hyloris is classified as a PFIC, see Section 13.11.3 (Certain U.S. Federal Income Tax Considerations – Passive Foreign Investment Company Considerations) of this Prospectus.

Prospective U.S. investors should review Section 13.11.3 (Certain U.S. Federal Income Tax Considerations – Passive Foreign Investment Company Considerations) of this Prospectus and are urged to consult with their own tax advisers regarding application of these rules in their particular circumstances.

Hyloris believes that the potential negative impact of this risk is low.

## **2.5 RISKS RELATED TO THE OFFERING**

### **2.5.1 *THERE HAS BEEN NO PRIOR PUBLIC MARKET FOR THE SHARES AND AN ACTIVE MARKET FOR THE SHARES MAY NOT DEVELOP, WHICH MAY CAUSE THE SHARES TO TRADE AT A DISCOUNT TO THE OFFER PRICE AND MAKE IT DIFFICULT TO SELL THE SHARES.***

Prior to the Offering, there has been no public trading market for the Shares. No assurance can be given that an active trading market for the Shares will develop or, if developed, that an active trading market can be sustained or that there will be sufficient liquidity following the closing of the Offering. There can be no assurance that the Offer Price will correspond to the market price of the Shares following the Offering or that the price of the Shares available in the public market will reflect Hyloris' actual financial performance. If an active trading market is not developed or maintained, the liquidity (which is also impacted by the amount of Shares that are effectively admitted to trading, see Risk Factor 2.5.2) and trading price of the Shares could be adversely affected.

Hyloris would, in normal market circumstances, consider this to be a low risk. However, taking into account the current market conditions and the recent volatility of, and persisting uncertainty in, the financial markets due to COVID-19 and the measures taken in that respect, Hyloris believes this risk to be medium.

### **2.5.2 *THE FACT THAT NO MINIMUM AMOUNT IS SET FOR THE OFFERING MAY AFFECT HYLORIS' INVESTMENT PLAN AND THE LIQUIDITY OF THE SHARES.***

Hyloris has the right to proceed with the capital increase in the context of the Offering in a reduced amount, corresponding to a number of New Shares that is lower than the 5,000,000 initially offered new Shares in the Offering. As no minimum amount is set for the Offering, if the 5,000,000 initially offered new Shares are not fully subscribed for in the Offering, the net proceeds from the Offering could, in a worst case scenario, be limited to the net proceeds from the Pre-commitments of the Participating Investors. As a result (i) a lower number of Shares could be available for trading on the market, which

could limit the liquidity of the Shares and (ii) Hyloris' financial means in view of the uses of proceeds as described in Section 6.5 (Reasons for the Offering and use of proceeds) would in such case also be reduced. If this were to be the case, Hyloris may have to reduce its level of investments or look for further external funding (see also Section 6.5 (Reasons for the Offering and use of proceeds)).

Assuming that the Offer Price is at the midpoint of the Price Range, the Pre-commitments of the Participating Investors would amount to EUR 22,725,000, represented by 2,113,937 New Shares (see also Section 14.3 (Pre-commitments)), while the Offering, if fully subscribed for (and not taking into account the exercise in part or full of the Increase Option and/or of the Over-allotment Option) would amount to EUR 53,750,000 represented by 5,000,000 New Shares.

In the event the net proceeds from the Offering would be limited to the net proceeds from Pre-commitments of the Participating Investors, Hyloris would use these proceeds for the further development and finalization of its current product candidate portfolio. The establishment of a commercial team in the United States, the expansion of the product candidate pipeline and the potential development opportunities would in such case be postponed until additional financing is available. Such additional financing would in turn entail various additional costs, such as financing costs (e.g., interest expense and other charges) in the event that the Issuer opts for debt financing, and transaction costs (e.g., legal fees, underwriters' fees and other charges) in the event that the Issuer opts for equity financing, which, depending on the manner in which such equity financing takes place (i.e., by way of a private placement or by way of a public offering with cancellation or limitation of statutory subscription rights), could also lead to dilution of existing shareholders.

Hyloris believes that the potential negative impact of this risk is medium.

**2.5.3 THE SHARES WILL BE LISTED AND TRADED ON THE REGULATED MARKET OF EURONEXT BRUSSELS ON AN "IF-AND-WHEN-ISSUED-AND/OR-DELIVERED" BASIS FROM THE LISTING DATE UNTIL THE CLOSING DATE. EURONEXT BRUSSELS MAY ANNUL ALL TRANSACTIONS EFFECTED IN THE SHARES IF THEY ARE NOT ISSUED AND DELIVERED ON THE CLOSING DATE.**

From the Listing Date until the Closing Date, the Shares will be listed and traded on the regulated market of Euronext Brussels on an "if-and-when-issued-and/or-delivered" basis, meaning that trading of the Shares will begin prior to the closing of the Offering. The Closing Date is expected to occur on the first Euronext Brussels trading day following the Listing Date. Investors that wish to enter into transactions in the Shares prior to the Closing Date, whether such transactions are effected on the regulated market of Euronext Brussels or otherwise, should be aware that the closing of the Offering may not take place on the expected date, or at all, if certain conditions or events referred to in the Underwriting Agreement (as defined below) are not satisfied or waived or do not occur on or prior to such date. Euronext Brussels may annul all transactions effected in the Shares if they are not issued and delivered on the Closing Date. For example, if there is a drop of more than 10% of the BEL20 Index, closing of the Offering would not take place. Euronext Brussels cannot be held liable for any damage arising from the listing and trading on an "if-and-when-issued-and/or-delivered" basis as of the Listing Date until the Closing Date.

Hyloris believes that the potential negative impact of this risk is low.



### **3       DISCLAIMERS AND NOTICES**

This Prospectus is intended to provide information to potential investors in the context of and for the sole purpose of evaluating a possible investment in the Offered Shares. It contains selected and summarized information, does not express any commitment or acknowledgement or waiver, and does not create any right, express or implied, towards anyone other than a potential investor. Investors must assess, with their own advisers if necessary, whether the Offered Shares are a suitable investment for them, considering their personal income and financial situation. In the event of any doubt about the risk involved in investing in the Offered Shares, investors should abstain from investing in the Offered Shares.

In making an investment decision, investors must rely on their own assessment, examination, analysis and enquiry of the Issuer, the terms of the Offering and the contents of this Prospectus, including the merits and risks involved. Any purchase of Shares should be based on the assessments that an investor may deem necessary, including the legal basis and consequences of the Offering, and including possible tax consequences that may apply, before deciding whether or not to invest in the Shares. In addition to their own assessment of the Issuer and the terms of the Offering, investors should rely only on the information contained in this Prospectus, including the risk factors described herein.

The summaries and descriptions of legal provisions, accounting principles or comparisons of such principles, legal company forms or contractual relationships reported in this Prospectus may under no circumstances be interpreted as a basis for credit or other evaluation, or as investment, legal or tax advice for prospective investors. Prospective investors are urged to consult their own financial adviser, accountant or other advisers concerning the legal, tax, economic, financial and other aspects associated with the trading or investment in the Shares.

Investors must also acknowledge that they have not relied on the Underwriters or any person affiliated with the Underwriters in connection with any investigation of the information contained in this Prospectus or their investment decision, and they have relied only on the information contained in this Prospectus, and that no person has been authorized to give any information or to make any representation concerning the Issuer or its subsidiary or the Shares (other than as contained in this Prospectus) and, if given or made, any such other information or representation should not be relied upon as having been authorized by the Issuer or the Underwriters.

None of the Issuer or the Underwriters, or any of their respective representatives, is making any representation to any offeree or purchaser of the Shares regarding the legality of an investment in the Shares by such offeree or purchaser under the laws applicable to such offeree or purchaser. Each investor should consult with his or her own advisers as to the legal, tax, business, financial and related aspects of a purchase of the Shares.

No person has been authorized to give any information or to make any representation in connection with the Offering other than those contained in this Prospectus, and, if given or made, such information or representation must not be relied upon as having been authorized. Without prejudice to the Issuer's obligation to publish supplements to this Prospectus when legally required (as described below), neither the delivery of this Prospectus nor any sale made at any time after the date mentioned on the cover of

this Prospectus shall, under any circumstances, create any implication that there has been no change in the Issuer's affairs since the date hereof or that the information set forth in this Prospectus is correct as of any time since its date.

The Underwriters are acting exclusively for the Issuer and no one else in connection with the Offering. They will not regard any other person (whether or not a recipient of this document) as their respective clients in relation to the Offering and will not be responsible to anyone other than the Issuer for providing the protections afforded to their respective clients nor for giving advice in relation to the Offering or any transaction or arrangement referred to herein.

Neither the Offering nor an investment in the Offered Shares are recommended by any competent federal, regional or local authority in the field of financial instruments, nor by any supervisory authority in Belgium or abroad. Investors are solely responsible for the analysis and assessment of the benefits and risks associated with subscribing for the Offered Shares.

## **4 RESTRICTION ON THE OFFERING AND THE DISTRIBUTION OF THIS PROSPECTUS**

### **4.1 NOTICE TO INVESTORS IN THE MEMBER STATES OF THE EUROPEAN ECONOMIC AREA (EXCEPT BELGIUM) AND THE UNITED KINGDOM**

No offer of the Shares has been or will be made to the public in any Member State of the European Economic Area and the United Kingdom (each a **Relevant State**) other than Belgium without this Prospectus having been approved by the competent authority in such Relevant State or notified to the competent authority in such Relevant State in accordance with Article 24 and following of the Prospectus Regulation, and subsequently published in accordance with the Prospectus Regulation and national legislation of the relevant Member State, unless the Offering in a Member State can take place under any of the following exemptions provided by the Prospectus Regulation:

1. to qualified investors within the meaning of Article 2(e) of the Prospectus Regulation;
2. to less than 150 natural or legal persons which are not qualified investors as defined in the Prospectus Regulation; or
3. in all other cases referred to in Article 1(4) of the Prospectus Regulation;

and to the extent that such an offering of Shares in the Relevant State does not require the Issuer to issue a prospectus in accordance with Article 3 of the Prospectus Regulation or to publish a supplement to this Prospectus in accordance with Article 23 of the Prospectus Regulation, or any other document in relation to such offering pursuant to the national legislation of such Relevant State.

For the purposes of this provision, the expression "offer to the public" means a communication to persons in any form and by any means, presenting sufficient information on the terms of the Offering and the Shares, so as to enable an investor to decide to purchase or subscribe for those securities.

The Offering is solely conducted by the Issuer, and neither the Issuer nor the Underwriters have authorized, nor do the Issuer or the Underwriters authorize, the making of any offer of Shares through any financial intermediary.

### **4.2 NOTICE TO INVESTORS IN THE UNITED KINGDOM**

Offers of Shares pursuant to the Offering are only being made to persons in the United Kingdom who are "qualified investors" or otherwise in circumstances which do not require publication by the Issuer of a prospectus pursuant to section 85(1) of the U.K. Financial Services and Markets Act 2000.

Any investment or investment activity to which this Prospectus relates is available only to, and will be engaged in only with, persons who (i) are investment professionals falling within article 19(5) or (ii) fall within article 49(2)(a) to (d) ("high net worth companies, unincorporated associations, etc.") of the U.K. Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or other persons to whom such investment or investment activity may lawfully be made available (together, **Relevant Persons**). Persons in the U.K. who are not Relevant Persons should not take any action on the basis of this Prospectus and should not act or rely on it.

#### **4.3 NOTICE TO INVESTORS IN SWITZERLAND**

The Shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (**SIX**) or on any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Shares constitutes a prospectus or a similar notice as such terms are understood pursuant to article 652a, article 752 or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of Art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this Prospectus nor any other offering or marketing material relating to the Shares or the Offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this Prospectus nor any other offering or marketing material relating to the Offering, the Issuer or the Shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this Prospectus will not be filed with, and the Offering will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA. The Offering has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (**CISA**). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of Shares.

#### **4.4 NOTICE TO INVESTORS IN THE UNITED STATES**

The Shares have not been and will not be registered under the U.S. Securities Act and are being offered and sold: (i) outside the United States in compliance with Regulation S, and (ii) in the United States only to persons who are reasonably believed to be QIBs in reliance on Rule 144A. Prospective investors are hereby notified that sellers of the Shares may be relying on the exemption from the registration requirements of Section 5 of the U.S. Securities Act provided by Rule 144A. For certain restrictions on transfer of the Shares, see Section 16 (Transfer restrictions).

The Shares have not been recommended by any U.S. federal or state securities commission or regulatory authority. Furthermore, the foregoing authorities have not confirmed the accuracy or determined the adequacy of this Prospectus. Any representation to the contrary is a criminal offense in the United States.

In the United States, this Prospectus is being furnished on a confidential basis solely for the purpose of enabling a prospective investor to consider subscribing for the particular securities described herein. The information contained in this Prospectus has been provided by the Issuer and other sources identified herein. Distribution of this Prospectus to any person other than the offeree specified by the Underwriters or their representatives, and those persons, if any, retained to advise such offeree with respect thereto, is unauthorized, and any disclosure of its contents, without the Issuer's prior written consent, is prohibited. Any reproduction or distribution of this Prospectus in the United States, in whole or in part, and any disclosure of its contents to any other person is prohibited. This Prospectus is personal to each offeree and does not constitute an offer to any other person or to the public generally to subscribe for, or otherwise acquire, the Shares.

#### **4.5 NOTICE TO INVESTORS IN JAPAN**

The Shares are not and will not be registered under the Financial Instruments and Exchange Law. This Prospectus is not an offer to sell or subscribe for any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (here, this term shall mean: any person residing in Japan, including any company or legal entity incorporated under Japanese law) or to any other person for repurchase or resale, directly or indirectly, in Japan, or to, or for the benefit of, any resident of Japan, except by virtue of an applicable exemption from the registration requirements of the Financial Instruments and Exchange Law and in compliance with this law and any other applicable legislations, regulations and ministerial directives in Japan.

#### **4.6 NOTICE TO INVESTORS IN CANADA, AUSTRALIA AND SOUTH AFRICA**

This Prospectus may not be distributed or otherwise made available in Canada, Australia or South Africa and the Shares may not be offered, sold or exercised, directly or indirectly, by any person in Canada, Australia or South Africa unless such distribution, offer, sale or exercise is permitted under the applicable securities laws of the relevant jurisdiction.

#### **4.7 NOTICE TO INVESTORS IN ISRAEL**

This Prospectus does not constitute a prospectus under the Israeli Securities Law, 5728-1968 (the **Israeli Securities Law**), and has not been filed with or approved by the Israel Securities Authority. In the State of Israel, this Prospectus is being distributed only to, and is directed only at, and any offer of the Shares is directed only (i) at a limited number of persons (35 investors or fewer during any given 12 month period) in accordance with Section 15A(a)(1) of the Israeli Securities Law and/or (ii) to investors listed in the first schedule to the Israeli Securities Law (the **Schedule**), consisting primarily of joint investment in trust funds, provident funds, insurance companies, banking corporations, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and high net worth individuals, each as described in the Schedule (as it may be amended from time to time), collectively referred to as “qualified investors” (in each case purchasing for their own account or, where permitted under the Schedule, for the accounts of their clients who are investors listed in the Schedule). Qualified investors will be required to submit written confirmation that they fall within the scope of the Schedule, and that they are aware of the consequences of such designation and agree thereto.

## **5 GENERAL INFORMATION AND INFORMATION CONCERNING THE RESPONSIBILITY FOR THIS PROSPECTUS AND FOR AUDITING THE ACCOUNTS**

### **5.1 APPROVAL BY THE FSMA**

In accordance with Article 20 of the Prospectus Regulation, the English language version of this Prospectus (including the Summary) was approved by the FSMA on 16 June 2020, as competent authority under the Prospectus Regulation. The FSMA only approves this Prospectus (including the Summary) as meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation. Such approval should not be considered as an endorsement of the Issuer or the quality of the Shares that are the subject of this Prospectus. Investors should make their own assessment as to the suitability of investing in the Shares.

This Prospectus and the Summary may be distributed separately. This Prospectus was drafted in English and translated into French. The Summary was drafted in English and translated into French and Dutch. The Issuer is responsible for the consistency of the French translation of this Prospectus and the French and Dutch translations of the Summary with the approved English versions thereof. Without prejudice to the responsibility of the Issuer for the translation of this Prospectus and the Summary, if there is an inconsistency between the different language versions, the language version approved by the FSMA (being the English version) shall prevail. If there is an inconsistency between this Prospectus and the Summary, this Prospectus shall prevail over the Summary.

### **5.2 RESPONSIBLE PERSONS**

#### **5.2.1 RESPONSIBILITY FOR THE CONTENTS OF THIS PROSPECTUS**

The Issuer, with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium) assumes responsibility for the information contained in this Prospectus. The Issuer declares that the information contained in this Prospectus is, to the best of its knowledge, in accordance with the facts and contains no omission likely to affect its import.

The content of this Prospectus should not be construed as an interpretation of the rights and obligations of Hyloris (with the exception of the relationship between Hyloris and the investors subscribing for the Offering), of market practices or of the agreements entered into by Hyloris.

The Underwriters make no representations or warranties, express or implied, with regard to the accuracy or completeness of the information contained in this Prospectus. The Underwriters therefore do not accept any responsibility, of any kind, with regard to the information contained in, or omitted from, this Prospectus. This Prospectus does not contain, and should not be considered as containing, any commitment or representation by the Underwriters.

#### **5.2.2 RESPONSIBILITY FOR AUDITING THE ACCOUNTS**

KPMG Réviseurs d'Entreprise SCRL, with registered office at Luchthaven Brussel Nationaal 1K, 1930 Zaventem (Brussels), has been appointed as Statutory Auditor of the Issuer on 31 December 2019 for a period of three years. The mandate will expire at the end of the general meeting called to approve the

accounts for the 2021 financial year. KPMG Réviseurs d'Entreprises SCRL has designated Mr. Olivier Declercq (IRE No. A02076), “réviseur d'entreprises”, as permanent representative. KPMG Réviseurs d'Entreprise SCRL is a member of the Belgian Institute of Certified Auditors (“*Institut des Réviseurs d'Entreprises*” / “*Instituut van de Bedrijfsrevisoren*”) (membership number B00001).

The Annual Financial Statements (see Section 5.5 (Presentation of financial and other information)) have been audited (in accordance with the International Standards on Auditing (ISAs) as issued by the IAASB) by the Statutory Auditor of the Issuer, who delivered an unqualified opinion with two emphasis of matter paragraphs on the subsequent events relating to the additional financing and Covid19 (see also the Statutory auditor's report to the board of directors of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2019 as included in the F-pages of this Prospectus) (the **Annual Financial Statements Statutory Auditor's Report**). The Interim Financial Information (see Section 5.5 (Presentation of financial and other information)) has been subjected to a review (in accordance with the International Standard on Review Engagements 2410, “Review of Interim Financial Information Performed by the Independent Auditor of the Entity”) by the Statutory Auditor of the issuer who delivered a review report with one emphasis of matter paragraph on the subsequent event relating to the additional financing (the **Interim Financial Information Statutory Auditor's Report**, and together with the Annual Financial Statements Statutory Auditor's Report, the **Auditor's Reports**).

Prior to 31 December 2019 the Issuer did not have a statutory auditor.

### 5.3 FORWARD-LOOKING STATEMENTS

This Prospectus contains forward-looking statements prepared by the Issuer with respect to Hyloris' expected future performance and the markets in which it operates.

All statements in this Prospectus that do not relate to historical facts and events are “forward-looking statements”. In some case, these forward-looking statements can be identified by the use of forward-looking terminology, including the words “believe”, “estimate”, “anticipate”, “expect”, “intend”, “may”, “will”, “plan”, “continue”, “ongoing”, “possible”, “predict”, “projects”, “target”, “seek”, “would”, “should” or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. These forward-looking statements appear in a number of places throughout this Prospectus. Forward-looking statements include statements regarding the Issuer's intentions, beliefs or current expectations concerning, among other things, its results of operations, prospects, growth, strategies and dividend policy and the industry in which it operates. In particular, certain statements are made in this Prospectus regarding Executive Management's estimates of future growth.

Such forward-looking statements are based on multiple assumptions and assessments of known or unknown risks, uncertainties and other factors that appear reasonable and acceptable at the time of the assessment, but that may or may not subsequently prove to be correct. Actual events are difficult to predict and may depend on factors outside Hyloris' control.

By their nature, statements about the future contain inherent risks and uncertainties, both general and specific, and there is a possibility that the forward-looking statements and other statements about the future, will not materialize. These risks, uncertainties and other factors include, among other things, those mentioned under Section 2 (Risk Factors) of this Prospectus, and those that appear elsewhere in this Prospectus. Investors should be aware that a number of important factors may cause the Issuer's actual results to differ materially from the plans, objectives, expectations, estimates and intentions expressed in such forward-looking statements.

Consequently, the actual results, financial situation, performance or achievements of Hyloris or the results of the market may in reality differ significantly from future results, financial situation, performance or achievements that are implicitly or explicitly included in such statements, forecasts and estimates. Taking into account these uncertainties, potential investors are requested not to place excessive reliance on forward-looking statements. Furthermore, the statements, forecasts and estimates are only valid on the date of Prospectus and the Issuer does not undertake to update these statements in order to take into account any changes in its expectations or changes in the conditions or circumstances on which such statements are based, unless it is obliged to do so in accordance with the Prospectus Regulation, in which case the Issuer will publish a supplement to this Prospectus.

#### **5.4 SECTOR INFORMATION, MARKET SHARE, RANKING AND OTHER DATA**

This Prospectus includes market, economic and industry data, which were obtained by the Issuer from scientific journals, industry publications, press releases, data published by government agencies, industry reports prepared by consultants and other market data providers. These market data are primarily presented in Section 8 (Business). The market, economic and industry data have primarily been obtained or derived and extrapolated from reports, articles and data provided by third parties such as IQVIA.

The third-party sources the Issuer has used generally state that the information they contain has been obtained from sources believed to be reliable. Some of these third-party sources also state, however, that the accuracy and completeness of such information is not guaranteed and that the projections they contain are based on significant assumptions. As the Issuer does not have access to the facts and assumptions underlying such market data, or statistical information and economic indicators contained in these third party sources, the Issuer is unable to verify such information. Thus, while the information has been accurately reproduced, and in as far as the Issuer is aware and is able to ascertain from such third-party information, no facts have been omitted which would render the reproduction of this third-party information inaccurate or misleading, the Issuer cannot guarantee its accuracy or completeness. The inclusion of this third-party industry, market and other information should not be considered as the opinion of such third parties as to the value of the Offered Shares or the advisability of investing in the Offered Shares.

In addition, certain information in this Prospectus is not based on published data obtained from independent third parties or extrapolations therefrom, but is based upon the Issuer's best estimates, which are in turn based upon information obtained from trade and business organizations and associations, consultants and other contacts within the industries in which the Issuer competes, information published by the Issuer's competitors and the Issuer's own experience and knowledge of

conditions and trends in the markets in which it operates. The Issuer cannot assure that any of the assumptions it has made while compiling this data from third party sources are accurate or correctly reflect the Issuer's position in the industry and none of the Issuer's internal estimates have been verified by any independent sources. Neither the Issuer, nor any of the Underwriters makes any representation or warranty as to the accuracy or completeness of this information. Neither the Issuer, nor any of the Underwriters have independently verified this information and, while the Issuer believes it to be reliable, neither the Issuer, nor any of the Underwriters can guarantee its accuracy.

## **5.5 PRESENTATION OF FINANCIAL AND OTHER INFORMATION**

For purposes of this Prospectus, the Issuer has prepared consolidated financial statements as of and for the years ended 31 December 2019, 31 December 2018 and 31 December 2017, prepared in accordance with International Financial Reporting Standards, as adopted by the European Union (**IFRS**), and with the legal and regulatory requirements applicable in Belgium, and which have been audited (in accordance with the International Standards on Auditing (ISAs) as issued by the IAASB) by the Statutory Auditor of the Issuer, who delivered an unqualified opinion with two emphasis of matter paragraphs on the subsequent events relating to the additional financing and Covid19 (see also the Statutory auditor's report to the board of directors of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2019 as included in the F-pages of this Prospectus) (the **Annual Financial Statements**).

In addition, the Issuer has also prepared consolidated interim financial information as at and for the three-month period ended 31 March 2020 (with comparative figures for the three-month period ended 31 March 2019), prepared in accordance with the International Accounting Standard 34, as adopted by the European Union (IAS 34), and which has been subjected to a review (in accordance with the International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity") by the Statutory Auditor of the Issuer (the **Interim Financial Information**, and together with the Annual Financial Statements and the Auditor's Reports, the **Financial Statements**). With respect to the Interim Financial Information included herein, the Statutory Auditor of the Issuer has reported that they applied limited procedures in accordance with professional standards for a review of such information. However, their separate report included herein states that they did not audit and they do not express an opinion on the Interim Financial Information. Accordingly, the degree of reliance on their report on such information should be restricted in light of the limited nature of the review procedures applied.

## **5.6 ROUNDING OF AND STATISTICAL INFORMATION**

Certain financial and statistical data in this Prospectus have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

## **5.7 CONSOLIDATION**

In this Prospectus, references to the “Issuer” are to Hyloris Pharmaceuticals NV, and references to “Hyloris”, “Company”, “we”, “us” or “our” are to the Issuer and its subsidiaries, Hyloris Developments (100%); RTU Pharma (100%) and Dermax (100%).

Unless the context or an explicit mention indicates otherwise, any reference to the portfolio, participations, statistics and activities of the Issuer in this Prospectus will be presented on a consolidated basis, *i.e.*, including its subsidiaries.

For an explanation of the common control by Hyloris Pharmaceuticals over Dermax and RTU Pharma, and the pooling of interest method resulting therefrom, reference is made to Note 8 to the Financial Statements attached to this Prospectus.

## **5.8 AVAILABILITY OF THIS PROSPECTUS AND THE DOCUMENTS OF THE ISSUER**

### **5.8.1 AVAILABILITY OF THIS PROSPECTUS**

This Prospectus and the Summary may be distributed separately.

This Prospectus and the Summary shall be made available to investors free of charge as of 17 June 2020 (before opening of the markets) at the registered office of the Issuer (Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium)). This Prospectus and the Summary shall also be made available free of charge to investors at (i) KBC Bank NV/SA, CBC Banque SA/NV, Bolero and KBC Securities NV/SA, upon request by phone: 078 152 153 (KBC Bank NV/SA & CBC Banque SA/NV) and 0800 628 16 (Bolero Orderdesk) and (ii) on its websites: [www.kbc.be/hyloris](http://www.kbc.be/hyloris), [www.bolero.be/nl/hyloris](http://www.bolero.be/nl/hyloris) and [www.kbcsecurities.com](http://www.kbcsecurities.com) (before opening of the market) and (iii) on the website of the Issuer ([www.hyloris.com](http://www.hyloris.com)), whereby the access on the aforementioned websites is each time subject to the usual limitations.

The availability of this Prospectus on the internet does not constitute an offer to sell or an invitation to make an offer to purchase Shares in, or towards any person located in, a country in which such an offer or invitation is prohibited. This Prospectus may not be copied, made available or printed for distribution.

Other information on the Issuer's website or any other website, does not form part of this Prospectus and has not been reviewed or approved by the FSMA.

### **5.8.2 AVAILABILITY OF THE ISSUER'S DOCUMENTS**

The Issuer must file its Articles of Association, any amendments thereto and all other documents to be published in the Annexes to the Belgian Official Gazette, with the registrar of the Enterprise Court of Liège, where they can be consulted by the public. A copy of the most recent version of the coordinated Articles of Association can also be consulted in the online database of the Royal Federation of Belgian Notaries (<http://statuten.notaris.be>). A copy of the most recent version of the coordinated Articles of Association and of the corporate governance charter of the Issuer can also be consulted on the Issuer's website.

Belgian law also requires the Issuer to prepare statutory and consolidated annual accounts. The statutory and consolidated annual accounts, the annual report of the Board of Directors and the report of the Statutory Auditor of the Issuer are filed with the National Bank of Belgium, where they can be consulted by the public.

Furthermore, as a company with shares admitted to trading on the regulated market of Euronext Brussels, the Issuer will also be required to publish an annual financial report (which includes its audited statutory and consolidated financial statements, the report of its Board of Directors and the report of the Statutory Auditor), as well as a half-yearly financial report on the first six months of its financial year (which includes a condensed set of financial statements and an interim management report). Copies of these documents will be made available on the Issuer's website and on STORI, the Belgian central storage mechanism, which is operated by the FSMA and can be accessed via [stori.fsma.be](http://stori.fsma.be) or [www.fsma.be](http://www.fsma.be).

The Issuer must also disclose inside information, information about its shareholder structure and certain other information to the public in accordance with the Belgian Royal Decree of 14 November 2007 on the obligations of issuers of financial instruments that are admitted to trading on a regulated market and Regulation (EU) 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse (the **Market Abuse Regulation**) and related rules, as amended. Such information and documentation will be made available through the Issuer's website, press releases, the communication channels of Euronext Brussels, on STORI, or a combination of these means. All press releases published by the Issuer will be made available on its website.

The Issuer's website is located at [www.hyloris.com](http://www.hyloris.com). The information on the website of the Issuer is not incorporated by reference in, and does not form part of, this Prospectus.

## 6 ESSENTIAL INFORMATION

### 6.1 SELECTED FINANCIAL INFORMATION

The following selected financial information should be read together with the other information contained in this Prospectus, including Section 9 (Operating and financial review and prospects) and the Financial Statements and related notes included elsewhere in this Prospectus. This financial information is historical and not necessarily indicative of results to be expected in any future period.

The following selected financial information has been derived from the Financial Statements included elsewhere in this Prospectus and should be read in conjunction with these Financial Statements and related notes. The Financial Statements have been prepared in accordance with IFRS as in effect at the time of preparation. For more information, see Section 5.5 (Presentation of financial and other information) of this Prospectus.

#### 6.1.1 CONSOLIDATED STATEMENTS OF PROFIT AND LOSS

in € thousand	Q1 2020	2019	2018	2017
Revenue	63	91	91	213
Other operating income	-	86	-	18
Cost of sales	(20)	(66)	(65)	(95)
<b>Gross profit</b>	<b>44</b>	<b>111</b>	<b>26</b>	<b>135</b>
Research and development expenses	(784)	(4,577)	(4,870)	(2,313)
General and administrative expenses	(523)	(808)	(622)	(1,657)
Other operating expenses	-	-	(3)	(31)
<b>Operating profit/(loss)</b>	<b>(1,264)</b>	<b>(5,274)</b>	<b>(5,469)</b>	<b>(3,866)</b>
Financial income	9	10	7	257
Financial expenses	(325)	(518)	(597)	(174)
<b>Profit/(loss) before taxes</b>	<b>(1,579)</b>	<b>(5,782)</b>	<b>(6,059)</b>	<b>(3,783)</b>
Income taxes	(1)	14	20	66
<b>PROFIT/(LOSS) FOR THE PERIOD</b>	<b>(1,580)</b>	<b>(5,768)</b>	<b>(6,039)</b>	<b>(3,717)</b>

#### 6.1.2 CONSOLIDATED BALANCE SHEET

ASSETS (in thousands of euros)	Q1 2020	2019	2018	2017
<b>Non-current assets</b>	<b>2,468</b>	<b>2,245</b>	<b>4,111</b>	<b>3,863</b>
Intangible assets	2,374	2,138	3,949	3,825
Property, plant and equipment	30	32	30	-
Right-of-use assets	55	66	119	35
Financial assets	9	9	12	3
<b>Current assets</b>	<b>18,025</b>	<b>3,739</b>	<b>3,837</b>	<b>502</b>
Trade and other receivables	1,742	333	1,141	216

Other financial assets	3,230	-	-	10
Current tax assets	-	-	-	-
Other current assets	1,840	3,200	10	5
Cash and cash equivalents	11,213	205	2,687	271
<b>TOTAL ASSETS</b>	<b>20,493</b>	<b>5,983</b>	<b>7,948</b>	<b>4,365</b>

<b>EQUITY AND LIABILITIES</b> <b>(in thousands of euros)</b>	<b>Q1 2020</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
<b>Equity attributable to owners of the parent</b>	<b>(8,425)</b>	<b>(10,188)</b>	<b>(2,246)</b>	<b>(4,286)</b>
Share capital	89	89	89	79
Share premium	23,982	23,982	23,982	18,243
Retained earnings	(37,661)	(36,081)	(28,097)	(24,324)
Other reserves	5,165	1,822	1,779	1,717
<b>Non-controlling interests</b>	<b>-</b>	<b>-</b>	<b>(2,216)</b>	<b>-</b>
<b>Total equity</b>	<b>(8,425)</b>	<b>(10,188)</b>	<b>(4,462)</b>	<b>(4,286)</b>
<b>Non-current liabilities</b>	<b>10,682</b>	<b>22</b>	<b>9,309</b>	<b>6,781</b>
Borrowings	12	22	66	15
Other financial liabilities	10,671	-	9,243	6,766
<b>Current liabilities</b>	<b>18,235</b>	<b>16,149</b>	<b>3,101</b>	<b>1,870</b>
Borrowings	43	44	52	20
Other financial liabilities	16,112	13,130	-	-
Trade and other liabilities	2,033	2,927	2,998	1,799
Current tax liabilities	47	47	51	51
<b>Total liabilities</b>	<b>28,918</b>	<b>16,171</b>	<b>12,410</b>	<b>8,651</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>20,493</b>	<b>5,983</b>	<b>7,948</b>	<b>4,365</b>

### 6.1.3 CONSOLIDATED STATEMENTS OF CASH FLOWS

<b>in € thousands</b>	<b>Q1 2020</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>				
Operating result	(1,264)	(5,274)	(5,469)	(3,866)
Adjustments to reconcile net loss to net cash provided by operating activities:				
Depreciation, amortisation and impairments	24	3,306	88	65
Share-based payment expense	113	-	-	1,329
Changes in working capital:				
Trade and other receivables	(1,409)	808	(925)	(178)
Other current assets	1,369	(3,180)	2	257
Trade and Other Payables	(1,277)	(218)	936	777
Other current liabilities	-	1	-	-
<b>Cash generated from operations</b>	<b>(2,443)</b>	<b>(4,558)</b>	<b>(5,368)</b>	<b>(1,615)</b>

Taxes paid	(1)	(3)	(1)	(1)
<b>Net cash generated from operating activities</b>	<b>(2,444)</b>	<b>(4,562)</b>	<b>(5,368)</b>	<b>(1,616)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>				
Interests received	-	-	-	-
Purchases of property, plant and equipment	-	(8)	(31)	-
Purchases of Intangible assets	(240)	(1,222)	-	(2,800)
Capital contributions in subsidiaries	-	-	250	62
Proceeds from other financial assets	-	3	-	2
Transaction under common control	-	-	(200)	-
<b>Net cash provided by/(used in) investing activities</b>	<b>(240)</b>	<b>(1,228)</b>	<b>19</b>	<b>(2,736)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>				
Reimbursements of borrowings and other financial liabilities	(11)	(52)	(43)	(21)
Proceeds from borrowings and other financial liabilities	13,702	3,364	2,060	4,408
Interests paid	-	(4)	(2)	(1)
Proceeds from issue of equity instruments of the Company (net of issue costs)	-	-	5,750	12
<b>Net cash provided by/(used in) financing activities</b>	<b>13,691</b>	<b>3,308</b>	<b>7,765</b>	<b>4,398</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>11,008</b>	<b>(2,482)</b>	<b>2,416</b>	<b>47</b>

#### 6.1.4 BEST-CASE FINANCIAL OUTLOOK

Hyloris could, by way of a positive and best-case scenario, based on its current product candidate portfolio (and on the hypothesis that its portfolio would remain unchanged) achieve operational profitability (on EBIT level) at the earliest by late 2022. Until such time, in view of increasing costs related to the further development of its current product candidate portfolio that will not be offset by its revenues, Hyloris is expected to continue to incur increasing losses.

#### 6.2 CAPITALIZATION AND INDEBTEDNESS

The following tables set forth the Issuer's consolidated capitalization and net financial indebtedness as at 31 March 2020 (i) on an actual basis and (ii) as adjusted to give effect to (a) the subscription to additional Convertible Bonds and the partial reimbursement of the shareholder loans, (b) the Pre-commitments, (c) the conversion of Convertible Bonds and (d) the Offering (assuming a placement of the maximum number of new Shares in the Offering (*i.e.*, including the exercise in full of the Increase Option and of the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range). This table should be read in conjunction with Section 6.1 (Selected Financial Information) and Section 9 (Operating and financial review and prospects), and the Condensed Consolidated Interim Financial Statement as for and for the period ended 31 March 2020. Other than as set forth below, there have been no material changes to the Issuer's consolidated capitalization and net financial indebtedness since 31 March 2020.

<i>(in €000)</i>	<b>As at 31 March 2020</b>	<b>Adjustments (Convertible bonds, shareholders loans) – certain outcome</b>	<b>Pre- commitments and Convertible Bonds conversion<sup>(1)</sup> – certain outcome</b>	<b>Offering – uncertain outcome<sup>(2)</sup></b>	<b>As Adjusted</b>
<b>Total current liabilities .....</b>	<b>18,235</b>	<b>(7,500)</b>		-	<b>10,735</b>
Guaranteed .....	-	-			-
Secured .....	43	-			43
Unguaranteed/unsecured.	18,192	(7,500)			10,692
<b>Total non-current liabilities .....</b>	<b>10,683</b>	<b>4,350</b>	<b>(15,021)</b>		<b>12</b>
Guaranteed .....	-	-			-
Secured .....	12	-			12
Unguaranteed/unsecured.	10,671	4,350	(15,021)		-
<b>Total indebtedness .....</b>	<b>28,918</b>	<b>(3,150)</b>	<b>(15,021)</b>		<b>10,747</b>
<b>Shareholders' equity</b>					
Share capital .....	89	-	21	22	132
Share premium .....	23,982	-	38,062	48,337	110,381
Other reserves .....	5,165	-	(3,230)		1,935
Retained earnings.....	(37,661)	-	(169)	(4,827)	(42,657)
Cumulative translation adjustment .....					
<b>Total equity attributable to owners of the parent .....</b>	<b>(8,425)</b>	<b>-</b>	<b>34,684</b>	<b>43,533</b>	<b>69,791</b>

**Notes:**

(1) Assuming the Offer Price is at the midpoint of the Price Range.

(2) It is assumed that (a) the maximum amount of New Shares (*i.e.*, including the exercise in full of the Increase Option) will be issued pursuant to the Offering, (b) the Stabilization Manager decides to fully exercise its Over-allotment Option and (c) the Offer Price is at the midpoint of the Price Range.

In April 2020, the Company recorded additional subscriptions to the Convertible Bonds for a total amount of EUR 4.35 million. In April and June 2020, the Company reimbursed shareholder loans for a total of EUR 7.5 million. The non-current liabilities are mainly composed of the Convertible Bonds (fair valued at EUR 10.67 million as at 31 March 2020). The Convertible Bonds (which comprise of subscriptions for a total aggregate nominal amount of EUR 15.15 million) will be converted using a 30% discount of the Offering price. The transaction costs associated to the Convertible Bonds amounted to EUR 0.2 million. The subscribers to the Convertible Bonds committed to participate to the Offering for an amount of EUR 22,73 million. The Capital increase resulting from the conversion of the Convertible Bonds (excluding the accrued interest) and from the Pre-commitments is expected to amount to EUR 37.9 million.

The current liabilities are mainly composed of the shareholders loans (EUR 15.7 million), of which EUR 7.5 million has been repaid in the course of the second quarter of 2020 and of trade and other liabilities (EUR 2.5 million). The remaining amount of the shareholders loans (EUR 8.2 million) will be reimbursed at the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.

The embedded derivatives valued at EUR 3.23 million and presented as 'Other financial assets' as of March 31, 2020 will be offset against the 'Other reserves' at conversion of the Convertible Bonds.

Assuming (i) the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option) will be subscribed for pursuant to the Offering, (b) the Stabilization Manager decides to fully exercise its Over-allotment Option and (iii) the Offer Price is at the midpoint of the Price Range, the gross proceeds of the Offering would amount to EUR 71,084,375 million. Transaction costs associated with the Offering would in such case amount to approximately EUR 4.8 million and will be recorded in the equity of the Company.

The total capital increase (including issue premium) resulting from the conversion of the Convertible Bonds and the Offering (assuming (i) the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option) will be issued pursuant to the Offering, (ii) the Stabilization Manager decides to fully exercise its Over-allotment Option and (iii) the Offer Price is at the midpoint of the Price Range) is expected to amount to EUR 86,442,400.

The following table sets out the net financial indebtedness of the Issuer as at 31 March 2020:

<i>(in €000)</i>	<b>As at 31 March 2020</b>	<b>Adjustments (Convertible bonds, shareholders loans) – certain outcome</b>	<b>Pre- commitments and Convertible Bonds conversion<sup>(1)</sup> – certain outcome</b>	<b>Offering – uncertain outcome<sup>(2)</sup></b>	<b>As Adjusted</b>
Cash and cash equivalents <sup>(3)</sup> .....	(11,213)	3,150	(22,725)	(43,533)	(74,321)
Trading securities .....	-	-		-	-
<b>Total liquidity .....</b>	<b>(11,213)</b>	<b>3,150</b>	<b>(22,725)</b>	<b>(43,533)</b>	<b>(74,321)</b>
Current bank debt .....	-	-	-	-	-
Current portion of non-current liabilities	43	-	-	-	43
Other financial liabilities .....	16,112	(7,500)	-	-	8,612
<b>Current financial liabilities .....</b>	<b>16,155</b>	<b>(7,500)</b>	<b>-</b>	<b>-</b>	<b>8,655</b>
<b>Net current financial indebtedness ...</b>	<b>4,942</b>	<b>(4,350)</b>	<b>(22,725)</b>	<b>(43,533)</b>	<b>(65,666)</b>
Non-current bank loans .....	12	-	-	-	12
Bonds issued .....	10,671	4,350	(15,021)	-	-
Other non-current liabilities .....	-	-	-	-	-
<b>Non-current financial indebtedness..</b>	<b>10,682</b>	<b>4,350</b>	<b>(15,021)</b>	<b>-</b>	<b>12</b>
<b>Net financial indebtedness .....</b>	<b>15,624</b>	<b>-</b>	<b>(37,746)</b>	<b>(43,533)</b>	<b>(65,654)</b>

Notes:

- (1) Assuming the Offer Price is at the midpoint of the Price Range.
- (2) It is assumed that (a) the maximum amount of New Shares (i.e., including the exercise in full of the Increase Option) will be subscribed for pursuant to the Offering, (b) the Stabilization Manager decides to fully exercise its Over-allotment Option and (c) the Offer Price is at the midpoint of the Price Range.
- (3) Cash and cash equivalents of the Offering are net of transaction costs.

End of March 2020, Hyloris had contractual commitments and contingent liabilities for a maximum amount of EUR 4.3 million (among which EUR 0,25 million and \$4.4 million converted in EUR at a rate of 1.0956) related to asset purchase, licenses and developments agreements recorded under intangible assets. The amounts due to the counterparties are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted.

As of 31 March 2020, out of the total value of EUR 4.3 million, USD 1.8 million (or EUR 1.6 million) should be considered as contingent liabilities as they are not triggered by a performance obligation from the counterparty (USD 1.3 million for Metolazone IV, USD 0.3 million for Atomoxetine Liquid and USD 0.2 million for HY-REF-004).

In April 2020, the Company recorded additional subscriptions for the Convertible Bonds for a total amount of EUR 4.35 million. In April and June 2020, the Company and reimbursed shareholder loans for a total of EUR 7.5 million. The net negative impact on the cash and cash equivalents amounts to EUR 3.15 million. The Convertible Bonds were fair valued at EUR 10.67 million as of 31 March 2020. The subscribers to the Convertible Bonds committed to participate to the Offering for an amount of EUR 22,73 million.

Assuming (i) the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option and of the Over-allotment Option) will be subscribed for pursuant to the Offering, (ii) the Stabilization Manager decides to fully exercise its Over-allotment Option and (iii) the Offer Price is at the midpoint of the Price Range, the gross proceeds of the Offering would amount to EUR 71,084,375. Transaction costs associated with the Offering would in such case amount to approximately EUR 4.8 million, and the net proceeds resulting from such Offering would then amount to approximately EUR 66.3 million.

### **6.3 WORKING CAPITAL STATEMENTS**

On the date of this Prospectus and not taking into account the proceeds of the Offering, the Company is of the opinion that taking into account its available cash and cash equivalents on the date of this Prospectus, it does not have sufficient working capital to meet its present requirements.

In the event that Hyloris is not be able to attract new funds (beyond its existing cash and cash equivalents), it expects to run out of working capital by the second quarter of 2021. The maximum working capital shortfall in the 12 months' period following the date of this Prospectus in the event Hyloris would not be able to attract any such additional funds and if it in that event maintains its current strategy and development activities, is projected to be approximately EUR 2 million at the end of the second quarter of 2021.

However, assuming the completion of the Offering, Hyloris is of the opinion that the amount of Pre-commitments (*i.e.*, EUR 22,725,000), together with its available cash and cash equivalents, will provide sufficient working capital to meet its present requirements and working capital needs for a period of at least 12 months from the date of this Prospectus.

### **6.4 INTEREST OF NATURAL AND LEGAL PERSONS INVOLVED IN THE OFFERING**

KBC Securities NV/SA, having its registered office at Havenlaan 2, 1080 Brussels, Belgium (**KBC Securities**) and Van Lanschot Kempen Wealth Management N.V., having its office at Beethovenstraat 300, 1077 WZ Amsterdam, the Netherlands (**Kempen & Co**) act as Joint Global Coordinators and Joint Bookrunners (together the **Underwriters**) in the context of the Offering, and are expected to, subject to certain conditions, enter into an "Underwriting Agreement" with the Issuer (see Section 15.1 (Underwriting Agreement)).

In connection with the Offering, each of the Underwriters and any of their respective affiliates, acting as an investor for its own account, may take up Offered Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Shares or related investments and

may offer or sell such Shares or other investments otherwise than in connection with the Offering. Accordingly, references in this Prospectus to Shares being offered or placed should be read as including any offering or placement of Offered Shares to any of the Underwriters or any of their respective affiliates acting in such capacity. None of the Underwriters intends to disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligation to do so. In addition, certain of the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Underwriters (or their affiliates) may from time to time acquire, hold or dispose of Shares.

As of the date of this Prospectus, the Underwriters have only signed an agreement with the Company to assist them with this Offering without having any other relationships with the Company. Certain of the Underwriters and/or their respective affiliates may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Issuer or any parties related to it, in respect of which they may in the future receive, customary fees and commissions. As a result of these transactions, these parties may have interests that may not be aligned or could possibly conflict with the interests of investors.

The Adjustment Warrants and Anti-dilution Warrants will be waived and cancelled if (i) the Offer Price is not lower than EUR 6.769525, (ii) subscription orders for an amount of at least EUR 40 million have been received no later than 30 June 2020 and (iii) the Shares of the Company are admitted to trading on the regulated market of Euronext Brussels on an “if-and-when-issued-and/or-delivered” basis within 3 business days following the closing of the Offering Period (see Sections 13.4.2 (Adjustment Warrants) and 13.4.3 (Anti-dilution Warrants)). Therefore, the existing shareholders of Hyloris that do not hold Anti-dilution Warrants and/or Adjustment Warrants have an interest in the closing of the Offering Period on or prior to 30 June 2020 and the admission of the Shares of the Company to trading on the regulated market of Euronext Brussels on an “if-and-when-issued-and/or-delivered” basis within 3 business days following the closing of the Offering Period, as they otherwise could face dilution of their shareholding in the Issuer upon the exercise of these warrants.

From the Listing Date, the financial service for the Shares will be provided by KBC Bank NV/SA, who will act as listing and paying agent of the Issuer. Should the Issuer alter its policy in this respect, this will be announced in accordance with applicable law.

See also Section 14.3 (Pre-commitments) and Section 14.4 (Intention of the shareholders, members of the Board of Directors and of the Executive Management of the Issuer).

## **6.5 REASONS FOR THE OFFERING AND USE OF PROCEEDS**

Assuming that the Offer Price is at the midpoint of the Price Range, and that the Offering is completely subscribed for, the gross proceeds from the Offering will amount to EUR 53,750,000 (assuming that only the 5,000,000 initially offered New Shares are issued), EUR 61,812,500 (assuming that the Increase Option is exercised in full) and EUR 71,084,375 (assuming that the Stabilization Manager decides to fully exercise its Over-allotment Option). The fees and commissions payable to the

Underwriters by the Issuer are then expected to respectively amount to maximum EUR 2.5 million, EUR 2.9 million and EUR 3.4 million.

In addition, the aggregate of the administrative, legal, tax and audit expenses as well as the other costs in connection with the Offering (including but not limited to legal publications, printing and translation of this Prospectus (including the Summary) and Offering related documents, and expenses incurred by the Underwriters (which are estimated at EUR 0.05 million)) and the remuneration of the FSMA (which are estimated at EUR 0.02 million) and Euronext Brussels, is expected to amount to approximately EUR 1.4 million.

Based on the aforementioned assumptions and the expenses of the Offering, the Issuer estimates that it will thus receive net proceeds of EUR 49.8 million (assuming that only the 5,000,000 initially offered New Shares are issued), EUR 57.4 million (assuming that the Increase Option is exercised in full) and EUR 66.3 million (assuming that the Stabilization Manager decides to fully exercise its Over-allotment Option).

The principal purpose of the Offering is to obtain additional capital to support the execution of Hyloris' strategy (as described in Section 8.4 (Strategy)). In particular, the Issuer intends to use the net proceeds of the Offering as follows:

- EUR 22.725 million is expected to be allocated to the development (up to and including the approval by the regulatory authority) of the existing portfolio of product candidates as described in Section 8.10 (Products), whereby the amount will differ per product candidate based on the current phase of development (see Section 9.2.3 (Research and development expenses));
- EUR 11 million is expected to be allocated to the establishment of a commercial team in the United States for the commercialization of its IV Cardiovascular Portfolio (except for Sotalol IV<sup>7</sup>);
- to fund the expansion of the pipeline both internally and through business development opportunities; and
- for general corporate purposes.

Through the Offering, the Company also aims to increase its visibility, diversify its shareholder base and accelerate its growth through different capital sources.

The Issuer cannot predict with certainty all of the particular uses for the proceeds from the Offering, or the amounts that it will actually spend on the uses set forth above. The amounts and timing of the Issuer's actual expenditures will depend upon numerous factors, including the progress, costs, timing and results of its further development of its pipeline; regulatory or competitive developments; the net proceeds actually raised in the Offering; the amounts received by way of revenues and the Issuer's

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<sup>7</sup> Sotalol IV was licensed to a U.S. based partner before Hyloris started the development of its other IV Cardiovascular Portfolio product candidates and therefore had not yet defined its strategy to establish its own commercial team in the United States for its IV Cardiovascular Portfolio

operating costs and expenditures. As such, the Issuer's management assumes certain flexibility in applying the net proceeds from the Offering and may change the allocation of these proceeds as a result of these and other contingencies. Pending the use of the proceeds from the Offering, the Issuer intends to invest the net proceeds in interest bearing, cash and cash equivalents instruments or short-term certificates of deposit.

Furthermore, as no minimum amount is set with respect to the Offering (see Section 14.2 (Conditions and nature of the Offering)) and Risk Factor 2.5.1 (The fact that no minimum amount is set for the Offering may affect Hyloris' investment plan and the liquidity of the Shares), the Issuer has the right to proceed with a capital increase in a reduced amount, corresponding to a number of new Shares lower than the 5,000,000 initially offered New Shares (*i.e.*, excluding the exercise, in part or in full, of the Increase Option) in the Offering, it being understood that, in a worst case scenario, the net proceeds of the Offering would be equal to the net proceeds from the Pre-commitments of the Participating Investors.

In the event that the net proceeds from the Offering are limited to the net proceeds from the Pre-commitments of the Participating Investors (*i.e.*, EUR 19,810,173), Hyloris would use these proceeds, together with the net proceeds from the Convertible Bonds (*i.e.*, EUR 7,650,000<sup>8</sup>), for the further development and finalization of its current product candidate portfolio. The establishment of a commercial team in the United States, the expansion of the product candidate pipeline and the potential development opportunities would potentially be delayed until additional financing were to become available.

In the event that the Issuer proceeds with the capital increase in a reduced amount, it may be required to raise additional capital in order to meet the funding requirements for the establishment of a commercial team in the United States, the expansion of the product candidate pipeline and the pursuit of potential development opportunities. Such additional funding could be a combination of external financing and further shareholders' financing, and, the final amount raised would determine the pace of expansion of the current product candidate portfolio.

## **6.6 DIVIDENDS AND DIVIDEND POLICY**

### **6.6.1 DIVIDENDS**

As of the closing of the Offering, all of the Shares, including the Offered Shares, will entitle the holders thereof to an equal right to participate in dividends declared after the Closing Date, in respect of the entire financial year ending on 31 December 2020 and future years. All of the Shares participate equally in the Issuer's profits (if any). Pursuant to the Belgian Code of Companies and Associations, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the Annual General Shareholders' Meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Issuer's Board of Directors. The Issuer's Articles of Association also authorize the Board of

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<sup>8</sup> This is the aggregate nominal amount of the Convertible Bonds (EUR 15,150,000) minus the repaid part of the shareholder loans after the reporting period (*i.e.*, 7.5 million, see Note 19 to the condensed consolidated financial statements).

Directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Issuer's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Issuer's stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Issuer's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e., summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased with the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves (which include, as the case may be, the unamortized part of any revaluation surpluses). In addition, pursuant to Belgian law and the Issuer's Articles of Association, the Issuer must allocate an amount of 5% of its Belgian GAAP annual net profit ("*bénéfices nets*" / "*nettoinst*") to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it meet the requirement at the time of the closing of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, further limiting the Issuer's ability to pay out dividends to its shareholders.

Additional financial restrictions and other limitations may be contained in future credit agreements. While no restrictions of this nature currently exist, certain covenants may be included in future credit agreements that, for example, may require debt service payments to be satisfied before dividends are paid.

There will be no distributable reserves (except for the issue premiums) nor will there be a legal reserve, as of the closing of the Offering.

#### **6.6.2 DIVIDEND POLICY**

The Issuer has not declared or paid dividends on its Shares in the past. In the future, the Issuer's dividend policy will be determined and may change from time to time by determination of the Issuer's Board of Directors. Any declaration of dividends will be based upon the Issuer's earnings, financial condition, capital requirements and other factors considered important by the Board of Directors. Belgian law and the Issuer's Articles of Association do not require the Issuer to declare dividends.

Currently, the Board of Directors of the Issuer expects to retain all earnings, if any, generated by the Issuer's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future (see also Section 6.6.1 (Dividends)). As a consequence of all of these factors, there can be no assurance as to whether dividends or similar payments will be paid out in the future nor, if they are paid, as to their amount.

## 7 INFORMATION ON THE ISSUER

### 7.1 IDENTITY OF THE ISSUER

#### 7.1.1 NAME, CORPORATE FORM AND REGISTRATION INFORMATION

The Issuer's corporate name is Hyloris Pharmaceuticals (in short 'Hyloris'<sup>9</sup>) and takes on the form of a public limited liability company ("*société anonyme*" / "*naamloze vennootschap*") under Belgian law.

The Issuer is registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0674.494.151, and has 875500LZIWS7QE0173 as Legal Entity Identifier (LEI).

#### 7.1.2 REGISTERED OFFICE AND OTHER CONTACT INFORMATION

The Issuer has its registered office at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium).

Tel: +32 4 346 02 07

E-mail: [contact@hyloris.com](mailto:contact@hyloris.com)

Website: [www.hyloris.com](http://www.hyloris.com) (the information on the website of the Issuer is not incorporated by reference in, and does not form part of, this Prospectus).

#### 7.1.3 INCORPORATION

The Issuer was originally incorporated in June of 2012 by Mr. Stijn Van Rompay and Mr. Thomas Jacobsen, as a limited liability company ("*société à responsabilité limitée*") under the laws of the Grand Duchy of Luxembourg with the name "EVERBRIGHT s.à r.l." and registered in the Luxembourg Business Register ("*Registre de Commerce et des Sociétés de Luxembourg*") under number B 149.546.

On 31 March 2017, the Issuer was redomiciled from Luxembourg to Belgium and transformed into a Belgian public limited liability company ("*société anonyme*" / "*naamloze vennootschap*") (the **Belgian Seat Transfer**). For this purpose, on 31 March 2017, the Issuer transferred its registered office, without liquidation or dissolution, from Luxembourg to Belgium, pursuant to which it changed its corporate name to "Hyloris Pharmaceuticals", and as a result of which the Issuer became a private limited liability company ("*société privée à responsabilité limitée*" / "*besloten vennootschap met beperkte aansprakelijkheid*") organized under Belgian law. Immediately thereafter (and after a capital increase (see Section 13.3.3 (Development of the share capital) for more details on this capital increase)), the Issuer was transformed from a private limited liability company ("*société privée à responsabilité limitée*" / "*besloten vennootschap met beperkte aansprakelijkheid*") organized under Belgian law to a public limited liability company ("*société anonyme*" / "*naamloze vennootschap*") organized under Belgian law.

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<sup>9</sup> Hyloris stands for "high yield, lower risk" and relates to the 505(b)(2) regulatory pathway for product approval on which the Issuer focuses, but in no way relates or applies to an investment in the Shares.

For more information related to the share capital and Articles of Association of the Issuer, reference is made to Section 13 (Share capital and Articles of Association).

## 7.2 ORGANIZATIONAL STRUCTURE

As of the date of this Prospectus, the Issuer wholly owns the following subsidiaries:

- (i) Hyloris Developments, a public limited liability company (“*société anonyme*” / “*naamloze vennootschap*”) organized under the laws of Belgium, registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0542.737.368, and with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium) (**Hyloris Developments**);
- (ii) RTU Pharma, a public limited liability company (“*société anonyme*” / “*naamloze vennootschap*”) organized under the laws of Belgium, registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0669.738.676, and with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium) (**RTU Pharma**); and
- (iii) Dermax, a public limited liability company (“*société anonyme*” / “*naamloze vennootschap*”) organized under the laws of Belgium, registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0667.730.677, and with registered office located at Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium) (**Dermax**).

The Issuer plans to streamline the organizational structure of Hyloris in the near future through corporate re-structuring, thereby reducing the number of subsidiaries.

### 7.2.1 HYLORIS DEVELOPMENTS

Hyloris Developments was founded by the Issuer (who subscribed for all but one of the shares in Hyloris Developments) and Mr. Stijn Van Rompay (who subscribed for one share in Hyloris Developments) on 3 December 2013, with the name “Hyloris Pharmaceuticals”. Through this subsidiary, the Issuer was able to benefit from access to the Belgian pharmaceutical market, which is known for its dynamic university spin-offs, highly trained and educated work force, experienced management and network of specialized investors. Mr. Stijn Van Rompay has since transferred his minority shareholding in the subsidiary to the Issuer, such that it has become a wholly-owned subsidiary of the Issuer.

On 31 March 2017, concomitantly with the Belgian Seat Transfer of the Issuer (see Section 7.1.3 (Incorporation) for more details on the Belgian Seat Transfer) and the changing of the Issuer’s name to “Hyloris Pharmaceuticals”, the name of this subsidiary was changed to its current name, “Hyloris Developments”.

Hyloris Developments is dedicated to its goal of developing innovative products to deliver solutions to currently unmet or underserved needs of patients, physicians and other stakeholders in the healthcare system with respect to the safety, efficacy and/or convenience of approved medicines by leveraging

existing data and products and investigating new formulations which offer faster clinical responses and improve patient compliance and quality of life.

Hyloris Developments holds the following product (candidates), which form part of Hyloris' product (candidate) portfolio:

- Sotalol IV (see Section 8.10.2.1 (Sotalol IV & Dofetilide IV))
- Dofetilide IV (see Section 8.10.2.1 (Sotalol IV & Dofetilide IV))
- Metolazone IV (see Section 8.10.2.2 (Metolazone IV))
- HY-CVS-073 (see Section 8.10.2.3 (HY-CVS-073 & HY-CVS-074))
- HY-CVS-074 (see Section 8.10.2.3 (HY-CVS-073 & HY-CVS-074))
- HY-REF-075 (see Section 8.10.3.4C (HY-REF-075))
- Maxigesic<sup>®</sup> IV (see Section 8.10.3.1 (Maxigesic<sup>®</sup> IV))
- HY-REF-004 (see Section 8.10.3.2 (HY-REF-004))
- Atomoxetine Oral Liquid (see Section 8.10.3.4A (Atomoxetine Oral Liquid))

### **7.2.2 RTU PHARMA**

RTU Pharma was founded in 2017. All shares in RTU Pharma were acquired by the Issuer on 17 September 2018 by way of a share sale and purchase agreement (reference is made to Section 12 (Related Party Transactions) of this Prospectus for more details on this acquisition).

RTU Pharma holds Tranexamic Acid RTU, which forms part of Hyloris' product candidate portfolio (see Section 8.10.3.3A (Tranexamic Acid RTU)).

RTU Pharma focuses on developing Ready-to-Use and Pre-Filled-Syringe of existing injectable products.

### **7.2.3 DERMAX**

Dermax was founded in 2016. All shares in Dermax were acquired by the Issuer on 31 December 2019 by way of a contribution in kind (reference is made to Section 12 (Related Party Transactions) of this Prospectus for more details on this acquisition).

Dermax is a company that initially was specialized in the development of established market topical products which do not have a generic drug equivalent because they require specialized manufacturing and complex clinical studies which represent an important hurdle to access the market. It now also focuses on re-formulations

The following product candidates, which form part of Hyloris' product (candidate) portfolio, are held by Dermax:

- HY-EMP-016 (see Section 8.10.4.1 (HY-EMP-016))
- HY-REF-029 (see Section 8.10.3.4B (HY-REF-029))
- Fusidic Acid Cream (see Section 8.10.4.2 (Fusidic Acid Cream))
- HY-REF-038 (see Section 8.10.3.3B (HY-REF-038)).

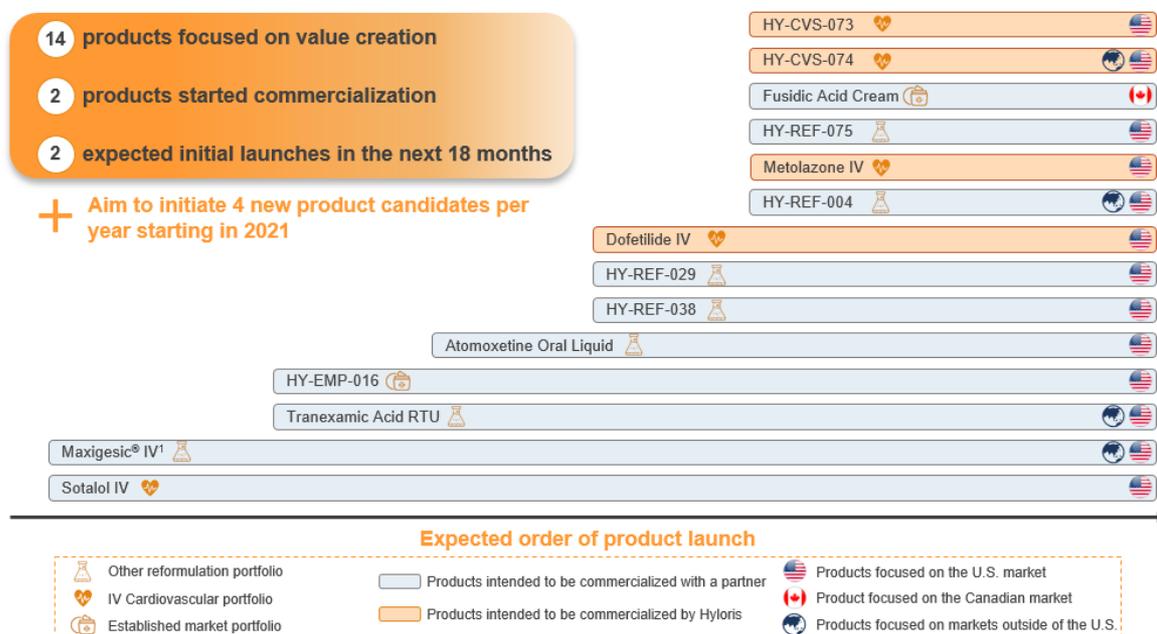
## 8 BUSINESS

### 8.1 OVERVIEW

Hyloris is an early-stage innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. The Company develops proprietary products it believes offer significant advantages compared to currently available alternatives, with the aim of addressing the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders in the healthcare system.

Hyloris' development strategy focuses on the FDA's 505(b)(2) regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule has already been established. As compared to traditional New Drug Applications (NDAs) using the FDA's 505(b)(1) regulatory pathway, the 505(b)(2) regulatory pathway can reduce the clinical burden required to bring a product to the market, significantly shorten the development timelines and reduce costs and risks.

To date, Hyloris' operations have consisted primarily of the identification of product candidates to build its pipeline and the formulation, testing and development of its existing portfolio. As of the date of this Prospectus, Hyloris has established a diversified portfolio of two early stage commercial products and 12 product candidates in various stages of development (which has been initiated prior to 2020 for all product candidates). The following chart is a depiction of Hyloris' portfolio as of the date of this Prospectus.



Note: 1. Expected order of product launch relates to commercial launch in Australia and New Zealand (Hyloris will however not receive any part of the profits generated from Australia and New Zealand).

Hyloris' portfolio has a particular focus on IV cardiovascular products, but it also contains other reformulation products and established market products, all of which are further detailed in Section 8.10

(Products) of this Prospectus. The Company is continuously evaluating new development candidates to add to its portfolio, both internally and externally.

Hyloris intends to primarily focus on the U.S. market for the commercialization of its product candidates. The high user awareness of the reference listed drugs in the United States and the intended added value to the U.S. healthcare system are expected to facilitate a fast market adoption of Hyloris' products in the United States.

For its IV Cardiovascular Portfolio, with the exception of Sotalol IV, which is commercialized by a partner, Hyloris intends to (i) create a U.S.-based internal sales and marketing function and (ii) establish a focused direct sales team in the United States. Because more than 70% of cardiologists in the United States are employed by hospitals or health systems<sup>10</sup>, Hyloris believes the prescribers can be addressed in a cost-efficient manner within the less than 6,200 U.S. based hospitals<sup>11</sup>. For non-cardiovascular products, Hyloris plans to adopt a flexible, product-by-product approach, with the aim of maximizing return on investment for each product candidate.

Hyloris' current commercial strategy per product category is summarized below:

<b>IV Cardiovascular Portfolio*</b>	<b>Other Reformulation Portfolio</b>	<b>Established Market Portfolio</b>
<u>United States:</u> Hyloris own commercial team.	<u>United States:</u> Strategic licensing.	<u>The target<sup>12</sup> market:</u> Strategic licensing.
<u>Outside the United States:</u> Strategic licensing.	<u>Outside the United States:</u> Strategic licensing.	

\* Excluding Sotalol IV, which was licensed to a U.S. based partner before Hyloris started the development of its other IV Cardiovascular Portfolio product candidates and therefore had not yet defined its strategy to establish its own commercial team in the United States for its IV Cardiovascular Portfolio.

Hyloris is led by an experienced management team that has a proven track record of building pharmaceutical companies that focus on developing, licensing and commercializing drugs, including generics, new chemical entities (**NCEs**) and reformulations of existing compounds. Hyloris' CEO Mr. Stijn Van Rompay and board member and executive director Mr. Thomas Jacobsen are currently the majority shareholders. The Company's CBDO Edward Maloney is also a shareholder (holding less than 5% of the voting rights). All members of Executive Management hold a participation in Shares and/or warrants, except for Ms. Astrid Heiremans (Acting CFO).

As of 31 March 2020, Hyloris and its subsidiaries had invested over EUR 19.5 million since inception, of which approximately EUR 10.0 million in outsourced and in-house research and development projects, approximately EUR 3.9 million in corporate overhead expenses and approximately EUR 5.6

<sup>10</sup> L. Samuel Wann, Consolidation and hybridization in the health care enterprise: How are cardiologists affected?, Cardiology Today, April 2018

<sup>11</sup> American Hospital Association, 2020 (2018 survey data)

<sup>12</sup> The term target market is used as the established market products are developed for a particular market (currently US/Canada) and cannot be registered elsewhere as both local U.S. and Canadian clinical trials, cannot be used outside these territories.

million in acquisition of intangible assets (which includes the costs in relation to the discontinued products and the development of HY-REF-028, which has been put on hold (see Note 19 to the Consolidated financial Statements)). In addition, on 31 December 2019, all shares in Dermax were contributed in kind into the Issuer (see Section 12.4 (Dermax Acquisition), pursuant to which Hyloris was able to add HY-EMP-016, HY-REF-029, Fusidic Acid Cream and HY-REF-038 to its product candidate portfolio.

## **8.2 MARKET OPPORTUNITY AND REGULATORY FRAMEWORK**

Current FDA-approved pharmaceuticals do not always fully address the needs of patients, hospitals, physicians, payors and other stakeholders in the healthcare system. Hyloris believes these unmet needs represent a large untapped market spanning different therapeutic areas that it can efficiently target by leveraging its expertise in reformulating, and by, in the future, possibly repurposing established pharmaceuticals. Almost all of Hyloris' product candidates are based on molecules that once enjoyed patent protection but for which the relevant patents have expired or will expire in the near future. Hyloris believes there are several different reasons why its product candidates may not have been developed by competitors including, but not limited to, the following reasons: the product candidate could require development and manufacturing technologies which were not available at the time an innovator was looking to develop the product candidate, the product candidate could target a market segment that was not compatible with the commercial portfolio of the innovator, or the product candidate may not have passed the innovator's internal expected market size or profitability requirement hurdle.

In the United States, Hyloris intends to use two regulatory pathways: principally, the 505(b)(2) regulatory pathway and, to a lesser extent, the 505(j), or ANDA, regulatory pathway. See Section 8.9 (Overview of the 505(b)(2) regulatory pathway), 8.19.2 (505(b)(2) New Drug Application) and 8.19.3(505(j) Abbreviated New Drug Application) of this Prospectus for more details.

The 505(b)(2) regulatory pathway is intended for FDA approval of pharmaceutical products that use molecules (pharmacological agents) that have been previously approved by the FDA or have already been proven to be safe and effective (by relying on the literature and physician usage of an FDA-unapproved, or DESI, drug). Products which rely on the 505(b)(2) regulatory pathway are technically NDAs. However, compared to the traditional approval route used for NCEs, which rely on the 505(b)(1) regulatory pathway, the clinical requirements are substantially reduced given that the sponsor may rely on existing safety and efficacy data. Products that may qualify for the 505(b)(2) regulatory pathway include modifications to the dosage form, formulation, strength, route of administration, dosing regimen or indication for use<sup>13</sup>. 505(b)(2) product candidates have the potential advantage of requiring significantly lower development costs and shorter development timelines compared to NCEs. In addition, 505(b)(2) product candidates can be granted exclusivity by the FDA or may enjoy patent protection. Where there are clinical requirements for a 505(b)(2) product candidate, these can vary widely from product to product and may include new clinical trials, bioequivalence trials, pharmacokinetics trials, limited safety and efficacy trials, or less likely full Phase 1 through 3 trials. Unless the FDA has released a relevant guidance document, the clinical requirements for a new product candidate are typically not known until the drug sponsor has a pre-investigational new drug (**IND**)

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<sup>13</sup> [https://www.chiltern.com/wp-content/uploads/Chiltern\\_What-is-505b2\\_11.19.15\\_VF.pdf](https://www.chiltern.com/wp-content/uploads/Chiltern_What-is-505b2_11.19.15_VF.pdf)

meeting with the FDA. Hyloris (or one of its partners) has conducted Pre-IND meetings with respect to most of its 505(b)(2) product candidates set forth in Section 8.10 (Products). See Section 8.9 (Overview of the 505(b)(2) regulatory pathway), 8.19.2 (505(b)(2) New Drug Application) of this Prospectus for more details on the FDA's 505(b)(2) regulatory pathway.

The ANDA regulatory pathway is intended for products that are identical to already approved products (*i.e.*, generics). ANDAs are termed "abbreviated" because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Hyloris intends to use this pathway to pursue the highly complex established market product candidates currently in its pipeline or for reformulations where the only difference to the reference listed drug is the container closure system (*e.g.*, a change from an ampule to a vial or from a vial to prefilled syringe). See Section 8.19.3 (505(j) Abbreviated New Drug Application) of this Prospectus for more details on the FDA's ANDA regulatory pathway.

Hyloris expects to utilize the 505(b)(2) regulatory pathway for all of its current product candidates, except for HY-EMP-016 and HY-REF-038, which both qualify as ANDAs, and for Fusidic Acid Cream, which is intended for Canada. Hyloris typically chooses products it believes meet all requirements to become eligible for the 505(b)(2) regulatory pathway. In the event that the FDA does not agree that a particular product candidate is eligible for use of the 505(b)(2) regulatory pathway, Hyloris will be made aware through the pre-IND meetings, and will be able to make an informed decision as to whether to continue pursuing such product at a relatively early stage in the process.

The table below gives a concise overview of some key differences between the different regulatory pathways (also see Section 8.9 (Overview of the 505(b)(2) regulatory pathway) and Section 8.19 (Regulations)):

	505(b)(2)	505(j) ANDA <sup>1</sup>	505(b)(1)
New chemical entity (NCE)	No	No	Yes
Clinical study requirements	Partial – bridging studies to reference listed drug	Bioavailability/bioequivalence	Full
Development timeline	3-5 years	2-3 years	8-15 years
Regulatory review timeline	10-12 months	15-24 months	10-12 months
Patented	Possible	No	Yes
Market exclusivity potential	3-5 years <sup>2,3</sup>	6 months (first-to-file only)	5 years
Hyloris strategy	Preferred pathway	Opportunistically utilized	Not used

Notes: 1. Generic; 2. Three years awarded for one or more clinical investigations required for approval, five years for drugs or combination of drugs that have previously never been approved by the FDA (often older drugs that were never approved); 3. With orphan designation, the FDA grants a seven-year market exclusivity for that medicine that applies specifically to that designated orphan use, during which an ANDA cannot be marketed. In general, Hyloris does not expect to rely on orphan drug designations but may in specific cases be able to obtain such designation.

Source: Bloomberg Law, T. Sullivan. FDA Under Pressure to Speed up Generic Approvals. 2018



### 8.3 HYLORIS' BUSINESS MODEL

Hyloris generates ideas internally for new product candidate developments and acquires product candidates' rights, typically in an early "conceptual" stage, through its network. In the event that product candidate rights are acquired or in-licensed, milestone payments and profit or sales-related commissions will typically be paid.

As of the date of this Prospectus, a diversified portfolio of two early stage commercial products and 12 product candidates in various stages of development has been established (see Section 8.10 (Products)). The Company aims to initiate four or more new product candidates per year starting in 2021, supported by the proceeds from this Offering (for more information, see Section 8.4.1 (Build a diversified and growing portfolio of proprietary products through the development and licensing of product candidates that address underserved medical needs utilizing the capital and time efficient 505(b)(2) regulatory pathway)). It is expected that once generic drugs (ANDAs) enter the market (See Section 8.9.5 (Market and product exclusivity)), a significant decline of the drug price and market share will result therefrom, depending on the number of ANDAs competing with Hyloris' product. Hyloris' ambition is to advance multiple new product candidates per year, resulting in a steadily growing pipeline to continue its growth, offsetting any erosion due to generic entries.

Hyloris selects, directs, coordinates and monitors external service providers, who perform all operational activities to transform Hyloris product ideas into products that satisfy unmet clinical needs on behalf of Hyloris. This includes contracting an API supplier, pharmaceutical experts able to develop a suitable formulation of the finished dosage form, a GMP approved manufacturing site, a CRO and when required other external advisors. The main advantages of outsourcing activities are development speed and efficiency (partly due to the lower overhead costs and lean management structure), flexibility to choose the most suitable resource and contractors for each development step depending on the required technology, capabilities or pharmaceutical forms. Hyloris is planning to continue to outsource all manufacturing to third party suppliers (See Section 8.15 (Supply of active pharmaceutical ingredients and manufacturing of finished dosage forms)).

Whether Hyloris develops, co-develops or outsources part of the development of its product candidates to third parties, the overall product development always occurs for the account of and under the responsibility (financial, or otherwise) of Hyloris (see Section 8.14 (Research and development, clinical trials)). Hyloris typically expects to spend less than EUR 7 million for the entire development (which, among other things, includes CMC (API procurement, formulation, manufacturing, stability), clinical trials, regulatory work (pre-IND, dossier compilation), and filing fees (if applicable)) of a product candidate.

Hyloris protects its intellectual property rights either by filing and obtaining its own patents or by obtaining exclusive licenses from third parties (see Section 8.17 (Intellectual Property)).

Hyloris intends to market its IV Cardiovascular Portfolio through its own commercial team (with the exception of Sotalol IV, see Section 8.10.2.1E (Sotalol IV's clinical status, regulatory status and commercial strategy)) hence generating sales revenues, with a particular focus on the U.S as its core market. For its other products, Hyloris intends to rely on third parties for commercialization, in which

case, Hyloris will receive license fees and/or sales/profit related payments from such commercial partners (for more information, see Sections 8.4.2 (Flexible go-to-market strategy with a focus on the U.S. market), 8.4.3 (Generate diversified revenue streams with the IV Cardiovascular Portfolio as the foundation for long-term growth) and 8.13 (Commercial Operations)).

## **8.4 STRATEGY**

Hyloris' goal is to become a leading specialty pharmaceutical company through the introduction of innovative pharmaceuticals that add value to the healthcare system (including patients, hospitals, physicians, payors and other stakeholders in the healthcare system) by reformulating well-known pharmaceuticals. Hyloris aims to achieve this goal by implementing the following strategy.

### **8.4.1 BUILD A DIVERSIFIED AND GROWING PORTFOLIO OF PROPRIETARY PRODUCTS THROUGH THE DEVELOPMENT AND LICENSING OF PRODUCT CANDIDATES THAT ADDRESS UNDERSERVED MEDICAL NEEDS UTILIZING THE CAPITAL AND TIME EFFICIENT 505(B)(2) REGULATORY PATHWAY**

Hyloris intends to aggressively pursue value creation through its product development activities. Its 505(b)(2) product candidates are selected based on their ability to address unmet market needs, to be easily understood, to get patent protection and their substantial commercial potential. Hyloris may also selectively in-license or acquire individual development-stage product candidates or commercial products to further grow its portfolio provided they also meet Hyloris' criteria including a product candidate development cost of less than EUR 7 million (which, among other things, includes CMC (API procurement, formulation, manufacturing, stability), clinical trials, regulatory work (pre-IND, dossier compilation), and filing fees (if applicable)), a development timeline of less than 5 years (with an additional 2 years for registration), a satisfactory expected return on investment and technical development feasibility.

Hyloris' ambition is to advance multiple new product candidates per year, resulting in a steadily growing pipeline distributed across various development and commercialization stages, with a particular focus on IV cardiovascular opportunities going forward. It is the Company's preference to develop multiple lower-cost product candidates, avoiding a concentrated specific product related company risk, as it does not believe the development cost is necessarily correlated with its return on investment.

In line with this approach, Hyloris intends to continue focusing on products that are eligible for the 505(b)(2) regulatory pathway, which allows the Company to lower the risks, costs and time necessary to develop its products compared to products developed under the traditional 505(b)(1) regulatory pathway. Hyloris also believes that it will be possible to protect the majority of its product candidates through patents and therefore expects a period of exclusivity with respect to most of them (see Section 8.9.5 (Patents and market exclusivity)).

For all of its 505(b)(2) product candidates, Hyloris has a long-term strategy to register and protect its intellectual property in the United States in order to maximize their commercial life-span. Outside the United States, Hyloris will seek to register patents when it believes such registration will add value. As of the date of this Prospectus, Hyloris has rights to 13 patents or patent families (including pending patent applications), as owner, co-owner and/or licensee (see also Section 8.17 (Intellectual Property)).

Finally, the high user awareness of the reference listed drugs and the intended added value to the healthcare system are also expected to facilitate a fast market adoption of Hyloris' products.

#### **8.4.2 FLEXIBLE GO-TO-MARKET STRATEGY WITH A FOCUS ON THE U.S. MARKET**

Hyloris intends to recruit an experienced staff with a long standing track record in launching and commercializing specialty products to manage its U.S. operations for its IV Cardiovascular Portfolio and (i) create an internal sales and marketing team and (ii) establish a focused direct sales team in the United States, as it believes the prescribers can be addressed in a cost-efficient manner as they are typically grouped in specialized care facilities such as hospitals.

There are currently 6,146 hospitals<sup>14</sup> and less than 33,000 cardiologists in the United States<sup>15</sup>, with more than 70% of cardiologists employed by hospitals or health systems<sup>16</sup>. Hyloris will be commercially targeting subsegments for the promotion of its products such as an estimated 3,200 electrophysiologists<sup>17</sup>. The sales force is expected to be established closer to the approval of Hyloris' first in-licensed IV cardiovascular product candidate, Dofetilide IV, which is currently expected to be commercially launched in 2023.

For its other product candidates, Hyloris intends to remain flexible and assess the optimal commercialization strategy on a case-by-case basis (e.g., through selectively out-licensing to commercialization partners) in an effort to maximize its return on investment.

For its existing commercial products, Sotalol IV and Maxigesic<sup>®</sup> IV, as well as HY-EMP-016, the Company has already entered into arrangements with strategic partners for marketing and/or selling those products (See section 8.12 (Partnerships and Collaborations) of this Prospectus for more details on existing commercial partners).

For its portfolio of 505(b)(2) product candidates, Hyloris intends to also pursue commercial opportunities outside the United States (where applicable) through agreements with licensees or strategic partners, relying on the data generated for the purpose of submitting a 505(b)(2) application in the United States.

For the product candidates relying on the ANDA regulatory pathway, approval outside the target market is restricted because of requirement for local clinical trials or contractual arrangements. Therefore, no sales are expected outside the United States for HY-REF-038 and HY-EMP-016, and outside Canada for Fusidic Acid Cream.

For Maxigesic<sup>®</sup> IV, Hyloris' partner, AFT Pharmaceuticals has licensed the product to third parties covering more than 80 countries and submitted the registration package to the authorities in 18 EU countries, South Africa, South Korea and Israel. AFT Pharmaceuticals also obtained approval in three countries (Australia, New Zealand and the United Arab Emirates) and has launched Maxigesic<sup>®</sup> IV in

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<sup>14</sup> American Hospital Association, 2020 (2018 survey data)

<sup>15</sup> Statista.com, 2019

<sup>16</sup> L. Samuel Wann, Consolidation and hybridization in the health care enterprise: How are cardiologists affected?, *Cardiology Today*, April 2018

<sup>17</sup> According to the American Board of Internal Medicine (on June 1 2019) it had certified 3.237 candidates in clinical cardiac electrophysiology of which 2.593 were valid certificates. The valid certificates exclude those are known to have deceased and /or those whose certificates are no longer valid (Physicians must meet requirements, ie pass an assessment, earn points, and provide attestation if applicable)

Australia and New Zealand in June 2020 and is expected to launch Maxigesic® IV in the United Arab Emirates in the summer of 2020. Hyloris is entitled to a share on any revenues, such as license fees, royalties, milestone payments (or other net considerations) received by AFT Pharmaceuticals, excluding, however, any profit generated from Australia and New Zealand (as contractually agreed with AFT Pharmaceuticals).

#### **8.4.3 GENERATE DIVERSIFIED REVENUE STREAMS WITH THE IV CARDIOVASCULAR PORTFOLIO AS THE FOUNDATION FOR LONG-TERM GROWTH**

Hyloris could, by way of a positive and best-case scenario, based on its current product candidate portfolio (and on the hypothesis that its portfolio would remain unchanged) achieve operational profitability (on EBIT level) at the earliest by late 2022. Until such time, in view of increasing costs related to the further development of its current product candidate portfolio that will not be offset by its revenues, Hyloris is expected to continue to incur increasing losses. Hyloris expects that sales of Maxigesic® IV (although the full roll out of this product in all target countries is expected to take several years) and Sotalol IV will be the primary drivers of short term revenue growth until additional products are launched but are not expected to independently generate substantial revenues. HY-EMP-016 and Tranexamic Acid RTU (expected to launch in 2021) should also contribute. In the longer term, Hyloris intends to support its growth and increase its profitability by further rolling out and launching its IV Cardiovascular Portfolio. Hyloris expects to complete the development (excluding FDA regulatory review timelines) of the current portfolio by or before Q1 2024. Assuming only the 5,000,000 initially offered New Shares (*i.e.*, excluding the exercise in full or in part of the Increase Option) are subscribed for, which would amount to EUR 49,789,704 net proceeds from the Offering, together with the net proceeds from the Convertible Bonds of EUR 7,650,000<sup>18</sup>, will be sufficient for the completion of the development of the current product portfolio, even without generating additional cash from its current operations (see Section 6.5 (Reasons for the Offering and use of proceeds) of this Prospectus for additional details).

For its IV Cardiovascular Portfolio, Hyloris expects to establish its commercial team and capabilities required to promote this portfolio in the United States (with exception of Sotalol IV, see Section 8.10.2.1E (Sotalol IV's clinical status, regulatory status and commercial strategy)).

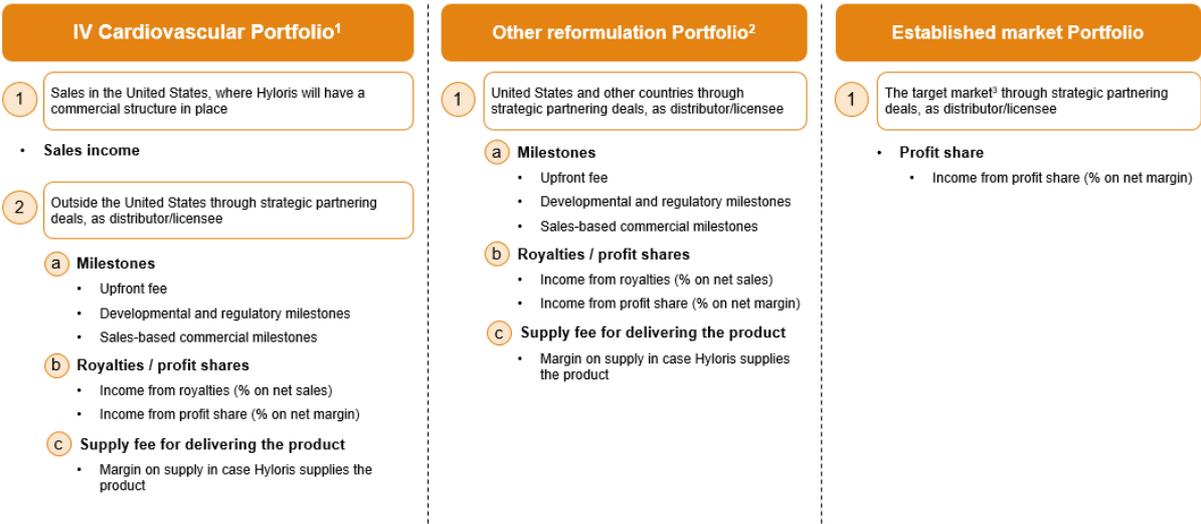
For its Other Reformulation Portfolio, Hyloris intends to out-license its products to commercial partners. Hyloris expects these commercial agreements will lead to milestone payments, royalty payments and product supply related payments from its commercial partners. The margin that Hyloris will retain will be dependent on a large number of variables including the (absence of) financial milestones payments, the extent of the required marketing and sales activities of the partner and its commercial strength, development risk sharing, time to completion, market evolution, overall product opportunity and the in-market product sales price. Hyloris is expecting to retain a large minority or small majority of the net product margin (being the gross profit after deduction of distribution and manufacturing related expenses, insurance, transport etc.) realized by its commercial partners. If significant development risk sharing occurs, meaningful development milestones will be paid, or substantial product promotion is required, the commercial partner will likely retain more of the product margin.

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<sup>18</sup> This is the aggregate nominal amount of the Convertible Bonds (EUR 15,150,000) minus the repaid part of the shareholder loans after the reporting period (*i.e.*, 7.5 million, see Note 19 to the condensed consolidated financial statements).

For the product candidates in its Established Market Portfolio, Hyloris expects to retain the majority of the product margin realized, due to the fact that generics do not require active promotion because, in the United States and Canada, there are only a limited number of wholesalers (buyers) that have a strong presence and can assign market share. In addition, Hyloris generally does not target upfront milestone payments from its commercial partners as Hyloris prefers to retain more product sales related income with respect to these product candidates.

Hyloris' various income streams are expected to be as follows:



Notes: 1. Excluding Sotalol IV, which was licensed to AFT Pharmaceuticals before Hyloris had developed its other IV Cardiovascular Portfolio product candidates and therefore had not yet defined its strategy to establish its own commercial team in the United States for its IV Cardiovascular Portfolio; 2. For Atomoxetine, Hyloris only holds rights in the United States, so there will be no partnering outside the United States; 3. The term target market is used as the established market products are developed for a particular market (currently US/Canada) and cannot be registered elsewhere as both local U.S. and Canadian clinical trials, cannot be used outside these territories.

\* Excluding Sotalol IV, which was licensed to AltaThera before Hyloris had developed its other IV Cardiovascular Portfolio product candidates and therefore had not yet defined its strategy to establish its own commercial team in the United States for its IV Cardiovascular Portfolio.

\*\* For Atomoxetine, Hyloris only holds rights in the United States, so there will be no partnering outside the United States.

Currently, the IV Cardiovascular Portfolio has one commercialized product. Additional product launches in this category are expected to start in 2023. Hyloris expects that the sales income generated by the IV Cardiovascular Portfolio will exceed the income of the Other Reformulation Portfolio in the course of 2025. From 2025 on, after its additional product launches, the IV Cardiovascular Portfolio sales are expected to be the driver for overall sales growth. The Established Market Portfolio category is the

smallest category and it is expected that its share in the Hyloris income will evolve to a low single digit percentage contribution.

It is expected that once generic drugs (ANDAs) enter the market (See Section 8.9.5: market and product exclusivity), a significant decline of the drug price and market share will result therefrom, depending on the number of ANDAs competing with Hyloris' product. Hyloris' ambition is to advance multiple new product candidates per year, resulting in a steadily growing pipeline to continue its growth, offsetting any erosion due to generic entries.

Hyloris' first commercial products (Sotalol IV, Maxigesic® IV and HY-EMP-016) will generate royalty-based, milestone-based or profit split-based income. It is expected that other products will be procured and sold directly or indirectly by Hyloris and generate supply related income.

For further information about sales and margin contribution: see Section 9.2.1(Revenue) and Section 9.2.2 (Cost of sales).

## **8.5 COMPETITIVE LANDSCAPE**

Hyloris is developing products for different therapeutic areas. For each of its products, it will often compete with (i) the approved drug that serves as a reference for the Hyloris product candidate, (ii) other existing products (branded and generic) in the same therapeutic category and (iii) potential new products or therapies currently under development.

The Hyloris product portfolio almost exclusively consists of products (candidates) of which the reference product is no longer patent protected or commercially promoted but still enjoys established sales and use. Notwithstanding most of the molecules of Hyloris' current product candidates have been out of patent for an extended period of time and Hyloris, to the best of its knowledge, is not aware of any other company that is currently actively working on the development of any of its current product candidates, it cannot be excluded that competing developments could occur, especially when taking into account that there is limited visibility on the pipeline of potential competitors (including generics).

Although Hyloris believes it will obtain a sufficient level of patent protection for its 505(b)(2) product candidates, it is expected that generic products will become available after the patent protection expires or if patents are invalidated or a settlement is reached due to generic companies challenging the validity of the patent (see Section 8.9.5 (Patents and market exclusivity)). Hyloris' patents will typically be on formulations, indications, or processes and not on the molecule itself. As 505(b)(1) products typically also have patents related to the active ingredient, they normally enjoy a stronger protection compared to 505(b)(2) products. Therefore, 505(b)(2) products can face earlier generic competition than 505(b)(1) products.

It is expected that, once generic drugs enter the market, a significant decline of the drug price and market share will result therefrom, depending on the number of ANDAs competing with Hyloris' product. Hyloris' ambition is to advance multiple new product candidates per year, resulting in a steadily growing pipeline to continue its growth and also offsetting any erosion due to generic entries.

For the product candidates in its Established Market Portfolio (high barrier generics), Hyloris believes there is a high barrier to entry, due to the requirements for clinical trials and, hence, does not expect severe competition (see section 8.10.4 (The Established Market Portfolio (high-barrier generics))).

## **8.6 STRENGTHS**

Hyloris believes that its business is built upon the following key strengths:

### **8.6.1 *IDEA GENERATOR ENABLING THE CONTINUOUS IDENTIFICATION OF NEW PRODUCT OPPORTUNITIES THAT ADDRESS UNDERSERVED MEDICAL NEEDS***

Hyloris believes it has a distinct ability to identify underserved medical needs and new product candidates based on its management's extensive knowledge and understanding of the pharmaceutical market, its wide network of contacts and its continuous effort to analyze how drugs are used, prescribed and labelled in the United States. Over the course of the last 20 or more years, Hyloris' management team has, through various roles in different companies, been involved in the development of more than 80 products that have been approved by various regulatory authorities and executed more than 250 licensing transactions of which a considerable number have led to approved products.

Furthermore, the Company has regular discussions on how to best address unmet medical needs with its network of U.S. and EU based key opinion leaders, healthcare professionals and physicians, who occasionally also become a source for new ideas and who ensure Hyloris is kept up to date on market trends.

During the last three years, Hyloris has initiated the development of ten of its product candidates. Hyloris is continuously evaluating multiple ideas in various therapeutic areas in order to maintain a consistent pipeline of product candidates. The Company aims to initiate four or more new product candidates per year starting in 2021, with the intention to accelerate, supported by the proceeds from this Offering.

### **8.6.2 *STRONG PRODUCT DEVELOPMENT ENGINE THAT REFORMULATES AND BRINGS PRODUCT CANDIDATES TO THE MARKET IN A CAPITAL EFFICIENT MANNER***

Hyloris is confident in its ability to bring its product candidates to market in an efficient fashion by relying on strong reformulation development capabilities internally and externally, its extensive product development experience, significant clinical development experience and a robust network of reliable, high quality subcontractors.

In addition, Hyloris believes in the importance of fast execution in a capital efficient manner. The executive team has considerable experience in negotiating costs for all services required for pharmaceutical development (see also Section 10.4.4 (Composition of the Executive Management)). Hyloris often uses European based CDOs, CDMOs, CMOs (such as SM Farmaceutici in Italy and Basic Pharma Manufacturing in The Netherlands) and CROs, that typically offer cost advantages compared to U.S. based service providers.

Hyloris believes that the combination of management's extensive experience and focus on cost minimization allows it to maximize the return on investment on each of its development candidates.

### **8.6.3 FOCUS ON TIME AND CAPITAL EFFICIENT 505(B)(2) REGULATORY PATHWAY SIGNIFICANTLY LOWERS THE RISKS AND COSTS COMPARED TO TRADITIONAL NEW DRUG APPLICATIONS**

The 505(b)(2) regulatory pathway is intended for molecules that have previously been approved by the FDA or have already been proven to be safe and effective outside of the United States. A 505(b)(2) product is typically a reformulation of a known molecule in a new strength or dosage form. The potential advantages offered by products eligible for the 505(b)(2) regulatory pathway include:

- Lower formulation risk versus 505(b)(1) pathway: Working with well-known molecules reduces certain risks in the formulation phase. The molecules will be well described in literature, not only from a clinical point of view, but also from a chemical point of view. Developing new formulations of drugs that are extensively described and documented reduces potential for unexpected negative formulation issues.
- Lower clinical and regulatory risk versus 505(b)(1) pathway: Reformulating approved and marketed molecules will typically have higher probability of clinical success and regulatory approval compared to developing NCEs. In order to rely on existing information of the approved product, the 505(b)(2) pathway requires the sponsor to establish a scientific or clinical bridge from its product candidate to the reference pharmaceutical. This process is frequently fulfilled through a Phase 1 bridging study. In contrast, a traditional 505(b)(1) or NCE application requires the sponsor to conduct all studies required for approval<sup>19</sup>. Due to this, the attrition rate of 505(b)(2) product candidates is substantially lower than for NCEs. All Hyloris' products candidates require less than three clinical phases.
- Shorter development timelines versus 505(b)(1) pathway: Developing a product through the 505(b)(2) regulatory pathway is typically much faster than the traditional 505(b)(1) regulatory pathway. Product candidates developed pursuant to the 505(b)(2) pathway tend to take 3 to 5 years compared to 8 to 15 years for 505(b)(1)<sup>20</sup>.
- Relatively lower cost versus 505(b)(1) pathway: Given the reduced clinical requirements associated with the 505(b)(2) pathway, the investments to complete development programs have the potential to be substantially lower than those needed for 505(b)(1) candidates. Hyloris typically expects to spend less than EUR 7 million for the entire development (which, among other things, includes CMC (API procurement, formulation, manufacturing, stability), clinical trials, regulatory work (pre-IND, dossier compilation), and filing fees (if applicable)) of a product candidate.
- Lower commercial risk versus 505(b)(1) pathway: Since 505(b)(2) products reference well-established drugs, there is already a high user awareness amongst physicians and payers. Hyloris aims to add value to the healthcare system with an easily understandable product that addresses a clear market need. Combined, these factors can potentially result in fast

<sup>19</sup> Back To Basics: 505(B)(2) FAQs Part 2: Clinical and Nonclinical Studies, [www.camargopharma.com, https://camargopharma.com/resources/blog/back-to-basics-505b2-faqs-part-2-clinical-and-nonclinical-studies](https://camargopharma.com/resources/blog/back-to-basics-505b2-faqs-part-2-clinical-and-nonclinical-studies)

<sup>20</sup> <https://camargopharma.com/assets/general/whitepapers/camargo-white-paper-generics-companies.pdf>.

market adoption. A broad product candidate portfolio provides mitigation to product specific dependency.

- Protection from competition: Notwithstanding that NCE patents are usually considered as offering superior patent protection and although 505(b)(2) regulatory pathway product candidates cannot patent the chemical entity, which 505(b)(1) regulatory pathway products typically can, protection from competition can still be obtained when utilizing the 505(b)(2) regulatory pathway. Hyloris intends to file other types of patents (such as formulation patents, process patents related to the manufacturing or method of use patents) and list these in the FDA Orange Book (see Section 8.19.2 (Section 505(b)(2) New Drug Application) for each of its 505(b)(2) product candidates. 505(b)(2) products may also gain market exclusivity for periods ranging from three to five years (seven, if granted an orphan drug designation) (reference is made to Section 8.9.5 (505(b)(2) Market Exclusivity) for more details). These protections will help protect Hyloris' product candidates from generic competition.

In conclusion, by mainly focusing on the 505(b)(2) regulatory pathway, Hyloris believes it will be able to significantly reduce the time, risks and costs in bringing its products and product candidates to the market, compared to products using the traditional 505(b)(1) regulatory pathway.

#### **8.6.4 BROAD AND DIVERSE PROPRIETARY PORTFOLIO OF PRODUCTS AND PRODUCT CANDIDATES PRESENTING POTENTIAL FOR RAPID SALES GROWTH**

With two early stage commercial products and 12 product candidates in various stages of development, Hyloris believes its portfolio offers a solid foundation to drive sales in the future, with its cornerstone IV Cardiovascular Portfolio providing a basis for sustainable long-term growth. The high user awareness of the reference listed drugs and the intended added value to the healthcare system are also expected to facilitate a fast market adoption of Hyloris' products.

In addition to the risk diversification benefits provided by its multi-product strategy, the Company expects its portfolio of products to enable a rapid sales ramp. Hyloris could, by way of a positive and best-case scenario, based on its current product development portfolio (and on the hypothesis that its portfolio would remain unchanged) achieve operational profitability (on EBIT level) at the earliest by late 2022. Until such time, in view of increasing costs related to the further development of its current product candidate portfolio that will not be offset by its revenues, Hyloris is expected to continue to incur increasing losses.

For all of its current 505(b)(2) product candidates, the Company believes it can obtain patent protection or market exclusivity (see Section 8.9.5 (Patents and market exclusivity)). The Company plans to continue submitting additional patents as it gains more formulation knowledge on the individual product candidates during the development phase. The Company owns, co-owns or has in-licensed the intellectual property of its product candidates. As of the date of this Prospectus, Hyloris has rights to 13 patents or patent families (including pending patent applications), as owner, co-owner and/or licensee (see also Section 8.17 (Intellectual Property) for more information on these patent applications and their expiry dates).

Hyloris, when it has the possibility to do so, protects its intellectual property rights by actively pursuing patent protection for its product candidates, it being understood that it will only pursue such protection in jurisdictions in which it makes commercial sense. The patent could typically cover the indication or the formulation and can potentially block the approval of a generic version during the lifetime of its patent protection (up to 20 years), it being understood that most patent litigation cases in the United States are resolved pursuant to a settlement agreement which results in an earlier launch of the generic competitor (see Section 8.9.5 (Patent and market exclusivity)).

#### **8.6.5 MANAGEMENT WITH SIGNIFICANT TRACK RECORD OF SUCCESS**

Hyloris' executive team possesses a wealth of experience and knowledge in the fields of drug identification and development. Hyloris' management team combines more than 100 years of experience in managing and growing pharma companies that develop drugs and bring them to the market and has built-up a substantial network of advisors, consultants and key opinion leaders over the years. It also benefits from extensive regulatory and product development experience, including some experience in the utilization of the 505(b)(2) regulatory pathway.

Since 1999, Mr. Stijn Van Rompay (co-founder, board member and CEO) has co-founded, managed and successfully exited several pharmaceutical companies including Docpharma (listed in 2001 on Euronext Brussels and sold to Matrix Laboratories (now wholly owned by Mylan) in June 2005 for a total consideration of EUR 218 million<sup>21</sup>), Uteron Pharma (sold to Watson Pharmaceuticals in 2013 for USD 150 million in cash up front, and up to USD 155 million in potential future milestone payments. In addition, the Uteron Pharma entity that was purchased back, was sold to Mithra Pharmaceuticals in 2015 for a total consideration of over EUR 250 million<sup>22</sup>), Novalon (sold a 50% stake to Mithra Pharmaceuticals in 2016 for a total consideration of EUR 9.4 million<sup>23</sup>) and Alter Pharma (sold in 2017 to the Riverside Company with a re-investment by most shareholders). Each transaction generated an attractive ROI and created substantial additional shareholder value. He also served with Mylan and Allergan. Since 2001, Mr. Stijn Van Rompay also has been involved in the acquisition or sale of over 15 companies outside the Hyloris group. Mr. Stijn Van Rompay does not have other executive engagements.

Mr. Thomas Jacobsen (co-founder, executive director) has a long track-record in business development, product development and licensing activities, with more than 200 licensing transactions closed over the last 20 years both for Alternova, Docpharma and Alter Pharma. In addition, Mr. Jacobsen was a co-founder of Alter Pharma (sold in 2017 to the Riverside Company with a re-investment by most shareholders) and was one of the founders of Growth House, a Danish based pharma company which was sold to Orifarm in 2015. Mr. Thomas Jacobsen currently holds an executive position within the Alter Pharma group.

Mr. Edward Maloney (CBDO) has built-up a long track record and experience in business development, product development and licensing activities during his 35-year career. He has managed the development of more than 50 products (including 505(b)(2)s) and executed more than 75 licensing

<sup>21</sup> <https://www.financialexpress.com/archive/matrix-buys-belgian-co-for-263-m-in-indias-largest-pharma-deal/143103/>

<sup>22</sup> <https://www.sec.gov/Archives/edgar/data/884629/000119312513023044/d472289dex21.htm>; <https://investors.mithra.com/wp-content/uploads/2019/10/2019-10-01-Earn-out-EN.pdf>

<sup>23</sup> <https://investors.mithra.com/wp-content/uploads/2015/12/2015-12-08-CP-NOVALON-ALL-FINAL-EN.pdf>

transactions while at Paddock Labs and Alter Pharma. Mr. Edward Maloney does not have other executive engagements.

For more information on the curriculum vitae of the Executive Management, reference is made to Section 10.4.4 (Composition of the Executive Management).

## 8.7 BUSINESS HISTORY

The table below sets forth the key milestones in Hyloris' history, up to the date of this Prospectus.

Year	Description
2012	<p>Hyloris Pharmaceuticals is founded in June of 2012 by Mr. Stijn Van Rompay and Mr. Thomas Jacobsen, as Everbright s.à r.l.", registered in Luxembourg. See Section 7.1.3 (Incorporation) for more information.</p> <p>Hyloris Pharmaceuticals (at that time named Everbright) signs a worldwide and exclusive co-operation and profit sharing agreement with AFT Pharmaceuticals limited, a New Zealand based pharmaceutical company, regarding Maxigesic® IV, a patented non-opioid analgesic. See Section 8.12.6.2 (AFT Pharmaceuticals – Development collaboration agreement) for more information.</p>
2013	<p>Hyloris Pharmaceuticals (at that time named Everbright) establishes Hyloris Developments (at that time named Hyloris Pharmaceuticals). Through this subsidiary, Hyloris was able to benefit from access to the Belgian market for pharma developments, which is known for its dynamic university spin-offs, highly trained and educated work force, experienced management and network of specialized investors. See Section 7.2.1 (Hyloris Developments) for more information on Hyloris Developments.</p>
2014	<p>Hyloris Developments (at that time named Hyloris Pharmaceuticals) signs an asset purchase agreement with Academic Pharmaceuticals Inc. to acquire their approved Sotalol IV product.</p> <p>Hyloris Developments signs an agreement with AltaThera Pharmaceuticals LLC, a Chicago based specialty pharmaceutical company, regarding Sotalol IV, allowing AltaThera to exclusively commercialize the product in the United States and setting out certain arrangements in the event of further development<sup>24</sup>.</p> <p>See Section 8.12.1 (Sotalol IV) for more information on these agreements.</p>
2015	<p>Hyloris Developments (at that time named Hyloris Pharmaceuticals) signs a product development and commercialization collaboration agreement with Paddock laboratories LLC (subsidiary of Perrigo), with the purpose to cooperate in the development and commercial manufacturing of HY-EMP-016 in the United States. See Section 8.12.13.2 (Paddock</p>

<sup>24</sup> AltaThera has subcontracted the development work to Academic Pharmaceuticals.

	<p>Laboratories - Product Development and Commercialization Agreement) for more information.</p> <p>Sotalol IV is marketed by AltaThera in the United States with the initial (orphan) indication (IV for patients who are unable to take oral sotalol). A label extension for Sotalol IV to include the indication of the rapid loading of patients starting on sotalol, was submitted to the FDA in 2018.</p>
2017	<p>The Belgian Seat Transfer takes place (Everbright changes its name to Hyloris Pharmaceuticals) and the (Belgian) subsidiary, Hyloris Pharmaceuticals, changes its name to Hyloris Developments. See Section 7.1.3 (Incorporation) for more information.</p> <p>Completion of first Phase 3 trial of Maxigesic® IV by AFT Pharmaceuticals in June 2017.</p> <p>Hyloris Developments signs an asset purchase agreement with Generic Specialty Pharma (a subsidiary of the Alter Pharma group<sup>25</sup>) to acquire all rights to HY-REF-028 a product candidate, the development of which was later (in 2019) put on hold because Hyloris ultimately decided to focus on its other product candidates as these showed higher potential, it being understood that Hyloris may restart the project at a later date.</p>
2018	<p>Hyloris Pharmaceuticals acquires RTU Pharma SA. At the time of the acquisition, RTU Pharma was actively working on Tranexamic Acid IV. See Section 7.2.2 (RTU Pharma) for more information on RTU Pharma, and Section 12.3 (RTU Pharma Acquisition) for more information on the acquisition of RTU Pharma.</p> <p>Hyloris Developments and Nordic Specialty Pharma (NSP) (a subsidiary of the Alter Pharma group<sup>26</sup>) enter into an “Asset Purchase and Development Agreement”, whereby NSP assigned to Hyloris Developments its rights and interests relating to HY-REF-075 for the United States market. See Section 8.12.12 (HY-REF-075).</p>
2019	<p>Dermax signs a development agreement with Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group<sup>27</sup>) regarding the development of HY-REF-038. See Section 12.6 (Business Agreements) for more information.</p> <p>Hyloris Pharmaceuticals’ partner receives approval from the Australian authorities TGA, to commercialize Maxigesic® IV in Australia and from the New Zealand authorities Medsafe, to commercialize Maxigesic® IV in New Zealand.<sup>28</sup></p> <p>Dermax signs a license agreement with Stasisport NV (a subsidiary of the Alter Pharma group<sup>29</sup>) pursuant to which Dermax is granted a personal, sub-licensable and exclusive right to use all available development data and registration documents concerning Fusidic Acid</p>

<sup>25</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

<sup>26</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

<sup>27</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

<sup>28</sup> Hyloris will however not receive any part of the profits generated from Australia and New Zealand (see also Section 8.12.6.2 (AFT Pharmaceuticals – Development collaboration agreement)).

<sup>29</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

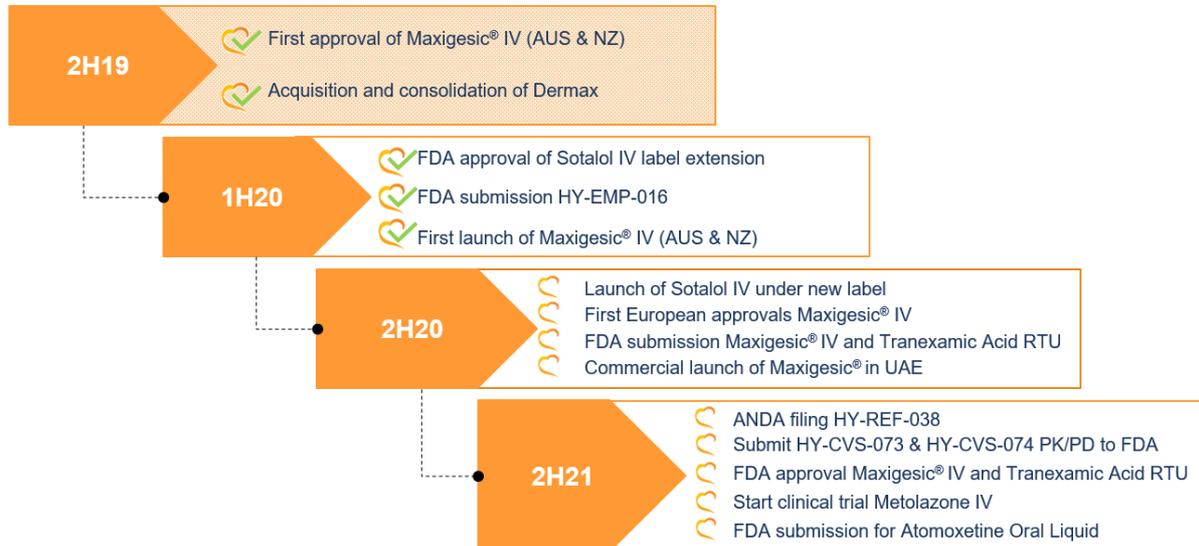
	<p>Cream, in order to obtain (one or multiple) marketing authorizations for Fusidic Acid Cream in Canada, and to subsequently market, sell and distribute Fusidic Acid Cream in that territory. See Section 8.12.14 (Fusidic Acid Cream) for more information.</p> <p>Hyloris Developments signs binding terms sheets with Academic Pharmaceuticals Inc. regarding the research and development of Metolazone IV, Dofetilide IV, HY-CVS-073 and HY-CVS-074 respectively. See Section 8.12.3 (Metolazone IV), Section 8.12.2 (Dofetilide IV), Section 8.12.4 (HY-CVS-073) and Section 8.12.5 (HY-CVS-074) for more information on these binding term sheets.</p> <p>Hyloris Developments and Tahoe Pharmaceuticals enter into a license agreement pursuant to which Tahoe Pharmaceuticals grants Hyloris Developments an exclusive, perpetual and irrevocable license to manufacture, register, sell, offer, import and/or otherwise claim a formulation of the product Atomoxetine Oral Liquid in the United States. See Section 8.12.10 (Atomoxetine Oral Liquid) for more information.</p> <p>The development of HY-REF-028, for which all (intellectual property) rights, title and interests had been acquired from Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group<sup>30</sup>) on 25 August 2017 was put on hold, because Hyloris ultimately decided to focus on its other product candidates as these showed higher potential, it being understood that Hyloris may restart the project at a later date (see also Section 12.6 (Business Agreements) and note 19 to the Financial Statements).</p> <p>Hyloris Pharmaceuticals acquires Dermax SA, a company initially specialized in the development of dermatological formulations. At the time of the acquisition, Dermax was actively working on HY-EMP-016, Fusidic Acid Cream and HY-REF-038. See Section 7.2.3 (Dermax) for more information on Dermax and Section 12.4 (Dermax Acquisition) for more information on the acquisition of Dermax.</p>
2020	<p>FDA approves the Sotalol IV label extension to include the indication of the rapid loading of patients starting on sotalol.</p> <p>Hyloris' partner Perrigo submits the ANDA for HY-EMP-016 to the FDA.</p> <p>Hyloris Pharmaceuticals' partner AFT Pharmaceuticals launched Maxigesic<sup>®</sup> IV in Australia and New Zealand in June 2020<sup>31</sup>.</p>

<sup>30</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

<sup>31</sup> Hyloris will however not receive any part of the profits generated from Australia and New Zealand (see also Section 8.12.6.2 (AFT Pharmaceuticals – Development collaboration agreement)).

## 8.8 RECENT & ANTICIPATED UPCOMING BUSINESS EVENTS

The below chart provides an overview of the recent and anticipated upcoming business events:

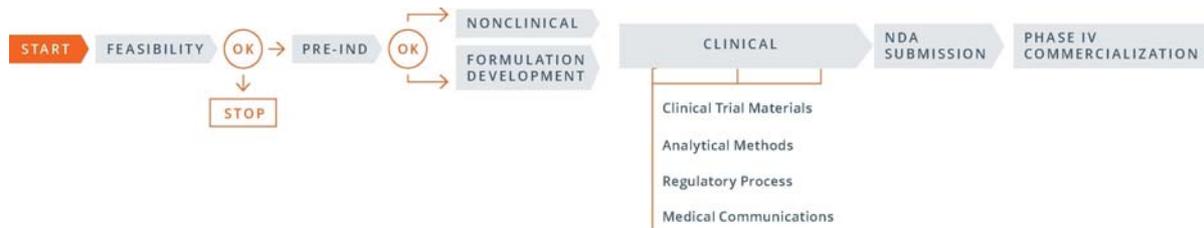


## 8.9 OVERVIEW OF THE 505(B)(2) REGULATORY PATHWAY

See section 8.19 (Regulations) for more information on various regulatory pathways.

### 8.9.1 505(B)(2) DEVELOPMENT PROCESS

The chart below is a depiction of the steps generally required to be taken before a new drug can be marketed in the United States:



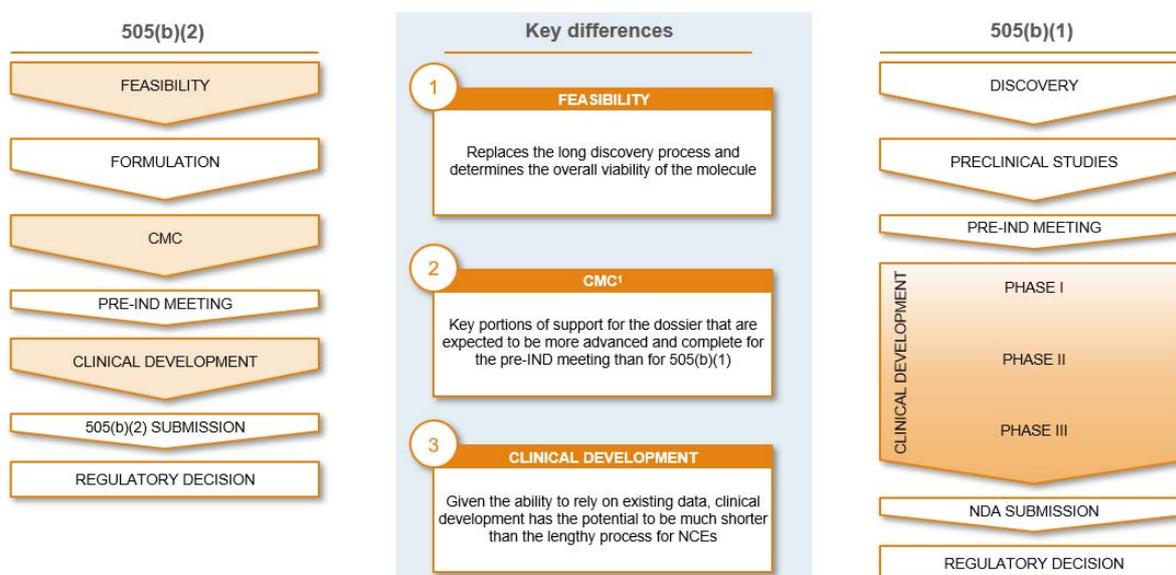
Source: Camargo (amended)

After product candidate identification a pre-development assessment (feasibility) occurs. Typically, the medical, scientific, regulatory and commercial viability are substantiated (at least initially) before moving forward. The 505(b)(2) development process usually begins with the pre-IND meeting with the FDA, then moves to formulation development (and non-clinical studies, if necessary) and then to the IND filing. In proposing a 505(b)(2) development strategy in a pre-IND meeting, the objective is to gain FDA input and concurrence with the studies, with the chemistry, manufacturing, and controls (**CMC**) strategy and with clinical research plans in a way that minimizes the number of new studies required.

A product filing typically contains CMC information on the active ingredient and the final product. As the active ingredient has been previously approved a 505(b)(2) applicant can refer to a drug master file (**DMF**) which is a confidential, detailed document submitted by active pharmaceutical ingredient manufacturers to the FDA.

Since the 505(b)(2) pathway allows the use of public data or the FDA's previous findings in lieu of novel trial data, some development programs may conduct bridging studies that preclude the need for nonclinical or clinical studies, or both. For a 505(b)(2) product, the clinical trial materials for Phase 1 studies (often demonstrations of clinical bioequivalence) must be representative of the commercial manufacturing process, including packaging. In general, the three stability batches that will be used for shelf-life determinations are also prepared at this time. Typically, a product stability of 12 months is required before submission. Clinical studies can often be initiated simultaneously and developed in parallel, significantly shortening the overall time to market.

The table below sets forth a concise overview of the differences in the development process between the 505(b)(2) regulatory pathway and the 505(b)(1) regulatory pathway:



1. As a 505(b)(2) needs to prove equivalence with the reference drug, the CMC work in relation to a 505(b)(2) involves more work  
Source: FDA, Camargo

### 8.9.2 INCREASING USE OF THE 505(B)(2) REGULATORY PATHWAY

The number of product approvals relying on the 505(b)(2) regulatory pathway has risen in recent years. As shown in the figure below, the FDA approved 644 products relying on the 505(b)(2) regulatory pathway between 2003 and 2018, of which 310 (ca. 48%) approvals were granted from 2013 through 2018, with a significant increase in the amount of approvals in 2017 and a record number of approvals in 2018.

Figure 1: 505(b)(2) approvals 2003 – 2019.



\*Number to date; however, review documents are not yet available to confirm the regulatory pathway of some approved NDAs  
 Source: Camargo

Between 1984 (when the 505(b)(2) regulatory pathway was created) and 2016, more than 60% percent of applicants were associated with only a single 505(b)(2) application and approximately 92% percent of applicants were associated with four or less 505(b)(2) applications<sup>32</sup>. 9% of the applicants relied in part on existing data of a sponsor that was the same as the 505(b)(2) applicant (in addition to relying on the data of at least one unrelated third party), while 69% relied on existing data only of unrelated third parties. For the remaining products, the reference product information is not always identifiable, for example, because the 505(b)(2) application relied on published literature.

The vast majority of companies that obtained FDA approval of a 505(b)(2) application in 2018 can be classified in two main groups: specialty pharma companies (such as Pacira BioSciences, Heron Therapeutics, Eagle Pharmaceuticals) and generics companies (such as Mylan, Sandoz, Teva, Cipla or Aurobindo) each with 41% of the approvals. Of the remaining companies, 4% can be categorized as “big pharma”, 3% as combined (“big pharma” and other such as Novartis) and 11% as other.<sup>33</sup>

Hyloris believes this breakdown is reflective of the fact that, while use of the 505(b)(2) regulatory pathway has increased (and is expected to increase further), there are relatively few companies who focus solely on pursuing a wide portfolio of 505(b)(2) products. Many applicants focus on ANDA or 505(b)(1) applications or focus on developing products in a very targeted therapeutic field. Hyloris believes that several 505(b)(2) applications submitted by generic companies have solely focused on increasing user convenience (e.g., converting a vial to a pre-filled syringe or converting a vial that requires dilution or other manipulation prior to use into a ready-to-use bag). In addition, the development of 505(b)(2) candidates requires funding which may be a barrier to especially generic players, as capital requirements are higher compared to ANDAs.

<sup>32</sup> Jonathan J. Darrow, Mengdong He & Kristina Stefanini, the 505(b)(2) Drug Approval Pathway

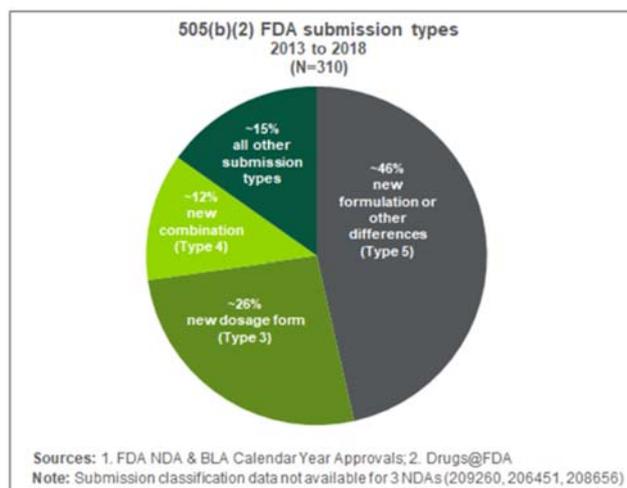
<sup>33</sup> pharmexec.com

The median review time for approval by the FDA after submission was 10 months in 2019 (compared to 13 months in 2018). Overall, 71% of 505(b)(2) NDA approvals had review times of 12 months or less, compared to 48% in 2018. Of the applications approved via the 505(b)(2) regulatory pathway from 2009 – 2015, 64.5% were approved with only 1 review cycle<sup>34</sup>. Of the remaining applications 73.2% involved CMC deficiencies (issues relating to with manufacturing plants, drug product, or drug substance). In 33% of applications CMC deficiencies were the only factor in triggering a second or subsequent review cycle/s. Other common reasons for additional review cycles were issues with 505(b)(2) strategy, and with demonstrating bioequivalence/conducting comparative bioavailability studies/scientific ‘bridging’ to other products.

### 8.9.3 505(B)(2) APPROVAL BY TYPE

The 310 products relying on the 505(b)(2) regulatory pathway, which were approved from 2013 through 2018, can be categorized as follows according to their submission type:

Figure 2: 505(b)(2) approvals by type 2013 – 2018.



Source: Pharmexec.com

The top three submission types: new formulation or other differences (Type 5 – approximately 46%), new dosage form (Type 3 - approximately 26%) and new combination (Type 4 – approximately 12%) have remained the same for overall 505(b)(2) approvals, dating all the way back to 2004.

Type 3 – new dosage forms: when passing from one administration type to another (example, from an oral tablet to an oral solution, or from an oral solution to an intravenous solution);

Type 4 – new combinations (example, the combination of paracetamol and ibuprofen, as they exist already separately);

<sup>34</sup> <https://camargopharma.com/resources/blog/505b2-approval-times-the-real-scoop>

Type 5 – other formulations or other differences (example, from an intravenous solution in vials to an intravenous solution in pre-filled syringe);

All others – others not listed above.

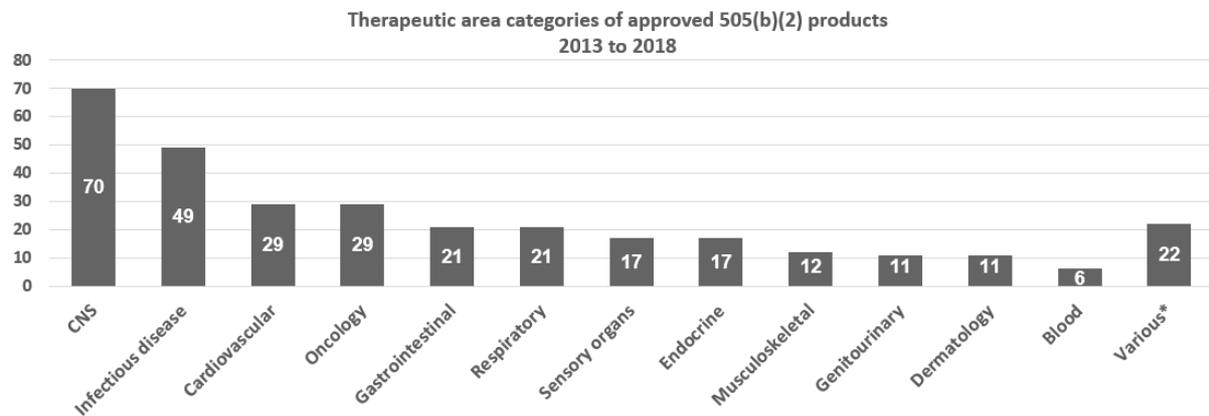
The Hyloris 505(b)(2) product candidates (except Maxigesic® IV, which is a Type 4, and Tranexamic RTU, which is a Type 5) fall into the Type 3 category. Hyloris' established market candidates as well as HY-REF-038 (which constitutes an ANDA) are not categorized, as they do not follow the 505(b)(2) regulatory pathway. While Sotalol has been approved utilizing the 505(b)(2) regulatory pathway, the label extension of Sotalol is also not a 505(b)(2) (it has been obtained through correspondence with the FDA).

The “all other submission types” category consists of products previously marketed without an approved NDA (approximately 5%), products with a new molecular entity (approximately 3%), products with a new active ingredient (approximately 3%), products with a new dosage form and new combination of ingredients (approximately 2%) and others (approximately 3%).

#### 8.9.4 505(B)(2) APPROVALS BY THERAPEUTIC CATEGORY

The 310 products relying on the 505(b)(2) regulatory pathway, which were approved from 2013 through 2018, can be categorized as follows according to their therapeutic area<sup>35</sup>:

Figure 3: 505(b)(2) approvals by therapeutic category 2013 – 2018.<sup>36</sup>



\*Note: Evaluate has classified Other therapeutic products and Diagnostic imaging under Various category  
Source: 1. FDA NDA & BLA Calendar Year Approvals; 2. Evaluate Pharma; 3. Global Data; 4. Drugs@FDA

Source: Pharmexec.com

<sup>35</sup> pharmexec.com

<sup>36</sup> Product applications are (unless disclosed by the filer) not public information until they are approved. Approvals in the cardiovascular therapeutic category mainly concern products targeting the retail market and products that did not change delivery form (a change of the container or formulation). and Hyloris does not expect these products to be directly competing with its current product candidates.

### **8.9.5 PATENTS AND MARKET EXCLUSIVITY<sup>37</sup>**

In the United States, the term of a patent is 20 years from the earliest filing date of the application on which the patent was granted. Such patents (reasonably related to drug product, drug substance or method of use) are listed in the Orange Book. A generic drug company can challenge patents covering the branded drug by filing a paragraph IV certification with its drug application and providing notice to the branded drug company and patent owner. A suit by the patent owner within 45 days of receiving the notice triggers a 30-month stay of regulatory approval, during which the FDA cannot approve the generic drug. Pharmaceutical patent litigations between branded and generic drug companies usually take place before the generic drug is marketed. Even if patents get annulled in court, the ANDA approval process provides an effective minimum market exclusivity. In practice, most patent infringement lawsuits get settled outside of court and a (future) launch date is agreed upon by parties, which is typically prior to the date of the last patent expiry date. The Company will not be able to patent the active ingredient but does expect to be able to patent formulations and/or methods of use<sup>38</sup>. Hyloris expects that most of its products will enjoy protection from generic competition even after the 30-month stay has ended, particularly with respect to its IV Cardiovascular Portfolio, where the formulation of most of the products is very complicated (and hence allows for better patent protection) and with respect to Maxigesic® IV, which has a wide range of patents covering dosing and formulation. In order to start selling a drug promptly after the patent on an innovator drug expires, a generic company has to file its ANDA well before the patent expires. ANDA applications typically occur for products that have demonstrated sufficient and confirmed commercial potential. ANDA applications also require time to develop (see also the table in Section 8.2 (Market opportunity and regulatory framework)) before an application can be submitted.

Because Hyloris will not be able to patent the active ingredient on which its product candidates rely, competitors will also be able to develop drug applications based on the same active ingredient.

Aside from patent protection (see also the table in Section 8.2 (Market opportunity and regulatory framework)), products can, if they fulfill certain conditions, also enjoy the following market exclusivity. Patents can be granted by the U.S. PTO at any point during the development timeline of a drug and can encompass a wide range of claims. The FDA can independently also grant exclusive marketing rights upon approval of a drug. This exclusivity refers to certain delays and prohibitions on the approval of competing drugs.

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<sup>37</sup> Market exclusivity is defined as a firm exclusivity granted by the FDA, whereas product exclusivity is exclusivity through patents.

<sup>38</sup> Hyloris will not have patent protection for the active ingredients in its product candidates. Therefore, it does not prevent its competitors from developing products using the same active ingredients as long as they do not infringe Hyloris' claim issued patents covering formulations, methods of use and processes. (cfr. Risk factor 2.1.16).

- A three-year period of exclusivity, during which an ANDA cannot be marketed, is granted for a drug product that contains an active moiety that has been previously approved when the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. For example, the changes in an approved drug product that affect its active ingredient(s), strength, dosage form, route of administration or conditions of use may be granted exclusivity if the new clinical investigations conducted were essential to approval of the application containing those changes<sup>39</sup>. Hyloris expects that only Maxigesic® IV and HY-REF-004 are eligible for such exclusivities. its product related patents are expected to, however, continue to provide protection after the three-year exclusivity period.
- A five-year period of exclusivity is granted to new drug applications for products containing chemical entities, or a combination of products, that have never been previously approved by FDA either alone or in combination (often older drugs that never were approved). No 505(b)(2) application or ANDA may be submitted during the five-year exclusivity period except that such applications may be submitted after four years if they contain a certification of patent invalidity or noninfringement. Hyloris is not expecting any of its product candidates to receive this five year exclusivity.
- With orphan designation, the FDA grants a seven-year market exclusivity for that medicine that applies specifically to that designated orphan use, during which an ANDA cannot be marketed. In general, Hyloris does not expect to rely on orphan drug designations but may in specific cases be able to obtain such designation. However, Hy-REF-004 may potentially be registered with an orphan designation if Hyloris decides to reduce the size of its target population (see Section 8.10.3.2E (HY-REF-004's clinical status, regulatory status and commercial strategy)).

Products may also be protected by a pediatric extension, which extends the lifetime of a patent or market exclusivity by a further six months for drugs studied in children.

In a study on 553 505(b)(2) products approved between 1993 and December 2016, 218 of such products had at least one associated patent listed in the Orange Book by the year following approval and 240 enjoyed FDA exclusivity. Altogether, 319 products (58%) had either patent or non-patent exclusivity. Of the 130 505(b)(2) products that had both a patent and non-patent exclusivity, 124 products had at least one patent with an expiration date that extended beyond the end of the last expiring non-patent exclusivity. Of these 124 505(b)(2) products, the average period by which patent exclusivity extended beyond non-patent exclusivity was 8.5 years<sup>40</sup>. Hyloris expects that the only product (candidates) in its current portfolio which would be eligible for such non-patent exclusivities in addition to a patent exclusivity, are Maxigesic® IV and HY-REF-004.

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<sup>39</sup><https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-new-drug-product-exclusivity>.

<sup>40</sup> Jonathan J. Darrow, Mengdong He & Kristina Stefanini, the 505(b)(2) Drug Approval Pathway

### **8.9.6 LOWER COSTS ASSOCIATED WITH THE 505(B)(2) REGULATORY PATHWAY<sup>41</sup>**

The standard PDUFA (Prescription Drug User Fee Act) fees in connection with the filing of a new drug application to the FDA amount to USD 2,942,965. However, if the FDA only needs to assess limited (e.g., a submission file containing the data of a single pharmacokinetic study) or no clinical data, which is the case for most of 505(b)(2) filings, a reduced fee of USD 1,471,483 may apply. As 505(b)(1) applications will, in most cases, require extensive review by the FDA of clinical data, they are generally not eligible for this reduced PDUFA fee and will be subject to the standard PDUFA fee. Hyloris expects that the majority of its current product candidates that utilize the 505(b)(2) regulatory pathway will be eligible for the reduced fee of USD 1,471,483.

PDUFA fees for 2020 have increased approximately 14% compared to 2019. The FDA's annual program fees have been assessed at USD 325,424<sup>42</sup>. Hyloris expects to pay the PDUFA and program fees for the IV Cardiovascular Portfolio, whereas fees for Other Reformulation Portfolio product candidates are expected to be borne by the commercialization partners. As Sotalol IV was submitted to the FDA by Academic Pharmaceuticals Inc. and the approval is currently held by AltaThera Pharmaceuticals, Hyloris has not yet paid fees to the FDA.

For filing of a generic product to the FDA, the Generic Drug User Fee Act, or GDUFA, fees amount to USD 176,237.

### **8.10 PRODUCTS**

Hyloris believes that all material information in relation to each of its products and product candidates has been disclosed in this Prospectus. However, certain commercially sensitive information with respect to a number of Hyloris' product candidates has not been disclosed due to the fact that Hyloris believes that, as these product candidates are generally in an early stage of development and have not yet received FDA approval or been granted patent protection, disclosure of such information would have a negative impact on its competitive position. Hyloris believes that the level of disclosure provided in relation to each of its products and product candidates is sufficient for investors to make a fully informed investment decision without compromising its competitive position in relation to such early-stage product candidates.

This Section 8.10 includes data gathered, to a large extent, from IQVIA. It should be noted that IQVIA data is only indicative for the specific markets they assess, and that this data is based on various assumptions and may contain extrapolations by IQVIA based on data they have gathered. In specific instances throughout this Prospectus, Hyloris refers to WAC (or wholesale acquisition cost). It should be noted that the WAC of a product does not necessarily reflect the realized pricing of a product, as the WAC may be heavily discounted, especially with respect to products facing generic competition.

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<sup>41</sup> U.S. FDA, Prescription Drug User Fee Amendments, <https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments>

<sup>42</sup> FDA, <https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments>

Hyloris engages with different third parties to develop its product candidates but manages the overall development process and strategy and bears the financial responsibility of the product development.

### 8.10.1 PORTFOLIO OVERVIEW

Hyloris has two commercial products (Maxigesic® IV and Sotalol IV) as well 12 product candidates in various stages of development (which has been initiated prior to 2020 for all product candidates). Hyloris' products and product candidates can be divided into the following areas:

- IV Cardiovascular Portfolio: one product, Sotalol IV, has been approved by the FDA<sup>43</sup> and Hyloris expects to file four additional product candidates by the end of 2023;
- Other Reformulation Portfolio (“other reformulations”): one product, Maxigesic®, has been approved in certain territories and one product, Tranexamic Acid RTU, is expected to be filed for approval in the early second half of 2020. Hyloris expects to file two additional product candidates, Atomoxetine Oral Liquid and HY-REF-038, in the second half of 2021 and three more over the course of 2022 and 2023 (HY-REF-075, HY-REF-029 & HY-REF-004);
- Established Market Portfolio (“high-barrier generics”): one product, HY-EMP-016, has been filed Fusidic Acid Cream is expected to be submitted to the Canadian Health Authority by the end of 2022.

The following chart is a depiction of Hyloris' portfolio and the current state of its developments, as of the date of this Prospectus:

Asset	Formulation /Analytical development	GMP clinical trial batches	Clinical trials <sup>1</sup>	Registration dossiers <sup>2</sup>	Approval	Commercialization
Sotalol IV	✓	✓	✓	✓	✓	3Q 2020 <sup>3</sup>
Dofetilide IV	In progress	2H 2020	4Q 2020	2022	2023	2023
Metolazone IV	In progress	2H 2021	2H 2021	2023	2024	After approval
HY-CVS-073	2H 2020	Not disclosed	2H 2021	2023	2024	After approval
HY-CVS-074	2H 2020	Not disclosed	2H 2021	2023	2024	After approval
Maxigesic® IV US	✓	✓	In progress	2H 2020	2H 2021	After approval
Maxigesic® IV EU	✓	✓	✓	✓	2H 2020	After approval
Maxigesic® IV ROW	✓	✓	✓	✓	In progress <sup>4</sup>	In progress <sup>5</sup>
Atomoxetine Oral Liquid	✓	Not disclosed	2H 2020	2H 2021	1H 2023	1H 2023
Tranexamic Acid RTU	✓	N/A	N/A	2H 2020	2H 2021	After approval
HY-REF-004	✓	✓	2Q 2020	End of 2022 / Start of 2023	2H 2023	2024
HY-REF-075	In progress <sup>6</sup>	Not disclosed	1H 2021	2022	2024	2024
HY-REF-029	In progress <sup>7</sup>	Not disclosed	2Q 2021	2022	2023	2023
HY-REF-038	In progress	N/A	N/A	2H 2021	After review	After approval
HY-EMP-016	✓	Not disclosed	✓	✓	2021	After approval
Fusidic Acid Cream	✓	Not disclosed	In progress	2022	Not disclosed	After approval



1. Clinical trials start; 2. Submission; 3. Commencement of marketing of label extension; 4. First registrations have been granted; 5. Launch in UAE is expected in 2H 2020; 6. Expected to complete in 2H 2020; 7. Expected to complete in 2H 2020; Note: Timing refers to the initiation of this step

<sup>43</sup> In March 2020, the FDA approved the label extension for the initiation of loading on sotalol in patients who are prescribed oral sotalol and for dose escalation for chronic administration of an increased dose of oral sotalol. See also Section 8.10.2.1E.

Hyloris believes that its products and product candidates will bring the following added value to the healthcare system (more detailed information on each of the product (candidates) of Hyloris, can be found further in this Section):

Sotalol IV	IV formulation of sotalol, a commonly used antiarrhythmic drug, allowing for a significantly shorter (required) hospital stay for therapy initiation.
Maxigesic® IV	IV formulation that is a unique combination of two trusted active (non-opioid) pharmaceutical molecules that work together in different, yet complementary ways to help relieve pain.
Tranexamic acid RTU IV	Ready To Use formulation of tranexamic acid (medication used to treat or prevent excessive blood loss), improving convenience and readiness to use of a (potential) critical care product.
HY-EMP-016	Generic of an off-patent branded reference product currently sold in the U.S. pharmaceutical market without generic competition.
Atomoxetine oral liquid	Liquid formulation based on atomoxetine, a molecule used primarily for the treatment of patients with ADHD, which allows for improved dosing (as dosing is also based on body weight) and convenience.
HY-REF-038	A prefilled syringe of a commonly used product (treating a specific deficiency) offering increased ease of use and possible health economic benefits.
HY-REF-029	Liquid form of an existing antiviral drug currently only available as an oral solid.
Dofetilide IV	IV formulation of the antiarrhythmic drug dofetilide currently only available as an oral capsule.
HY-REF-004	Liquid formulation that allows for treatment of patients undergoing a specific dental procedure.
Metolazone IV	IV formulation of metolazone (an existing diuretic) providing faster onset of treatment in patients requiring diuresis and solving possible poor absorption related issues of the oral formulation.
HY-REF-075	Liquid formulation of a commonly used molecule for the treatment of cardiovascular conditions requiring frequent dose adjustments.
Fusidic acid cream	Generic of an off-patent reference product currently sold in the Canadian pharmaceutical market without generic competition.
HY-CVS-073	IV formulation of an oral antiplatelet product, offering needed faster onset of action in patients suffering from Acute Coronary Syndrome.

HY-CVS-074	IV formulation of an oral antiplatelet product, offering needed faster onset of action in patients suffering from Acute Coronary Syndrome.
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### 8.10.2 THE IV CARDIOVASCULAR PORTFOLIO

Cardiovascular diseases are the leading cause of death in the United States with 647,000 deaths per year, which accounts for almost 25% of all deaths (excluding sudden deaths)<sup>44,45</sup>. These conditions cost the United States approximately USD 219 billion each year<sup>46</sup>, including the cost of health care services, pharmaceuticals, and lost productivity due to death.

Hyloris focuses on IV cardiovascular products because it believes it is an area that has the potential for (i) significant growth due to an aging population and the increasing prevalence of obesity, (ii) effective and cost-efficient product promotion due to an identifiable and limited number of cardiovascular centers, care facilities, physicians and buyers, and (iii) identification of further promising product improvement ideas that can offer added value for different stakeholders in the healthcare system.

The current IV Cardiovascular Portfolio of Hyloris is focused on three types of cardiovascular diseases: Atrial Fibrillation (**AFib**), Heart Failure and Coronary Heart Disease.

#### 8.10.2.1 SOTALOL IV & DOFETILIDE IV

##### **A Disease: Atrial Fibrillation (AFib)**

##### General Description

Abnormalities in the heart's electrical system can disrupt the normal functioning of the heart, causing it to beat too fast, too slow or irregularly. The most common heart rhythm disorder is AFib<sup>47</sup>. In AFib, there is a very fast and chaotic heart rhythm in the atria, which cannot contract and/or squeeze blood effectively into the ventricles. This results in the heart beating faster than it should or quivering (as seen in the below figure).

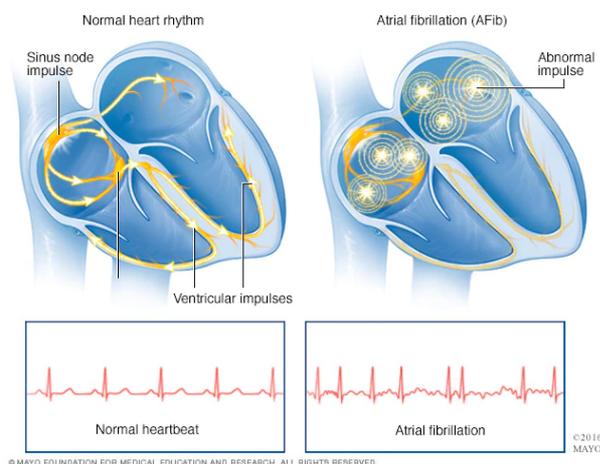
*Figure 4: Atrial Fibrillation.*

<sup>44</sup> Melonie Heron, Deaths: Leading Causes for 2017, June 24, 2019, National Vital Statistics Reports, Volume 68, Number 6

<sup>45</sup> Cheryl D. Fryar, Prevalence of Uncontrolled Risk Factors for Cardiovascular Disease: United States, 1999–2010, August 2012, NCHS Data Brief No. 103

<sup>46</sup> Center for Disease Control and Prevention, Heart Disease Home, [www.cdc.gov/heartdisease/facts.htm](http://www.cdc.gov/heartdisease/facts.htm)

<sup>47</sup> Cátia Ferreira, et al, Atrial Fibrillation and Non-cardiovascular Diseases: A Systematic Review, *Arq Bras Cardiol.* 2015 Nov; 105(5): 519–526



Source Mayo Clinic 2016

Untreated AFib can lead to serious and even life-threatening complications, such as the forming of blood clots as a consequence of blood not being properly pumped out of the atria. If a blood clot forms, it can dislodge from the heart and travel to the brain resulting in a stroke. In addition, excessive or irregular heartbeats, especially if left unchecked, can weaken the heart muscle, leading to heart failure. AFib carries a negative impact on quality of life and is associated with increased mortality. AFib is associated with a five-fold increase in the risk of a stroke<sup>48</sup> and a three-fold increase in the risk of heart failure<sup>49</sup>.

### AFib in the United States

An estimated 6.1 million<sup>50</sup> adults live with AFib in the United States in 2019 and that number is expected to increase to 12.1 million patients by 2030<sup>51</sup>. AFib is responsible for most arrhythmia related hospital admissions and is the most common cause of ischemic stroke. A 2014 estimate shows 1.2 million new AFib cases and 454,000 hospitalizations occur every year in the United States<sup>52</sup> that is growing<sup>53</sup>. The increase in AFib-related emergency room visits in the U.S. increased more than 30% from 2007 to 2014<sup>54</sup>. AFib occurs in 2.3% of U.S. adults above 40 years of age and in 5.9% of those above 65 years old<sup>55</sup>. It is most common in males over the age of 60 years of age with a family history<sup>56</sup>. Without proper

<sup>48</sup> Leila et al, 2011, Stroke Prevention in Nonvalvular Atrial Fibrillation

<sup>49</sup> Dipak Kotecha and Jonathan P. Piccini, Atrial fibrillation in heart failure: what should we do?, Eur Heart J. 2015 Dec 7; 36(46): 3250–3257.

<sup>50</sup> Centers for Disease Control and Prevention, Atrial Fibrillation (Factsheet, Website CDC)

<sup>51</sup> Colilla et al, 2013, Estimates of Current and Future Incidence and Prevalence of Atrial Fibrillation in the U.S. adult Population

<sup>52</sup> Benjamin EJ et al. Heart disease and stroke statistics—2019 update: a report from the American Heart Association. Circulation. 2019;139(10):e56–528.

<sup>53</sup> Chugh SS et al, Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study, Circulation. 2014 Feb 25;129(8):837-47

<sup>54</sup> Patszek et al, JAHA, 2019.

<sup>55</sup> Joon Hoon Jeong, 2005, Prevalence of and Risk Factors for Atrial Fibrillation in Korean Adults Older than 40 Years, J Korean Med Sci. 2005 Feb; 20(1): 26–30.

<sup>56</sup> Joon Hoon Jeong, 2005, Prevalence of and Risk Factors for Atrial Fibrillation in Korean Adults Older than 40 Years, J Korean Med Sci. 2005 Feb; 20(1): 26–30.

treatment, 49% of patients diagnosed with AFib will die within five years following the onset of symptoms<sup>57</sup>. In 2017, AFib was mentioned on around 166,000 death certificates in the United States<sup>58</sup>.

Studies show the annual U.S. hospitalization costs associated with AFib amount to USD 6 billion per year<sup>59</sup> and the total U.S. healthcare costs related to AFib are approximately USD 26 billion per year<sup>60</sup>.

## **B Current standard of care**

Treatments for AFib may include lifestyle changes, medications and other interventions (catheter ablation and/or surgery) to try to alter the heart's electrical system. The majority of hospitalized patients with AFib will receive an antiarrhythmic drug, which covers a variety of pharmaceuticals. The potassium channel blockers (a class of drugs that interfere with the conduction through potassium channels and prolong the action duration potential and refractory period which is the period of time in which the cardiac cell is unable to initiate another action) are the principal rhythm control drugs in the United States for the treatment of AFib. The main potassium channel blockers in the United States are amiodarone, dronedarone, sotalol and dofetilide. Other commonly used antiarrhythmic drugs are flecainide and propafenone.

The selection of the appropriate drug is dependent on the patient's underlying heart disease. Antiarrhythmic drug selection for AFib patients, is guided by efficacy considerations, convenience, cost, discontinuation and safety considerations. Figure 5 below sets out the recommended drug for to the maintenance of sinus rhythm cardiovascular conditions according to the 2014 AHA/ACC/HRS (American Heart Association/ American College of Cardiology/ Heart Rhythm Society) Guideline for the Management of Atrial Fibrillation. The update does not include any changes related to the use of antiarrhythmic drugs<sup>61</sup>.

*Figure 5: Rhythm control strategy in patients with AFib - 2014 AHA/ACC/HRS Guideline for the Management of Atrial Fibrillation.*

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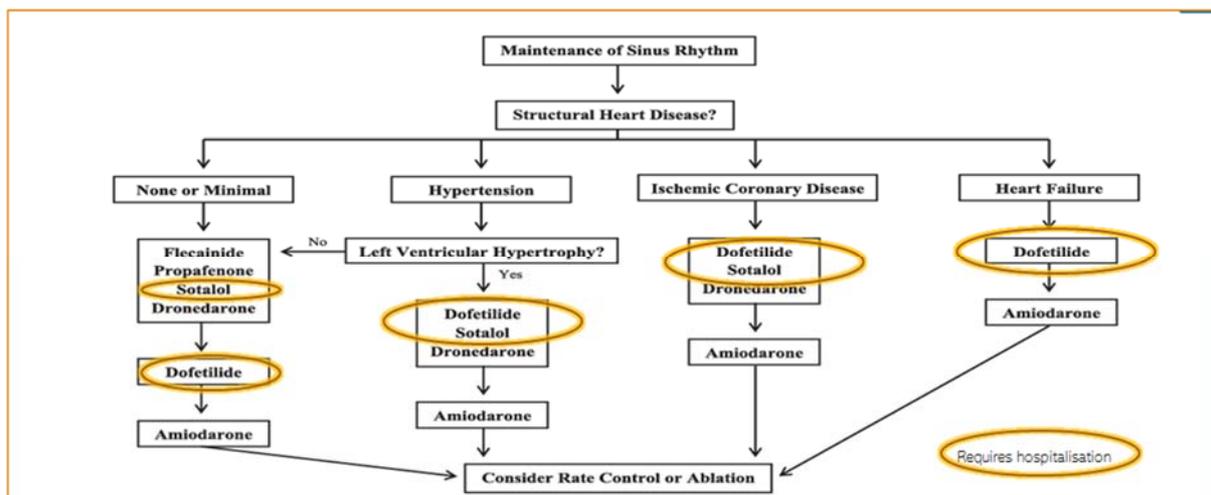
<sup>57</sup> <https://www.afibsurgeons.org/why-treat-afib/health-medical-economic-burden/>

<sup>58</sup> Centers for Disease Control and Prevention, Atrial Fibrillation (Factsheet, Website CDC).

<sup>59</sup> CDC Fibrillation Fact Sheet, 2017

<sup>60</sup> Kim et al, 2011, Estimation of Total Incremental Health Care Costs in Patients With Atrial Fibrillation in the United States, AHA Journal, Circulation: Cardiovascular Quality and Outcomes. 2011;4:313–320; Wolowacz et al, 2011, The cost of illness of atrial fibrillation: a systematic review of the recent literature

<sup>61</sup> Ref: 2019 AHA/ACC/HRS (American College of Cardiology/American Heart Association/Heart Rhythm Society) Focused Update of the 2014 AHA/ ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society.



Source: Mitchell A. Psotka and Byron K. Lee, *Atrial fibrillation: antiarrhythmic therapy, Current Problems in Cardiology, Volume 39, Issue 10, October 2014, Pages 351-391*

Antiarrhythmic drug selection for AFib patients, is guided by efficacy considerations, convenience, cost, discontinuation and safety considerations. Although sotalol and dofetilide are both antiarrhythmics for the prevention or treatment of AFib they are often administered to a different subset of patients. Dofetilide appears to be hemodynamically<sup>62</sup> safe and recommended as a first line therapy for patients with heart failure<sup>63</sup> and only as a second line therapy in patients with no or minimal structural heart disease, whereas sotalol is recommended as a first line general therapy.

In 2018, approximately 750 million tablets and capsules of rhythm control drugs were sold in the United States<sup>64</sup>. Amiodarone commanded the largest share at just under 30%, closely followed by sotalol with 27.5%. Dofetilide made up a minority share of 5.5%. Even though oral sotalol, due to required hospital initiation, is challenging to start new patients on, it consistently remains the second most widely used antiarrhythmic in the United States with two million written prescriptions<sup>65</sup>. Oral sotalol was launched in the United States under the trade name Betapace® (and Betapace AF®) in 1992 and is sold in tablet strengths of 80, 120, 160 and 240 mg. Dofetilide was launched in the United States in 1999 under the trade name Tikosyn® and is sold in capsules of 125, 250, and 500 µg. Both products are usually taken twice a day and have generic alternatives available.

Table 1: Main U.S. oral rhythm control drugs.

Drug molecule	Annual oral units (in thousands)			% Market share			Hosp. Initiation
	2016	2017	2018	2016	2017	2018	
AMIODARONE	194,555	193,164	215,172	27.0%	26.8%	29.9%	NO
SOTALOL	196,835	192,698	198,040	27.3%	26.8%	27.5%	YES
FLECAINIDE	154,601	171,147	175,967	21.5%	23.8%	24.4%	NO

<sup>62</sup> Hemodynamics are the dynamics of the blood flow, and explains the physical laws that govern the flow of blood through the cavities of the heart and all the blood vessels. Stable blood flow provides a steady supply of oxygen to all tissues and organs in the body. Maintaining stable blood flow in the heart and vessels is important in supporting normal organ functions.

<sup>63</sup> <https://www.uptodate.com/contents/therapeutic-use-of-dofetilide>

<sup>64</sup> IQVIA

<sup>65</sup> ClinCalc, 2018, The Top 300 of 2019, Archived from the original on 21 November 2018

PROPAFENONE	83,076	77,284	72,986	11.5%	10.7%	10.1%	NO
DRONEDARONE	52,642	48,286	46,503	7.3%	6.7%	6.5%	NO
DOFETILIDE	38,608	38,421	39,772	5.4%	5.3%	5.5%	YES
<b>TOTAL</b>	<b>720,317</b>	<b>721,000</b>	<b>748,439</b>				

Source: IQVIA.

In addition to oral dosage forms, a number of rhythm control drugs are available as an IV for emergency use, including IV amiodarone (of which 4.6 million units were sold in 2018) that can be administered for a number of heart related issues including AFib.

### C Limitations of the current standard of care

Amiodarone is the most commonly prescribed oral antiarrhythmic, despite having numerous and sometimes serious side effects, including amiodarone induced pulmonary toxicity (APT)<sup>66</sup>. Sotalol and dofetilide do not have pulmonary toxicity, hepatotoxicity and photosensitivity compared to amiodarone<sup>67,68,69</sup>. Sotalol and dofetilide however do carry FDA black box warnings intended to alert healthcare professionals of life-threatening drug induced proarrhythmic risks (*i.e.*, irregular heartbeat due to antiarrhythmic drugs) in patients when initiating or re-initiating on dofetilide or sotalol.

The major risk for patients is a serious side effect called Torsades de Pointes, which is a specific type of abnormal heart rhythm that can lead to sudden cardiac death. 0.5%-5.8%<sup>70</sup> and 0.3%-10.5%<sup>71</sup> of patients who receive sotalol and dofetilide, respectively, show signs of Torsades de Pointes. Torsades de Pointes is dose-related, with increased incidence associated with higher doses and normally occurs within the first three days of initial dosing<sup>72</sup>.

The FDA black box warnings require patients to be continuously monitored for at least three days or until steady state drug levels (*i.e.*, a constant level of the drug in the blood) are achieved in a setting where cardiac resuscitation is possible. Hyloris believes that the use of sotalol and dofetilide is impacted by this requirement to hospitalize the patient for treatment initiation. The required hospital admission results in personal and financial burden, use of hospital resources, and potential for iatrogenic risk to the patient.

### D Hyloris' product: Sotalol IV

Sotalol IV, which was purchased from Academic Pharmaceuticals in December 2014 (see Section 8.12.1 (Sotalol IV)), was until recently only approved by the FDA for treating patients who are unable to

<sup>66</sup> Aasbo JD, Lawrence AT, Krishnan K, et al. Amiodarone prophylaxis reduces major cardiovascular morbidity and length of stay after cardiac surgery: A meta-analysis. *Ann Intern Med.* 2005;143:327-36/ Rotmensch HH, Belhassen B, Swanson BN, et al. Steady-state serum amiodarone concentrations: Relationship with antiarrhythmic efficacy and toxicity. *Ann Intern Med.* 1984;101:462-9)

<sup>67</sup> F. R. Costa-Jussà, Amiodarone lung toxicity: A human and experimental study, *The journal of Pathology*, October 1984, Volume 144, Issue 2, Pages 73-79

<sup>68</sup> Babatin M et al, Amiodarone hepatotoxicity *Curr Vasc Pharmacol.* 2008 Jul;6(3):228-36.

<sup>69</sup> Walter JF et al, Amiodarone photosensitivity, *Arch Dermatol.* 1984 Dec;120(12):1591-4.

<sup>70</sup> ECG, McGill Case, [https://en.ecgpedia.org/index.php?title=McGill\\_Case\\_86](https://en.ecgpedia.org/index.php?title=McGill_Case_86)

<sup>71</sup> Source: Lenz TL, Hilleman DE, Dofetilide: A new antiarrhythmic agent approved for conversion and/or maintenance of atrial fibrillation/atrial flutter, *Drugs Today (Barc).* 2000 Nov;36(11):759-71.

<sup>72</sup> Torp-Pedersen C, Møller M, Bloch-Thomsen PE, et al. Dofetilide in patients with congestive heart failure and left ventricular dysfunction. Danish Investigations of Arrhythmia and Mortality on Dofetilide Study Group. *N Engl J Med* 1999; 341:857.

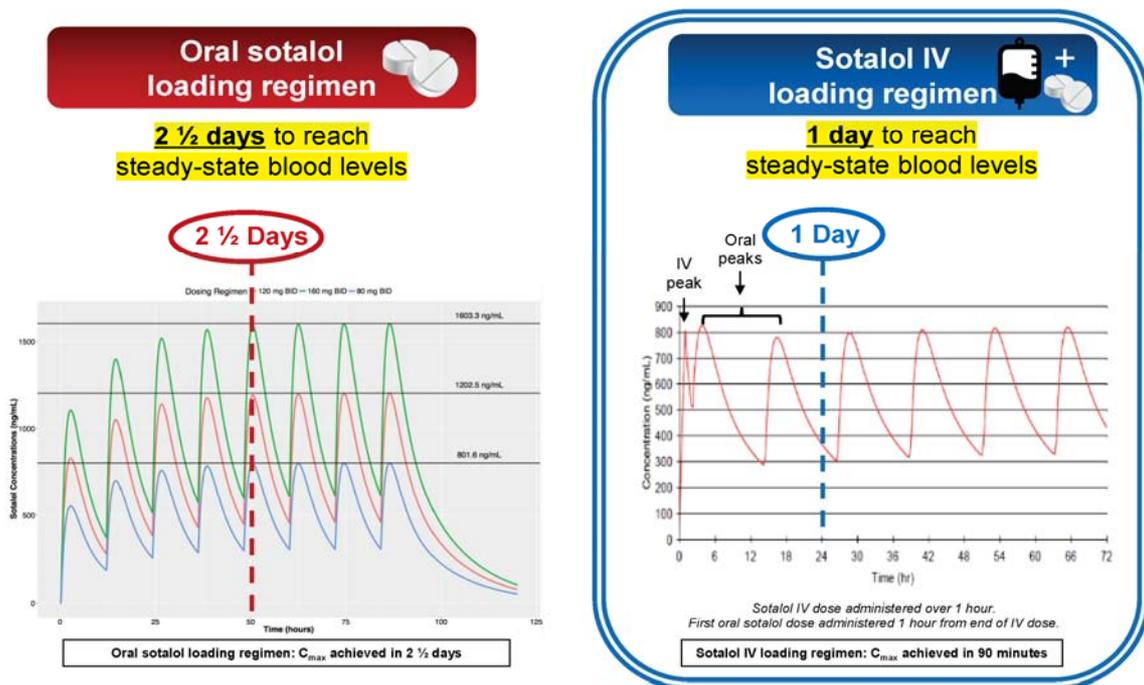
take oral sotalol, which represents a very limited market and it was mainly used by pediatric cardiac specialists in a limited number of specialized children's hospitals for the acute treatment of arrhythmias and recurrent atrial arrhythmias. The current sales of Sotalol IV, which was made available in the United States in 2015, are therefore very limited (USD 2.1 million in 2019 with a drug price that was above USD 2,000 per vial at the end of 2019).

In order to broaden the potential market for Sotalol IV, AltaThera (i) engaged with the FDA to expand the labelling of Sotalol IV to loading in new adult AFib patients until steady state is reached, which was filed in 2018 under the FDA Drug Model Informed Development Program and approved in March 2020 and (ii) obtained a safety and method of use patent that has a 2038 expiry date. The label expansion allows significant reduction in the length of the hospital stay required for loading, by bringing patients to a steady state at a faster pace.

As seen in Figure 6 below, after oral administration, peak plasma concentrations are reached in two and a half to four hours and steady state plasma concentrations are attained within two to three days (*i.e.*, after five to six doses when administered twice daily).

Sotalol IV (diluted in appropriate diluents) is administered by an infusion pump over one hour at a constant infusion rate, allowing to reach steady state significantly faster. As a representative example, for a patient with good kidney function whose initial target maintenance oral sotalol dose is 80 mg twice a day, an intravenous loading dose of sotalol 60 mg can be infused over one hour, followed by an 80 mg oral sotalol minimum four hours after the end of the infusion. The pharmacometric simulations demonstrated that by utilizing this IV loading regimen, steady state can be achieved within two hours after the first oral dose.

*Figure 6: Plasma concentration levels simulations when initiating oral sotalol (left) and when initiating on Sotalol IV followed by oral sotalol (right).*



Source: *AltaThera*

This novel Sotalol IV loading indication can therefore decrease the length of hospital admission from three days to one day and potentially significantly decrease overall cost of care, while at the same time improve patient satisfaction and safety. In addition, the availability of a formulation allowing an intravenous administration should allow a faster drug onset compared to the oral formulation, which is crucial in an acute setting as is the case for patients admitted to hospital with a suspected AFib.

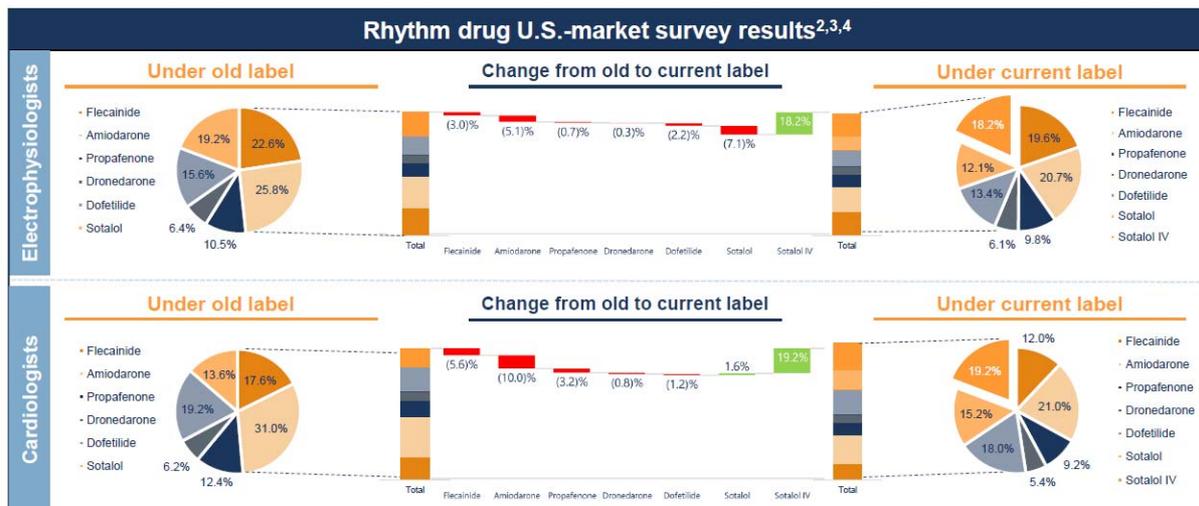
According to an article published in the Journal of American College of Cardiology, the potential cost reductions are a mean total cost saving of USD 3,123 (95% confidence interval (CI), USD -3,640, USD -2,607) for a two-day inpatient length of stay and a cost saving of USD 4,820 (95% CI, USD -5,352, USD -4,288) for a one-day inpatient length of stay with IV loading<sup>73</sup>. Initiation of sotalol using an IV loading strategy, compared to the traditional oral formulation, minimized costs due primarily to decreased length of stay despite increased drug acquisition costs.

### Market Survey

<sup>73</sup> Cost minimization analysis of Atrial Fibrillation and Atrial Flutter through intravenous sotalol loading, Kathy Tang, T. Joseph Mattingly II, Joshua Ayres, Vincent See and Brent Reed, Journal of the American College of Cardiology

In 2018, AltaThera conducted a survey of 30 electrophysiologists and cardiologists in order to assess the adult AFib opportunity for Sotalol IV in the United States. The physicians indicated that, if Sotalol IV obtains the loading dose label extension (in the meantime obtained in March 2020), it could capture approximately 19% of new patients who are administered an arrhythmic drug. For electrophysiologists, the new regimen for Sotalol IV captured over 18% of all treated patients, comparing with amiodarone (approximately 21%) and flecainide (approximately 20%).

## U.S. Physicians understand the value proposition of Hyloris' solution<sup>1</sup>



Sotalol IV has the potential to take a significant market share from competing oral products



Source & Notes: 1. Yartagadda et al., 2017, Safety and Efficacy of Inpatient Initiation of Dofetilide Versus Sotalol for Atrial Fibrillation 2. AltaThera survey performed in the U.S., 2018 3. Percentages for Sotalol IV indicate the share cardiologists think this product can capture of patients who are administered an arrhythmic drug 4. The number of total persons surveyed (n) was 30

37

### E Sotalol IV's clinical status, regulatory status and commercial strategy

In March 2020, the FDA approved a label extension to include the initiation of loading on Sotalol IV in patients who are prescribed oral sotalol and for dose escalation for chronic administration of an increased dose of oral sotalol. No clinical trial has been performed. Hyloris expects that it will not incur further development costs on Sotalol IV.

Sotalol IV is commercialized by AltaThera, which acquired the commercial U.S. product rights and a right of first refusal for Canada and Mexico and which is also involved in the product's development (see Section 8.12.1.2 (AltaThera – Licensing, development and supply agreement) for additional information)) and it is expected that the promotion of the new label will commence in Q3 2020, which then must be approved for use by hospital pharmacy and therapeutic committees and subsequently placed on hospital formularies.

AltaThera is currently building and will continue to do so during the coming quarters, a dedicated sales force expanding their reach with an initial focus on key U.S. states with the highest number of electrophysiologists and the largest adult AFib hospitals.

Hyloris will receive sales related royalties ranging from a high single digit percentage to a low double digit percentage as well as up to five one-time (increasing) milestone payments, that become payable when defined aggregate sales targets are exceeded, with a maximum total aggregate of USD 18 million (Section 8.12.1.2 (AltaThera – Licensing, development and supply agreement) for additional information)).

When AltaThera acquired the commercial U.S. product rights, Hyloris had not yet started development of its other IV Cardiovascular Portfolio product candidates and therefore had not yet defined its strategy to establish its own commercial team for its IV Cardiovascular Portfolio.

As Hyloris has acquired all rights, titles and interests in Sotalol IV, including the relevant NDA, all other authorizations, approvals and regulatory findings (INDs) and all data and other relevant information and know-how relating to Sotalol IV from Academic Pharmaceuticals Inc., Hyloris will pay a low double digit percentage of its net profits received from the distribution of Sotalol IV in the United States to Academic Pharmaceuticals (see Section 8.12.1.1 (Academic Pharmaceuticals Inc. – Asset purchase agreement) for additional information).

Hyloris believes growth of sales of Sotalol IV could continue during the effective patent exclusivity period. Not only could there be bigger adoption and more potential AFib patients but also a broader indication is possible enlarging the product potential.

#### ***F Hyloris' product candidate: Dofetilide IV***

Based on the similarities between sotalol and dofetilide, Hyloris has adopted a very similar development strategy for Dofetilide IV, which is currently only available as an oral capsule. Hyloris will therefore develop Dofetilide IV and propose a new loading dose strategy based on the same scientific rationale with a faster loading followed by oral therapy. As a result, patients should reach steady state of dofetilide faster, reducing hospitalization duration. Because of the risk of proarrhythmia including Torsades de Pointes, dofetilide is no longer commercially available in any market except for the United States, Puerto Rico and Portugal.

An IV formulation of dofetilide can create side effects similar to the tablet but due to the close monitoring during the shortened loading period and the possibility to stop the treatment, the QT prolongation leading to Torsades de Pointes happens gradually. In other words, the loading related risk is different. In addition, steady state will be achieved faster so the period when patients can experience the side effects is shorter with the IV drug than oral. In a recent study in atrioventricular re-entrant tachycardia, Belgian

investigators demonstrated the safe use of Dofetilide IV at five different doses (1.5, 3, 6, 9, and 15 µg/kg). Prolonged QT occurred in some patients but did not develop into Torsades de Pointes<sup>74</sup>.

In contrast to some other antiarrhythmic medications, dofetilide appears to be hemodynamically safe for use in patients with heart failure or a prior myocardial infarction<sup>75</sup>. Although Hyloris believes that dofetilide is currently primarily used in these patients, the number of new dofetilide patients may increase once Dofetilide IV is launched, given that an IV formulation of dofetilide is expected to provide advantages including:

- Shortening the hospital stay for patients (which is typically longer for loading on dofetilide compared to the hospital initiation of a sotalol therapy as dofetilide has more potential side effects such as the occurrence of Torsades de Pointes (see Figure 6 “Plasma concentration level simulations when initiating oral sotalol (left) and when initiating on Sotalol IV followed by oral sotalol (right)” in Section 8.10.2.1.D (Hyloris’ product: Sotalol IV)) and is given to a population that typically requires additional monitoring due to other health related considerations;
- Decreasing healthcare costs; and
- Facilitating the use of antiarrhythmic therapy in patients who are unable to swallow tablets (swallowing difficulties, surgery, intubation, acute illness, etc.).

Hyloris believes that, based on the Sotalol IV numbers of the survey performed by Hyloris’ partner AltaThera (see Section 8.10.2.1D (Hyloris’ product: Sotalol IV)), a significant portion of the existing dofetilide use in hospitals for loading of patients could be converted to IV.

The survey also indicated the use of dofetilide oral would be slightly reduced once Sotalol IV would be made available (respectively -1.2% and -2.2%). Sotalol and dofetilide are both anti-arrhythmics for the prevention or treatment of AFib, but they are often administered to a different subset of patients. As such, these two IV products are able to exist simultaneously in the market and it is not expected that the availability of Dofetilide IV will have a significant impact on the use of Sotalol IV.

### **G      *Dofetilide IV’s clinical status, regulatory status and commercial strategy***

Hyloris is developing Dofetilide IV, which was in-licensed from Academic Pharmaceuticals (see Section 8.12.2.1 (Academic Pharmaceuticals – Binding Term Sheet) who will continue to support the development. The (non-GMP) formulation feasibility work has been completed and Hyloris has selected Excite Pharma Services, a U.S.-based manufacturer, to complete the prototype development, to upscale the formulation and to produce GMP batches, which are expected for H2 2020 (see Section 8.12.2.2 (Excite Pharma Services – Clinical Trial Manufacturing agreement)). Hyloris plans to start a pharmacokinetic study in (less than 100) healthy volunteers in Q4 2020 that will include the objective to show a similar pharmacokinetic and pharmacodynamics profile between the intravenous and oral administration of dofetilide.

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<sup>74</sup>Cobbe et al, Cardiovascular medicine, 2020.

<sup>75</sup> <https://www.uptodate.com/contents/therapeutic-use-of-dofetilide>

Hyloris expects to submit the 505(b)(2) application for Dofetilide IV to the FDA in the course of 2022 and intends to commence commercialization of Dofetilide IV in the United States with its own sales force, after approval by the FDA, in 2023.

On average, the duration of the hospital stay required for dofetilide oral loading is lengthier compared to a sotalol oral loading. As the Dofetilide IV loading pathway should allow for a quick therapy initiation (comparable to Sotalol IV), Hyloris expects the sales price of Dofetilide IV to be higher than Sotalol IV given the greater value added to the healthcare system.

#### **8.10.2.2      METOLAZONE IV**

##### **A      *Disease: Congestive Heart Failure***

Heart failure occurs when the heart fails to pump a sufficient amount of blood through the body. The disease often develops as a consequence of other conditions that have damaged or weakened the heart (e.g., narrowed arteries, high blood pressure, heart attack). When the heart is failing, blood and other liquids can accumulate inside the lungs, abdomen, liver and lower body, which is called an edema. While often referred to as heart failure, congestive heart failure specifically refers to the stage in which fluid builds up around the heart and causes it to pump inefficiently, which can be life threatening.

Heart failure is the most rapidly growing cardiovascular condition globally. At the age of 40, the lifetime risk of developing heart failure is one in five<sup>76</sup>. Between 2013 and 2016 an estimated 6.2 million<sup>77</sup> individuals in the United States lived with heart failure and 870,000 new cases are diagnosed every year<sup>78</sup>. In 2014, there were an estimated 1.1 million emergency department visits, 1 million hospitalizations, and 80,000 deaths due to primary heart failure. There were 4 million emergency department visits, 3.4 million hospitalizations, and 230,000 deaths with comorbid heart failure<sup>79</sup>. It is expected that by 2030 more than 8 million people will suffer from this condition in the United States alone<sup>80</sup>.

Heart failure is the leading cause of hospitalization among Medicare beneficiaries in the United States. Patients hospitalized with heart failure have the highest 30-day readmission rate (~25%) of any diagnosis<sup>81</sup>. This is likely because patients with heart failure are often elderly patients with multimorbidity and still represent a challenge for patient-centered care<sup>82</sup>.

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<sup>76</sup> Statistical Fact Sheet 2013 Update, 2013, American Heart Association

<sup>77</sup> Heart Disease and Stroke Statistics -2019 Update: A report from the American Heart Association

<sup>78</sup> Boback Ziaeeian and Gregg C. Fonarow, Epidemiology and aetiology of heart failure, *Nat Rev Cardiol.* 2016 Jun;13(6):368-78

<sup>79</sup> Sandra L. Jackson et al, National Burden of Heart Failure Events in the United States, 2006-2014, *Circ Heart Fail.* 2018 Dec; 11(12): e004873.

<sup>80</sup> Benjamin EJ, Muntner P, Alonso A, Bittencourt MS, Callaway CW, Carson AP, et al. Heart disease and stroke statistics—2019 update: a report from the American Heart Association. *Circulation.* 2019;139(10):e56–528.

<sup>81</sup> Shannon M. Dunlay, et al, 2014, Understanding the Epidemic of Heart Failure: Past, Present, and Future, *Curr Heart Fail Rep.* 2014 Dec;11(4):404-15.

<sup>82</sup> Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *New Engl J Med.* 2009;360:1418–28

In 2012, total cost for heart failure in the United States was estimated to be USD 30.7 billion, of which over two thirds were attributable to direct medical costs. Projections suggest that by 2030, the total cost of heart failure in the United States will increase by 127% to USD 69.8 billion, amounting to approximately \$244 for every U.S. adult<sup>83</sup>.

**B Current standard of care**

Congestive heart failure is progressive and has no cure. Some treatments, such as diuretics and lifestyle changes can reduce symptoms. The use of diuretics is common in patients with heart failure to relieve the congestive symptoms. For inpatient treatment of acute heart failure, an intravenous dose of a loop diuretic is typically given. Most diuretics inhibit reabsorption of water at one of five functional zones along the nephron and the renal tubular system (kidneys). When the kidneys excrete more water (urine volume) this will lower blood volume and pressure and prevents excess fluid accumulation (reducing edema).

The potency of diuretics depends on the exact site of action. Loop diuretics that act on the loop of Henle are the most potent. Furosemide is currently, by far, the most commonly used loop diuretic. Diuretics are typically available in an oral dosage form. Two loop diuretics (furosemide and bumetanide) have both an oral and an IV available. Chlorothiazide (a thiazide diuretic (which has the distal convoluted tubule as site of action) is also available in an oral and an IV form.

Table 2: IV Diuretics sold in the U.S.

Sales in Units	2 016	2 017	2 018
Furosemide 10 mg/ml 2.4 and 10 ml	34,148,976	35,548,846	35,580,517
Bumetanide 0.25 mg/ml 4 and 10 ml	6,007,065	6,277,411	5,133,267
Chlorothiazide 500 mg	253,842	283,758	285,424

Source: IQVIA

Approximately 99.5% of the IV diuretics are sold in the U.S. hospital market. In 2018, both furosemide IV and bumetanide IV had significant use compared to tablets in the U.S. hospital market (respectively 8.8% and 14.3% of the molecule use)<sup>84</sup> and chlorothiazide sold 294,000 tablets in the U.S. hospital market.

A common issue in patients is a reduced response to diuretic therapy where congestion persists despite adequate diuretic therapy. Diuretic agent resistance is associated with insufficient symptom relief, higher risk of in-hospital worsening of heart failure, increased mortality after discharge, and a three-fold increase in re-hospitalization rates<sup>85</sup>. Another approach therefore is to administer two classes of diuretics together, a loop diuretic combined with a thiazide-like diuretic.

<sup>83</sup> Heart disease and Stroke Statistics, 2019 update, American heart association

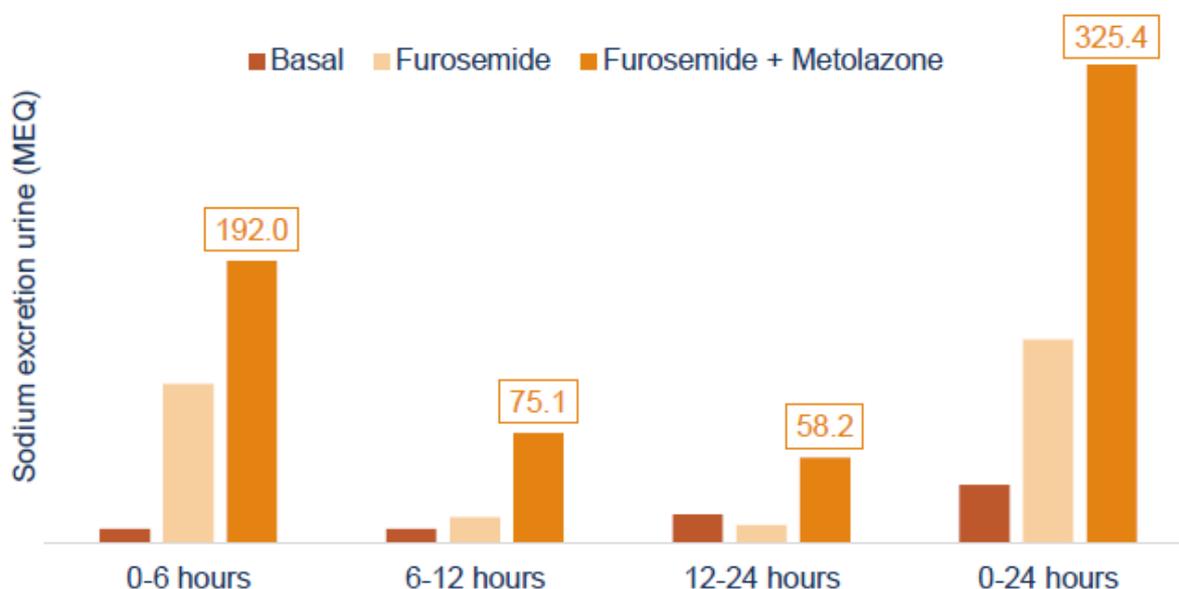
<sup>84</sup> IQVIA 2018 data

<sup>85</sup> Ellison et al, N Eng J Med, 2017

Metolazone is a thiazide-like diuretic launched in the United States in 1987 as an oral tablet under the name of Zaroxolyn® in tablets of 2.5, 5 and 10 mg. Metolazone is indicated for the concurrent treatment with furosemide in patients with congestive heart failure and hypertension where the edema or ascites are resistant to treatment with the maximum recommended doses of other diuretics administered alone. 38% of the patients with chronic heart failure have concurrent renal impairment, translating into an increased risk of diuretic resistance<sup>86, 87</sup>.

In congestive heart failure, patients with edema or ascites or being refractory to loop diuretics administered alone a marked diuresis (demonstrated through urine output, weight loss and sodium excretion) is produced with Metolazone and Furosemide administered concurrently.

Table 3: Average sodium excretion after furosemide or furosemide + metolazone



Source: D Sica and TWD Gehr, Diuretic Combinations in Refractory Oedema States: Pharmacokinetic-Pharmacodynamic Relationships, Clin Pharmacokinet, 1996 Mar;30(3):229-49.

Metolazone possesses a greater potency than other thiazide-like diuretics. It causes sodium excretion and diuresis even in advanced renal failure, coexisting renal insufficiency, chronic kidney disease and nephrotic syndrome. Metolazone also has a lower toxicity than other thiazide-like diuretics and can be used for patients with chronic kidney disease when given with furosemide, where it could have a better effect than other thiazide diuretics. Metolazone is rarely given as a monotherapy.

<sup>86</sup> McClellan WM et al, Anemia and renal insufficiency are independent risk factors for death among patients with congestive heart failure admitted to community hospitals: a population-based study, J Am Soc Nephrol 2002; 13: 1928–1936.

<sup>87</sup> Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. New Engl J Med. 2009;360:1418–28

The metolazone label includes a warning related to unusually large and prolonged losses of fluids and electrolytes resulting from the concomitant administration of metolazone with furosemide. In addition, severe electrolyte disturbances, and deterioration of renal function parameters, have been reported in clinical trials involving heart failure patients treated with metolazone in combination with furosemide<sup>88</sup>.

The sales of metolazone tablets in the United States in 2018 amounted to 44 million tablets of which 9 million tablets were sold in hospitals<sup>89</sup>.

### **C      *Limitations of the current standard of care***

Metolazone tablet formulations have highly variable bioavailability and erratic absorption, particularly in patients with severe gastrointestinal edema. Gastrointestinal edema leads to structural and functional abnormalities of the gastrointestinal tract which reduces the rate of drug absorption and leads to a delay in the time to achieve an effective therapeutic dose, with the consequent development of a diuretic resistance. Diuretic IV formulations have an improved bioavailability as demonstrated with the comparison of furosemide IV with the oral formulation<sup>90</sup>.

Furosemide IV has a 250% higher diuresis compared to furosemide tablets in edematous patients over a 24-hour period<sup>91</sup> (compared to only 15% in non-edematous patients) and had a five-fold reduction in body weight in edematous patients over a 24-hour period (7.5 kg versus 1.5 kg). As only 17.3% of the drug taken orally got absorbed in edematous patients the drug exposure of the IV (ng/ml/h) was 479% higher.

The  $T_{max}$  of the oral metolazone tablets (*i.e.*, the time when the maximum concentration of the drug is achieved in the blood) varies between three to seven hours post administration, which significantly delays the speed of onset of the drug<sup>92</sup>.

Since the effect of orally administered diuretics can be detrimentally impacted in these patients due to inadequate gastrointestinal absorption<sup>93</sup>, the use of intravenous formulations of diuretics is common. In order to be co-administered with IV furosemide, metolazone tablets must inconveniently be dosed two hours earlier to appropriately synergize the combination<sup>94</sup>. Due to these factors, Hyloris believes that existence of an intravenous metolazone may increase the use of metolazone.

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<sup>88</sup> K S Channer, K A McLean, P Lawson-Matthew, M Richardson, Combination diuretic treatment in severe heart failure: a randomised controlled trial, *Br Heart J* 1994;71:146-150; and Jens Rosenberg et al., Combination Therapy with Metolazone and Loop Diuretics in Outpatients with Refractory Heart Failure: An Observational Study and Review of the Literature, *Cardiovascular Drugs and Therapy* 19 301–306 2005.

<sup>89</sup> IQVIA 2018 data

<sup>90</sup> B.O. G. Odland And B. Beermann, 1980, *British Medical Journal*, Diuretic Resistance: Reduced Bioavailability and Effect Of Oral Frusemide

<sup>91</sup> B.O. G. Odland And B. Beermann, 1980, *British Medical Journal*, Diuretic Resistance: Reduced Bioavailability and Effect Of Oral Frusemide

<sup>92</sup> Mykrox® and Zaroxolyn® labelling

<sup>93</sup> Se Won Oh and Sang Youb Han, 2015, Loop Diuretics in Clinical Practice. *Electrolyte Blood Press.* 2015 Jun; 13(1): 17–21.

<sup>94</sup> Ernst ME, Moser M. Use of diuretics in patients with hypertension. *N Engl J Med.* 2009;361(22):2153–2164. doi: 10.1056/NEJMra0907219.

In a market study performed by Ridge Therapeutics, >60% of the surveyed physicians (cardiologists specializing in heart failure, nephrologists, and internists) indicated that furosemide required an add-on diuretic 21-40% of the time. Chlorothiazide IV and metolazone tablets are typically used as add-on diuretic (to Furosemide IV or Bumetanide IV) in the hospital in case of loop diuretic resistance. In the market study failure of other diuretics and *nil per os* (NPO, medical instruction meaning to withhold food and fluids) or absorption issues listed as major areas of potential use for IV metolazone. All participants in the study preferred IV versus oral diuretics for hospitalized patients and 85.7% indicated they currently prescribe metolazone tablets.

Furosemide and bumetanide (oral and IV) have been fully genericized. IV chlorothiazide was launched in 2000. Before generic entry in 2009, chlorothiazide sales in the United States amounted to USD 62 million with a sales price per vial of USD 276<sup>95</sup>.

#### **D Hyloris' product candidate: Metolazone IV**

Hyloris is developing an intravenous formulation of metolazone for the U.S. market that can be directly given to the patient when needed. Its benefits will include accelerating onset of action, allowing simultaneous administrations with furosemide, and improving drug absorption for patients with concomitant gastrointestinal edema. The intravenous formulation will also allow drug administration in patients who are too ill to receive oral medications or who are unconscious.

When available, diuretic products have a significant IV consumption in the hospital segment. In 2018, IQVIA hospital data for furosemide IV and bumetanide IV showed that they had an 8.8% and 14.3% share, respectively, of total molecule unit sales. Metolazone had sales of 9 million tablets in the hospital segment in 2018 in tablets of 2.5, 5 and 10 mg. Hyloris believes that the current use of furosemide IV and bumetanide IV could be an indication of the potential market size of Metolazone IV, and therefore believes Metolazone IV could capture a significant market share of the metolazone market.

#### **E Metolazone IV's clinical status, regulatory status and commercial strategy**

Metolazone is poorly soluble in water making the formulation of an IV product complex. Hyloris has worked on different formulation approaches including very complex formulation technologies which can be administered intravenously. Once the final product formulation is selected, Hyloris plans to manufacture a GMP clinical batch and start a clinical study in H2 2021 with the primary objective to show that metolazone tablets can be substituted by IV administered metolazone. This will be established by showing attainment of similar drug concentrations using two routes of administration (IV and tablet) of metolazone in a cross-over study in less than 100 patients. The secondary objectives are to show similar safety profiles for oral and intravenous administered metolazone. Nonclinical studies will be performed prior to human studies. Additional (Phase 4) studies are planned to support the approval and commercialization. The development plan has integrated the feedback received mid-2019 from the pre-IND meeting which recommended a PK/PD-clinical study and non-clinical toxicology studies. The Company intends to submit the PK/PD-clinical study for IND filing to the FDA in the course of H2 2021. Hyloris commenced the product development collaboration with Academic Pharmaceuticals in 2019 (reference is made to Section 8.12.3 (Metolazone IV) for more information on this collaboration) and

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<sup>95</sup> IQVIA

intends to submit Metolazone IV for approval in 2023 and, once approved (expected in 2024), to commercialize Metolazone IV in the U.S. hospital market, through its own sales force.

### **8.10.2.3 HY-CVS-073 & HY-CVS-074**

#### **A *Disease: Coronary Heart Disease***

Coronary heart disease develops when the coronary arteries become damaged. The condition is usually caused by atherosclerosis (a build-up of fatty material and cholesterol-containing deposits or plaque inside the coronary arteries), which can lead to the formation of blood clots that block the blood flow and provoke acute coronary syndrome (ACS). Coronary heart disease could result in (i) a stable angina: episodic chest pain occurring on exertion and lasting two to five minutes, (ii) unstable angina: severe chest pain occurring at rest and lasting more than ten minutes, (iii) acute myocardial infarction: heart attack accompanied by a sensation of tightness, pressure or squeezing and (iv) sudden cardiac death: sudden death caused by loss of heart function.

Heart attack is the leading cause of death in the United States with more than 370,000 deaths every year<sup>96</sup>. About 18.2 million adults age 20 and older had a coronary heart disease in 2017 (about 6.7%)<sup>97</sup>. The estimated annual incidence of heart attack in the United States amounted to 605,000 new attacks and 200,000 recurrent attacks between 2005 and 2014<sup>98</sup>. Measured prior to the year 2000 approximately yearly 1.5 million people suffered from an unstable angina<sup>99</sup>. The risk of coronary heart disease increases with family history of coronary heart disease before the age of 50, older age, smoking tobacco, high blood pressure, high cholesterol, diabetes, lack of exercise and obesity.

#### **B *Current standard of care***

When ACS occurs, fast diagnosis and treatment is crucial and potentially lifesaving. The sooner treatment begins, the better the chances of survival<sup>100</sup>. If the blood flow is not restored quickly, the damage to the heart muscle can be permanent or the patient may die. Half of all deaths due to a heart attack occur in the first three to four hours after symptoms begin.

Therefore, when patients present symptoms of ACS, treatment with drugs dissolving the blood clots (*i.e.*, thrombolytic drugs) and drugs preventing the aggregation of blood platelets (*i.e.*, antiplatelet drugs) will be initiated immediately in order to improve blood flow, restore the heart function as quickly and best as possible and help relieve pain and distress. The main antiplatelet drugs currently used in the United States are the P<sub>2</sub>Y<sub>12</sub> inhibitors (such as Ticagrelor, Clopidogrel and Prasugrel), acetylsalicylic acid, cilostazol and glycoprotein IIb/IIIa receptor antagonists (such as abciximab, eptifibatide, tirofiban). Over

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<sup>96</sup> American Heart Association, Heart Disease & Stroke Statistics (2016)

<sup>97</sup> Centers for Disease Control and Prevention

<sup>98</sup> American Heart Association, Heart Disease & Stroke Statistics (2019)

<sup>99</sup> Manhapra and Borzak, 2000, Treatment Possibilities for Unstable Angina.

<sup>100</sup> The Complete Encyclopaedia of Medicine & Health, Johannes Schade

4.9 billion antiplatelet tablets are sold in the United States annually, of which over 660 million tablets in the hospital<sup>101</sup>.

A recently approved IV anti-platelet drug is cangrelor, which is indicated as an adjunct to percutaneous coronary intervention (PCI), for reducing the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients in who have not been treated with other anti-platelet therapies<sup>102</sup>. Cangrelor had sales of USD 25 million in 2018<sup>103</sup> (an increase of 30% over 2017) at an ex-factory price of USD 665 per IV<sup>104</sup>. Besides Cangrelor only the glycoprotein IIb/IIIa receptor inhibitors (tirofiban, abciximab and eptifibatide) are available in an IV form.

### **C      *Limitations of the current standard of care***

The major platelet aggregation inhibitors in the United States (except for cangrelor) are commercialized only in an oral form, which results in a significant delay in treatment onset (and are therefore not fully efficient to prevent a second cardiac event) as the maximum plasma concentration is reached only after 0.5 and 3 hours and there are potentially significant intra-individual differences in absorption rate. This is a major drawback for treating ACS, considering fast treatment is crucial and potentially lifesaving. Patients treated in the first three postinfarction hours have a reduction of risk of death of 26% compared to patients receiving first treatments after three hours<sup>105</sup>.

An effective administration requires an intravenous administration of the emergency drug therapy, followed by rapid transfer to an area with a high level of supervision and resuscitation facilities<sup>106</sup>. Furthermore, an IV formulation would permit circumvention of common comorbidities such as lack of consciousness or vomiting that complicate oral administration.

Existing IV antiplatelet products are mainly used during percutaneous coronary intervention (PCI, angioplasty with or without intracoronary stent placement) and require continuous infusion. There is no oral form available for these IV antiplatelet products. Cangrelor must be given as a bolus (i.e a single intravenous administration of a drug in a short timeframe) before PCI and followed by continuous administration as it has an ultra-short half-life. Guideline recommendations on how to transition from intravenous to oral therapies are lacking<sup>107</sup>, while potential drug interactions have been described in the scientific literature<sup>108,109,110</sup>.

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<sup>101</sup> IQVIA 2015-2018

<sup>102</sup> Label, KENGREAL® (cangrelor) for injection, for intravenous use, Revised 10/2019

<sup>103</sup> IQVIA 2018 data

<sup>104</sup> IQVIA 2018 data

<sup>105</sup> Rogério Sarmiento-Leite et al, Acute Myocardial Infarction. One Century of History, Arq Bras Cardiol, volume 77 (n° 6), 602-10, 2001

<sup>106</sup> Simon Maxwell, 1999, Emergency management of acute myocardial infarction

<sup>107</sup> Fabiana Rollini et al, Switching P2Y12-receptor inhibitors in patients with coronary artery disease, Nature Reviews Cardiology volume 13, pages11–27(2016)

<sup>108</sup> Dominick J. Angiolillo, International Expert Consensus on Switching Platelet P2Y12 Receptor–Inhibiting Therapies, Circulation. 2017;136:1955–1975.

<sup>109</sup> Schneider DJ et al, Pharmacodynamic effects during the transition between cangrelor and prasugrel, Coron Artery Dis. 2015 Jan;26(1):42-8.

<sup>110</sup> Steinhubl SR et al, Transitioning patients from cangrelor to clopidogrel: pharmacodynamic evidence of a competitive effect, Thromb Res. 2008;121(4):527-34

The (optimal) switching strategy from an IV antiplatelet product to a different (oral) anti-platelet therapy is a concern because of the potential drug interactions between the intravenous and the oral therapies.

Hyloris' product candidates will be available in intravenous form and are currently available in oral form which will allow an optimal switching strategy from intravenous to (currently available) oral anti-thrombotic therapy.

#### **D      *Hyloris' product candidates: HY-CVS-073 and HY-CVS-074***

Hyloris is developing two intravenous injectable product candidates, each based on a platelet aggregation inhibitor that is currently available in an oral form only.

Previous clinical trials have shown that the oral form of HY-CVS-073 as well as HY-CVS-074 are efficient in the reduction of mortality rate in patients suffering of myocardial infarction. Both drugs work in different places of the clotting cascade and prevent platelet adhesion. They are recommended by several guidelines such as the 2013 American College of Cardiology Foundation/American Heart Association (ACCF/AHA) Guideline for the Management of STEMI and the 2014 American College of Cardiology/American Heart Association (ACC/AHA) Guideline for the Management of Non–ST-elevation Acute Coronary Syndrome.

Hyloris believes all patients with severe ACS (i.e. patients with acute myocardial infarction and unstable angina) are eligible to receive a dose of HY-CVS-073 and 50% to 60% are eligible to receive HY-CVS-074. Hyloris believes that a very significant market share can be captured. HY-CVS-073 and HY-CVS-074 should allow healthcare providers to achieve a faster onset of the inhibition of platelet aggregation, which is crucial when suffering from a myocardial infarction or from an unstable angina condition, compared to the oral dosage form in patients with ACS. In addition, HY-CVS-073 and HY-CVS-074 can be administered when a patient is nauseated or unconscious.

As HY-CVS-073 and HY-CVS-074 each target a different molecule, no cannibalization is expected. Hyloris does not expect that the medical community will change the molecule of choice for treatment rather it will make the treatment more efficient. HY-CVS-073 and HY-CVS-074 have both been in-licensed by Hyloris from Academic Pharmaceuticals, which will also be involved in the development of these product candidates (see Section 8.12.4 (HY-CVS-073) and Section 8.12.5 (HY-CVS-074) for more information on the binding term sheets regarding HY-CVS-073, respectively, HY-CVS-074).

#### **E      *HY-CVS-073 and HY-CVS-074's clinical status, regulatory status and commercial strategy***

Both HY-CVS-073 and HY-CVS-074 are in formulation development where focus is on finding technologies that allow the development of intravenous injectable products of low water-soluble molecules. Due to their inherent chemical instability and poor solubility, they present formulation challenges. However, Hyloris believes, based on its extensive reformulation experience, that it should be able to develop appropriate formulations for HY-CVS-073 and HY-CVS-074 in intravenous form, and expects to do so by H2 2020.

A pre-IND meeting has not yet been requested by the Company for either product candidate. The Company intends to initiate a pharmacokinetics/pharmacodynamics-clinical study for each candidate and file an IND with the FDA in the course of H2 2021.

Both HY-CVS-073 and HY-CVS-074 are targeted to be filed with the FDA in or before 2023 and can, once approved, be used for the immediate treatment of patients who are unable to take the product orally and for all patients who are presented with ACS. Additional target markets (such as patients requiring a stent) are under investigation. Hyloris expects the FDA's approval in the course of 2024, after which it intends to commercialize HY-CVS-073 and HY-CVS-074 through its own sales force in the United States.

### **8.10.3 OTHER REFORMULATION PORTFOLIO**

Hyloris has a portfolio of various other reformulations outside of the cardiovascular space. Two of these are reformulations, Maxigesic® IV and HY-REF-004, while the others can be subdivided into two main categories – (a) IV RTU conversions and (b) oral solid to oral liquid conversions.

#### **8.10.3.1 MAXIGESIC® IV**

##### **A Pain**

Pain is a distressing sensory and emotional feeling which normally occurs due to tissue damage or illness. The duration of pain varies from short term, known as acute pain, to long term referred to as chronic pain.

Acute pain is generally defined as pain with relatively short duration and recent onset, with an easily identifiable cause. In the hospital setting, acute pain is generally classified as post-operative or non-operative. Post-operative pain is a response to tissue damage during surgery that stimulates peripheral nerves, which signal the brain to produce a sensory and emotional response. Post-operative pain may occur not only at the surgical site but also in areas not directly affected by the surgical procedure.

Although acute pain is predictable after operations, the management of postoperative pain is a difficult challenge for anesthesiologists.

In 2010, 28.6 million surgical procedures were performed in the United States and despite the increased knowledge about nociception and advance in pharmacology, over 80% of surgical patients are reported to experience moderate pain and 31-37% of patients experience severe or extreme pain<sup>111</sup>.

Chronic or persistent pain carries on for longer than 12 weeks despite medication or treatment<sup>112</sup>. Most people get back to normal after pain following an injury or operation. But sometimes the pain carries on for longer or comes on without any history of an injury or operation.

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<sup>111</sup> Wonuk Koh et al, Intravenous non-opioid analgesia for peri- and postoperative pain management: a scientific review of intravenous acetaminophen and ibuprofen, Korean J Anesthesiol. 2015 Feb; 68(1): 3–12

<sup>112</sup> Koes BW et al, An updated overview of clinical guidelines for the management of non-specific low back pain in primary care, European Spine Journal. 2010, 19 (12): 2075–94

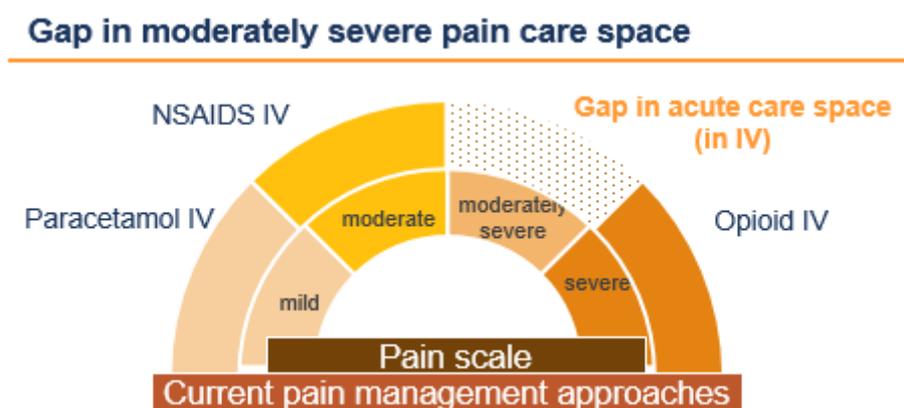
## B Current standard of care and its limitations

The management of pain involves treatment using a particular set of drugs and is one of the most frequently dealt-with issues by physicians. Despite major improvements in surgical techniques and the introduction of novel drugs, the overall treatment of post-operative pain has not substantially improved over the last 20 years. Drugs used to treat pain can be categorized in two groups: anesthetics and analgesics. Anesthetics temporarily affect, and in some instances, completely eliminate sensation. Analgesics achieve this effect by acting on the brain or peripheral nervous system to suppress responses to sensory stimulation.

Analgesics are typically classified in two groups: opioids and non-opioids. Opioids are substances that act on opioid receptors to produce a morphine-like effect and are frequently referred to as narcotics. Opioids are critical for post-surgical pain management because of their powerful effect. But side effects can be significant, including nausea, vomiting, constipation, urinary retention, drowsiness, impaired thinking skills and poor respiratory function. Overdosing (130 American die from opioid-related overdoses every day<sup>113</sup>, a six-fold increase from 1999 to 2017)<sup>114</sup> and abuse (in 2018 10 million Americans misused prescription opioids)<sup>115</sup> of opioids also pose a risk, particularly when opioids are used to treat chronic pain.

Paracetamol and ibuprofen are considered non-opioid analgesics (they do not bind to the opioid receptors). Paracetamol is the most widely used drug for pain relief and the reduction of fever in the world. The mechanism of action of paracetamol remains not fully understood. Ibuprofen is an NSAID (non-steroidal anti-inflammatory drug), which is a group of drugs that decrease pain, lower fever and, at higher doses, decrease inflammation. In the United States, there is traditionally a high use of opioids<sup>116</sup>. The Company believes that an underlying reason for this is the gap in moderately severe pain management, for which currently available non-opioids are not considered strong enough.

Figure 7: Gap in pain care space.



<sup>113</sup> U.S. Department of Health and Human Services, 2019, What is the U.S. Opioid Epidemic

<sup>114</sup> Nature, September 11th 2019, Tracing the US opioid crisis to its roots

<sup>115</sup> U.S. Department of Health and Human Services, 2019, What is the U.S. Opioid Epidemic

<sup>116</sup> Traci Green et al, Epidemiologic trends and geographic patterns of fatal opioid intoxications in Connecticut, USA: 1997–2007, Drug and Alcohol Dependence, Volume 115, Issue 3, 1 June 2011, Pages 221-228

Source: Hyloris.

Injectable formulations of analgesics are typically used when patients are unable to take oral medications, when faster onset of analgesia is required, or when it is more convenient to administer drugs in injectable form. Hospitalized patients may be unable to take oral medications for a variety of reasons including post-anesthesia sedation, other forms of sedation, nausea, vomiting, gastrointestinal limitations or other conditions.

In 2018, more than 260 million vials of IV paracetamol were sold globally, representing a global market in excess of USD 700 million with a compounded annual growth rate (**CAGR**) of approximately 5%<sup>117</sup>, evidencing the growing need of intravenous non-opioid analgesics. These figures include Ofirmev, the U.S. reference brand of IV paracetamol, which has a CAGR of 5.5% on a unit basis and 8.7% on value basis over the period of 2016 – 2018<sup>118</sup>. A total 1.2 billion injections (including IV paracetamol) for non-narcotic analgesics were sold in 2018<sup>119</sup>. Research, by life science consulting and market research firm Delveinsight, estimates the market for postoperative pain relief will grow at a CAGR of 10.26% from USD 1.1 billion in 2019 to reach USD 2.6 billion in 2028<sup>120</sup>.

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<sup>117</sup> IQVIA

<sup>118</sup> IQVIA

<sup>119</sup> IQVIA

<sup>120</sup> <https://www.delveinsight.com>

The following table shows the main analgesic IV drugs that are used to manage pain on the U.S. market, primarily in hospitals:

Table 4: Use of major non-narcotic and narcotic IV analgesics in the U.S. 2016 – 2018.

	Sales units 2016 (1,000)	Sales units 2017 (1,000)	Sales units 2018 (1,000)	Sales USD 2016 (1,000)	Sales USD 2017 (1,000)	Sales USD 2018 (1,000)
<b>Total IV market</b>	286,428	273,675	244,975	730,830	729,836	748,800
<b>Non-narcotics</b>	57,078	59,825	62,015	366,720	389,270	406,675
Paracetamol (under Ofirmev brand name)	9,725	10,095	10,824	280,969	304,784	332,485
Ketorolac	45,628	48,225	49,752	72,888	73,551	61,395
Nalbuphine	1,365	1,187	1,154	8,962	7,607	9,239
Ibuprofen	291	278	272	2,648	2,733	3,309
<b>Narcotics</b>	229,350	213,851	182,960	364,110	340,566	342,125
Morphine	69,182	61,803	54,476	111,594	103,874	113,016
Hydromorphone	81,778	71,333	47,644	142,678	129,715	104,454
Fentanyl	69,735	73,364	74,083	67,428	69,175	91,519
Buprenorphine	1,943	1,446	1,265	13,605	13,467	14,072
Pethidine	5,807	5,078	4,678	14,809	11,760	9,331
Methadone	34	26	21	10,806	9,424	6,665
Butorphanol	871	799	793	3,189	3,150	3,069
<b>Non-narcotic IV analgesics in% of total</b>	20%	22%	25%	50%	53%	54%
<b>Non-narcotic IV analgesics price/unit (USD)</b>				6.42	6.51	6.56
<b>Narcotic IV analgesics price/unit (USD)</b>				1.59	1.59	1.87

Source IQVIA.

As set out in the table above, the IV analgesic market decreased from 286.4 million units in 2016 to 245.0 million units in 2018. This decrease was primarily driven by the decrease in the use of opioids. Despite the overall market decline, sales of non-opioids actually increased from 57 million to 62 million units over the same period. The table also shows that, even though the market share of the non-narcotic IV analgesics increased from approximately 20% in 2016 to 25% in 2018, its share in the total market value is about 54%. This is largely due to the sales of Ofirmev, which enjoys premium pricing as it is patent protected in the United States. Ofirmev was launched in 2011 in the United States by Cadence, acquired by Mallinckrodt in 2014 for USD 1.4 billion. Following the settlements between numerous generic filers and Mallinckrodt Pharmaceuticals, generic entry is expected in December 2020. Unit sales of paracetamol IV are expected to increase after generics become available.

The table above does not contain anesthetics, such as Pacira's Exparel<sup>®</sup>, which is used in a variety of surgical procedures and can block nerve impulses. Exparel<sup>®</sup> generated U.S. sales of more than USD 400 million in 2019<sup>121</sup>, aided by evidence that it reduces opioid use.

### **C Hyloris' product: Maxigesic<sup>®</sup> IV**

Maxigesic<sup>®</sup> IV is a novel combination of paracetamol (also called acetaminophen in the United States) and ibuprofen in an intravenous form. Maxigesic<sup>®</sup>'s fixed-dose combination tablets containing paracetamol and ibuprofen tablets have been previously developed by AFT Pharmaceuticals and are already available in many countries (including specific EU and Asian countries and Canada). A fixed-dose combination of ibuprofen 300 mg combined with paracetamol 1,000 mg, when formulated as oral tablets, has been shown (in a Phase 3 trial with 408-patients) to provide superior acute pain relief when compared to its individual components<sup>122</sup>.

Where Maxigesic<sup>®</sup> tablets are typically a self-administered home care product, Maxigesic<sup>®</sup> IV is a hospital product. An intravenous formulation of Maxigesic<sup>®</sup> tablets has been developed for administration to patients in whom the use of oral analgesics is limited by various patient factors, such as inability to swallow, the presence of postoperative nausea and vomiting, or reduced gastric motility.

AFT Pharmaceuticals has demonstrated in various clinical studies that Maxigesic<sup>®</sup> is as safe as paracetamol and ibuprofen used separately<sup>123</sup> and that the drugs do not interact when co-administered.

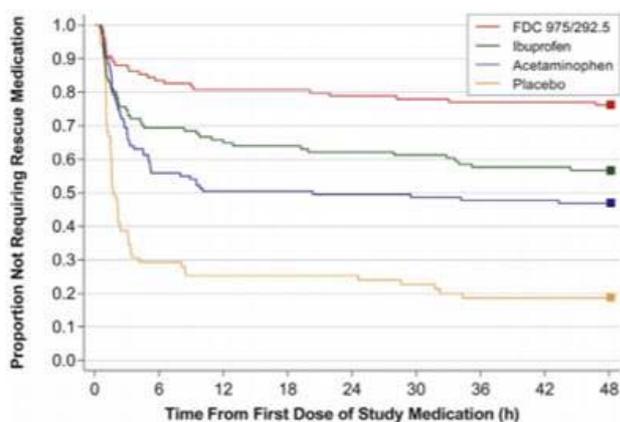
Although clinical data generated for Maxigesic<sup>®</sup> tablets is used to support filings of Maxigesic<sup>®</sup> IV, Hyloris is exclusively involved in the development of Maxigesic<sup>®</sup> IV and expects financial income exclusively related to Maxigesic<sup>®</sup> IV sales in all territories with the exception of Australia and New Zealand.

*Figure 8: Time to first use of rescue medication. FDC 975/292.5 = fixed-dose combination of acetaminophen 975 mg + ibuprofen 292.5 mg.*

<sup>121</sup> <http://investor.pacira.com/news-releases/news-release-details/pacira-reports-record-fourth-quarter-and-full-year-revenues-0>

<sup>122</sup> S.E. Daniels et al, 2018, Analgesic Efficacy of an Acetaminophen/Ibuprofen Fixed-dose Combination in Moderate to Severe Postoperative Dental Pain: A Randomized, Double-blind, Parallel-group, Placebo-controlled Trial, Clin Ther. 2018 Oct;40(10):1765-1776

<sup>123</sup> Aitken et al, 2019



Source: Stephen E. Daniels, Hartley C. Atkinson et al, Analgesic Efficacy of an Acetaminophen/Ibuprofen Fixed-dose Combination in Moderate to Severe Postoperative Dental Pain: A Randomized, Double-blind, Parallel-group, Placebo-controlled Trial. *Pharmacokinetics and Bioavailability of a Fixed-Dose Combination of Ibuprofen and Paracetamol after Intravenous and Oral Administration*, *Clinical Therapeutics*, volume 40, issue 10, p1765-1776. *Clin Drug Investig.* 2015; 35(10): 625–632. FDC 975/292.5 refers to Maxigesic® tablets; Acetaminophen is the U.S. name for Paracetamol tablets

AFT Pharmaceuticals has previously performed a clinical trial on Maxigesic® tablets. The Phase 3 study demonstrated that pain management with Maxigesic® oral tablets reduced the use of opioid rescue medication. The mean total dose of the opioid oxycodone in the Maxigesic® oral group was significantly lower than in the other groups. 87.2% of subjects the Maxigesic® group achieved at least a 50% reduction in baseline VAS pain (a Visual Analogue Scale (VAS) pain is a measurement instrument allowing the patient to self-evaluate the pain during a clinical trial) without the use of rescue medication. The response rates were significantly lower for paracetamol alone (69.4%), ibuprofen alone (76.6%), and placebo (37.3%; all,  $P < 0.05$ )<sup>124</sup>.

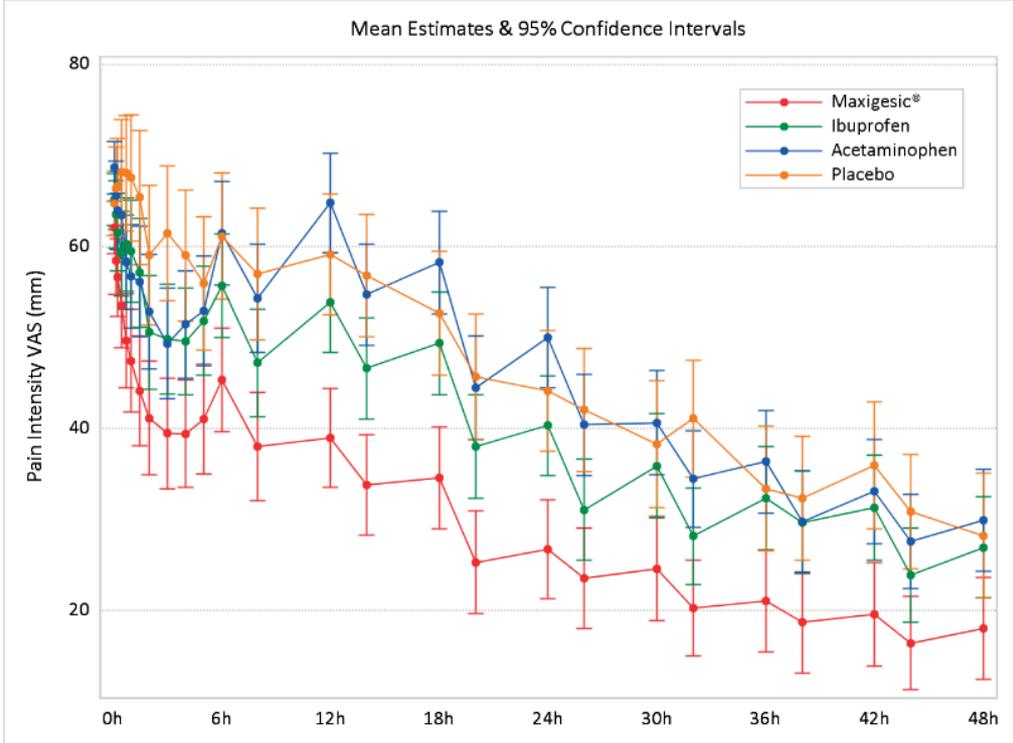
These findings were also demonstrated in a prospective, randomized, double-blind, multicenter, placebo-controlled factorial Phase 3 clinical trial conducted in the United States conducted by Hyloris' partner AFT Pharmaceuticals using the IV formulation. Maxigesic® IV was clinically proven to perform significantly better than either paracetamol or ibuprofen alone without compromising in tolerability<sup>125</sup>. In particular, it was found that the onset of pain relief was significantly faster with the combination than for placebo or paracetamol or ibuprofen alone. The trial, which examined pain relief measured by Visual Analog Scales (VAS) score in 276 patients following bunion surgery, found that the amount of pain relief provided by Maxigesic® IV was approximately double that of either IV paracetamol or IV ibuprofen alone and had significantly greater pain relief at the majority of scheduled time points. In addition, the Maxigesic® IV treatment group was found to have approximately 30% less median opioid consumption

<sup>124</sup> S.E. Daniels et al, Analgesic Efficacy of an Acetaminophen/Ibuprofen Fixed-dose Combination in Moderate to Severe Postoperative Dental Pain: A Randomized, Double-blind, Parallel-group, Placebo-controlled Trial, *Clin Ther.* 2018 Oct;40(10):1765-1776

<sup>125</sup> Daniels, S. E., Playne, R., Stanescu, I., Zhang, J., Gottlieb, I. J., & Atkinson, H. C. (2019). Efficacy and Safety of an Intravenous Acetaminophen/Ibuprofen Fixed-dose Combination After Bunionectomy: a Randomized, Double-Blind, Factorial, Placebo-controlled Trial. *Clinical therapeutics*

than the paracetamol and ibuprofen groups. At every time interval measurement point, the pain score was statistically better:

Figure 9: VAS Pain Intensity Scores Over Time, for Maxigesic®, Ibuprofen, Paracetamol and placebo.



Source AFT Pharmaceuticals

Reference is made to Section 8.12.6 (Maxigesic® IV) for more information on the agreements with Neogen Developments (a member of the Alter Pharma group<sup>126</sup>) and AFT Pharmaceuticals regarding Maxigesic® IV.

Hyloris expects to convert market share from paracetamol IV and to a (lesser) extent Ketorolac IV, and expects the opioid consumption will decline in patients using Maxigesic® IV.

**D Maxigesic® IV's clinical status, regulatory status and commercial strategy**

The pain reduction profile demonstrated by Maxigesic® IV in the Phase 3 leads Hyloris to believe that it can be positioned for relief of mild to moderate pain or as an adjunct or alternative to intravenous opioids for moderate to severe pain in the U.S. hospital setting. Maxigesic® IV also allows for administration to patients in whom the use of oral analgesics is limited by various factors such as inability to swallow, the presence of post-operative nausea and vomiting, or reduced gastric motility.

To be able to submit to the FDA, a second Phase 3 open-label, multiple-dose, single-arm exposure study of Maxigesic® IV has been initiated. The trial focuses on patients with acute pain following

<sup>126</sup> The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

orthopedic, general or plastic surgery study. The results of this second Phase 3 clinical trial are expected to be available in H2 2020.

Maxigesic® IV has been launched by AFT Pharmaceuticals in June 2020 in Australia and New Zealand, from which Hyloris will not receive any part of the profits generated (see also Section 8.12.6.2 (AFT Pharmaceuticals – Development collaboration agreement), and is expected to be launched in the summer of 2020 in the United Arab Emirates where the approval of relevant regulatory authority has been obtained earlier in 2020. Maxigesic® IV has also been submitted with regulatory authorities in 18 EU countries (in relation to which a number of approvals by European regulatory authorities are currently in the administrative phase of marketing authorization issuance and are expected throughout H2 2020), South Africa, South Korea and Israel. In each of these countries, Maxigesic® IV will be launched soon after the necessary approvals by the relevant regulatory authorities have been obtained. After product approval typically several months are needed to obtain other necessary approvals (such as price and reimbursement from the appropriate authorities) before the product is launched commercially. Hyloris expects that Maxigesic® IV will be submitted to the FDA in H2 2020 and expects the FDA's approval for H2 2021. The launch in the United States is expected to take place shortly after the FDA's approval.

The ambition is to ensure Maxigesic® IV will be available in all major territories as Hyloris believes that Maxigesic® IV has global potential. AFT Pharmaceuticals, which is involved in the product's development and is responsible for its commercialization strategy (see Section 8.12.6.2 (AFT Pharmaceuticals – Development collaboration agreement), has already out-licensed Maxigesic® IV to partners covering more than 80 countries and is in discussions to cover other territories including Japan, China and the United States. Hyloris expects Maxigesic® IV to be commercialized through AFT Pharmaceuticals in the United Arab Emirates and a number of Asian countries. Maxigesic® IV has several patents (see Section 8.17 (Intellectual Property)).

IV paracetamol, when launched in 2002 (as a replacement of IV propacetamol), had in most countries a price between USD 2.50 and USD 11.00 per vial, with an average of USD 3.00 per vial, excluding the United States<sup>127</sup>. Paracetamol IV was only launched in the United States in 2011, with U.S. patents providing protection. As there was no propacetamol previously available and the U.S. reimbursement and payor system is significantly different, the price of the reference brand is substantially higher than in Europe and has increased substantially since its launch<sup>128</sup>. Currently, multiple generic versions are available outside of the United States and European generic entry occurred already in 2010. Current WAC pricing of IV paracetamol in the United States is USD 47.00<sup>129</sup> with an IQVIA ex-factory price of USD 34.00 per vial, which the Company believes will decrease significantly following generic competition entry in December 2020. Maxigesic® IV is expected to have a reasonable price premium in most territories, due to its superior effect to IV paracetamol.

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<sup>127</sup> AFT Pharmaceuticals & Delveinsight (Postoperative Pain Market Insights, Epidemiology and Market Forecast—2028)

<sup>128</sup> AFT Pharmaceuticals & Delveinsight (Postoperative Pain Market Insights, Epidemiology and Market Forecast—2028)

<sup>129</sup> PriceRX.

IV ibuprofen has been in existence for many years in two strengths: a 10 mg injection used to treat patent ductus arteriosus in newborn premature babies – a rare (orphan) disease – and in higher doses (mainly 300, 400 and, occasionally, 800 mg) as a painkiller. In 2017 to 2019, B.Braun has launched a 400 and 600 mg Ibuprofen in 100 ml infusion in a range of European countries with prices between EUR 1.13 and EUR 5.65 (weighted average EUR 4.03 EUR) for the 400 mg/100 ml and between EUR 1.43 and EUR 6.85 (weighted average EUR 3.55 ) for the 600 mg/100 ml<sup>130</sup>.

According to Delvensight<sup>131</sup>, the market size of postoperative pain therapies in the United States is expected to increase to USD 1,705.55 million by the end of 2028 (up from USD 743.27 million in 2017) with Maxigesic® IV surpassing forecasts for all other currently marketed and all other identified emerging drug therapies, and expects the sales of the Maxigesic®-platform (*i.e.*, including the oral form of Maxigesic®) in the United States, Japan and the top five European countries (*i.e.*, France, Germany, Italy, Spain and the United Kingdom) in 2028 to amount to USD 442 million.

### **8.10.3.2 HY-REF-004**

#### **A *Complications during and following dental procedures:***

HY-REF-004 is a reformulation of an approved and well-established molecule. Hyloris is targeting HY-REF-004 for use following a dental procedure that approximately 500,000 people undergo each year in the United States, with complications that occur in the vast majority of the patients. HY-REF-004 allows for a new, more convenient route of administration that can be applied by dental care professionals or the patient.

#### **B *Current standard of care***

Currently, no other drugs are approved for the method of use by which HY-REF-004 is applied, however the product is being sold on a compounded basis.

#### **C *Limitations of the current standard of care***

Patients currently may experience procedure related complications and hence have to stay at or return to the dental office (or a hospital) to receive treatment for these. This dental procedure may occasionally require the altering or the temporarily interrupting of the intake of a drug (for a chronic disease) in order for the procedure to take place, which may cause health related issues and require additional monitoring of the patient.

#### **D *Hyloris' product candidate: HY-REF-004***

The commercialization of HY-REF-004, an oral liquid, will meet an unmet need in the dental practice, where HY-REF-004 will address an acute issue or possible procedural related complications.

Hyloris acquired all rights, titles and interests in HY-REF-004, including all intellectual property rights, proprietary information, authorizations and approvals related to HY-REF-004 from Kiel Laboratories Inc

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<sup>130</sup> IQVIA.

<sup>131</sup> DelveInsight Report (2020). Postoperative Pain Market Insights, Epidemiology and Market Forecast—2028. DelveInsight

and Codadose Inc, who will also be involved in the development. Reference is made to Section 8.12.7 (HY-REF-004) for more information on this agreement.

### ***E HY-REF-004's clinical status, regulatory status and commercial strategy***

Hyloris has completed the formulation of HY-REF-004, completed the manufacturing batches (which has been outsourced to a U.S. based manufacturer) of the registration batches and has long term stability data available.

The FDA confirmed following a Pre-IND meeting that no non-clinical study was needed. A pharmacokinetics clinical study assessing the pharmacokinetics profile of the product candidate must be conducted in healthy adult subjects that are undergoing a particular dental procedure. Hyloris plans to initiate the study in Q2 2020 with the objective to assess the pharmacokinetic profile (*i.e.*, the maximum drug concentration in the blood and in the saliva, the time to achieve the maximum drug concentration and the total patient exposure to the drug). The pharmacokinetics study will be performed by Biorasi LLC in Ukraine.

A Phase 3 study demonstrating safety and efficacy of the product in the targeted indication and population must be conducted. Specific exclusion criteria and endpoints were recommended by FDA and a pediatric study plan must be issued. The study initiation is expected for H1 2021. The CRO has not yet been selected.

The Company expects HY-REF-004 to be (i) filed with the FDA at the end of 2022/the beginning of 2023, (ii) approved by the FDA in H2 2023 and (iii) launched in 2024.

Currently no other drugs are approved for the method of use by which HY-REF-004 is applied and no immediate competitors have been identified. The product may potentially be registered with an orphan designation if Hyloris decides to reduce the size of its target population, potentially followed by the approved use in a wider population.

Hyloris intends to partner with a pharmaceutical or dental company to commercialize HY-REF-004 and expects to receive supply and (limited) licensing milestones related income. Hyloris anticipates selling HY-REF-004 at a price of approximately 200 USD/bottle<sup>132</sup>, however not all patients may receive a full bottle.

#### **8.10.3.3 IV RTU CONVERSIONS (READY-TO-USE)**

Hyloris has two product candidates that are IV RTU conversions. The principle of RTU conversions is to avoid unnecessary steps to prepare the product for administration in the hospital. The typical preparation process can include a dilution of a concentrate into an infusion or a conversion of an ampule/vial into a prefilled syringe. The intention of such conversions is to avoid unnecessary manual manipulations, which can lead to dosing errors, as well as to ensure that the health care professionals can focus on the actual healthcare.

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<sup>132</sup> Indicative management pricing assumption. For reference and only for indicative purposes the WAC pricing (*i.e.* pre discounting) for four oral liquids in the cardiovascular space: (i) Enalapril (USD 537/150 ml), (ii) Lisinopril (USD 540/150 ml), (iii) Sotalol (USD 446/240 ml, USD 856/480 ml), and (iv) Spironolactone (USD 3 20/ 118 ml, USD 1,154/473 ml) (Source: PriceRX).

## **A      *Tranexamic acid RTU***

### *Disorder: Hemophilia and bleeding complication*

Tranexamic acid is a product approved for hemophilia. Hemophilia is a rare genetically inherited disorder, primarily occurring in men, where the blood does not clot normally<sup>133</sup>. The total number of people living with hemophilia in the United States is estimated to be around 20,000<sup>134</sup> and around 400,000 worldwide<sup>135</sup>. Tranexamic acid is however also used in a series of other indications relating to bleeding complications outside of the United States (e.g., hemorrhage and fibrinolysis).

### *Current standard of care*

Tranexamic acid is an antifibrinolytic drug, meaning that it is able to stop bleeding by interfering with the bleeding process (fibrinolysis). By inhibiting the fibrinolysis, tranexamic acid promotes the formation of blood clots.

In the United States, tranexamic acid injection is indicated in patients with hemophilia for short-term use (two to eight days) to reduce or prevent hemorrhage and reduce the need for factor replacement therapy during and following tooth extraction and has to be administered as an intravenous bolus or an infusion. The use of Tranexamic acid reduces the risk of bleeding complications and therefore, reduces the usage of factor replacement therapies. Sales of Tranexamic acid injectable vials, have grown significantly from 49,000 vials in 2007 to 4,040,000 in 2018<sup>136</sup>. The Company believes this significant growth is due to the use of the product for a wider variety of conditions, such as prehospital injectable antifibrinolytic therapy during transport to trauma center of patients with non-compressible bleeding as it is also recommended in the U.S. guidelines<sup>137</sup>.

Outside of the United States, the drug is approved for a wide series of indications, such as hemorrhage or risk of hemorrhage in patients with increased fibrinolysis or fibrinogenolysis. Recent studies such as the CRASH-2<sup>138</sup> and MATTERS<sup>139</sup> studies suggest that tranexamic acid injectable should be used for additional indications other than hemophilia, especially in emergency trauma situations other than for preventive uses<sup>140</sup>. CRASH-2 studied death, vascular occlusive events, and transfusion requirement in bleeding trauma patients, whereas MATTERS studied trauma emergency resuscitation.

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<sup>133</sup> Mayo Clinical, Hemophilia, 22 Aug 2019

<sup>134</sup> Soucie et al, 1998, Occurrence of hemophilia in the United States, Am J Hematol. 1998 Dec;59(4):288-94.

<sup>135</sup> Stonebraker et al, 2010, A study of variations in the reported haemophilia A prevalence around the world. Haemophilia. 2010 Jan;16(1):20-32

<sup>136</sup> IQVIA

<sup>137</sup> Peter E. Fischer et al, Guidance Document for the Prehospital Use of Tranexamic Acid in Injured Patients, 2016, Prehospital Emergency Care, 20:5, 557-559

<sup>138</sup> I. Roberts et al, 2013, The CRASH-2 trial: a randomised controlled trial and economic evaluation of the effects of tranexamic acid on death, vascular occlusive events and transfusion requirement in bleeding trauma patients. Health Technol Assess. 2013 Mar;17(10)

<sup>139</sup> J. Morrison et al, 2012, Military Application of Tranexamic Acid in Trauma Emergency Resuscitation (MATTERS) Study. Arch Surg. 2012 Feb;147(2):113-9.

<sup>140</sup> Lier and Shander, Tranexamic acid: the king is dead, long live the king!, BJA, Volume 124, ISSUE 6, P659-662, JUNE 01, 2020

Hyloris does not intend to pursue any new indications for the product candidate.

#### Limitations of the current standard of care

For the preparation of an intravenous infusion, tranexamic acid injection 100 mg/ml must be diluted with a solution such as electrolyte, carbohydrate, amino acid or Dextran to obtain a concentration of 10 mg/ml before it can be used.

Recent scientific papers describe how an early administration of tranexamic acid safely reduces the risk of death in bleeding trauma patients<sup>141</sup>. Additionally, the use of tranexamic acid with blood component-based resuscitation following combat injury results in improved measures of coagulopathy and survival<sup>142</sup>. The CRASH-3 study<sup>143</sup>, a randomized, placebo-controlled trial conducted with adults having traumatic brain injury, showed that tranexamic acid is safe in patients with a traumatic brain injury and that treatment within three hours of injury reduces head injury-related death.

Recent scientific papers have concluded that patients should be treated with tranexamic acid as soon as possible after injury<sup>144</sup>. This conclusion was confirmed by a meta-analysis of randomized, placebo-controlled trials done with more than one thousand patients that assessed the effects of antifibrinolytics. The authors of that article concluded that tranexamic acid improves survival, but treatment delay reduces the benefit. Every 15 minutes of treatment delay decreases the pharmaceutical's effectiveness by about 10% with no benefit after three hours<sup>145</sup>.

*Figure 10: Reduction in effectiveness of tranexamic acid with increasing treatment delay.*

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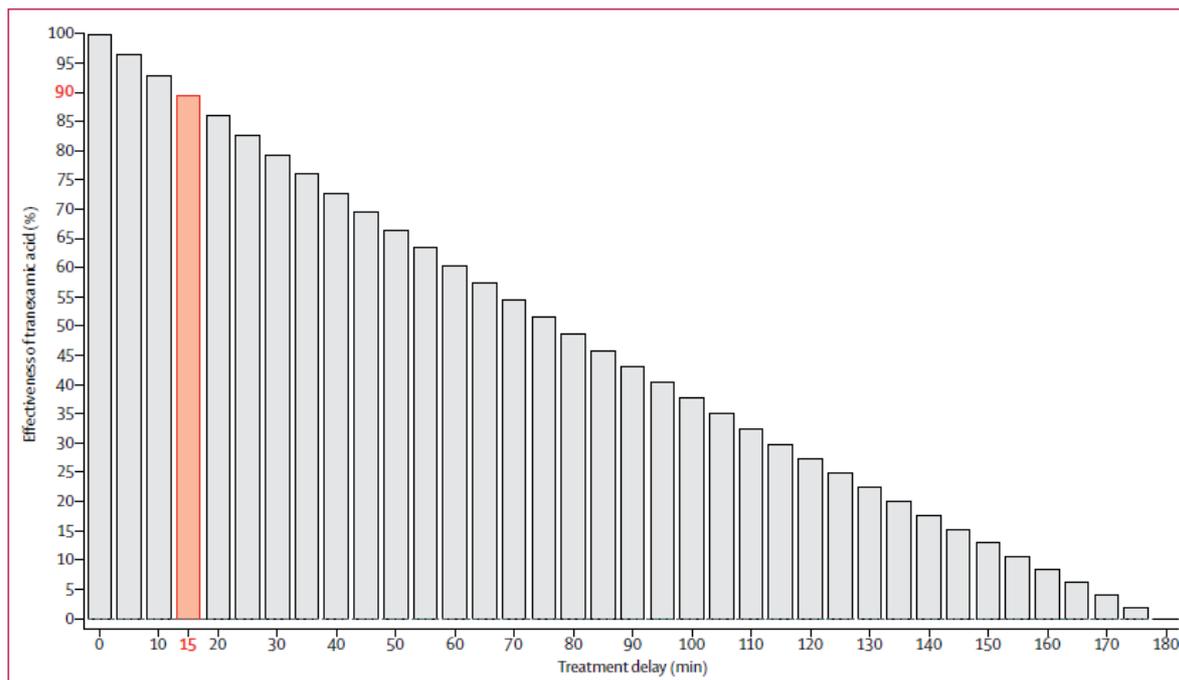
<sup>141</sup> I. Roberts et al, 2013, The CRASH-2 trial: a randomised controlled trial and economic evaluation of the effects of tranexamic acid on death, vascular occlusive events and transfusion requirement in bleeding trauma patients. *Health Technol Assess.* 2013 Mar;17(10)

<sup>142</sup> J. Morrison et al, 2012, Military Application of Tranexamic Acid in Trauma Emergency Resuscitation (MATTERs) Study. *Arch Surg.* 2012 Feb;147(2):113-9.

<sup>143</sup> Ian Roberts et al, Effects of tranexamic acid on death, disability, vascular occlusive events and other morbidities in patients with acute traumatic brain injury (CRASH-3): a randomised, placebo-controlled trial, *The Lancet*, volume 394, issue 10210, p1713-1723, november 09, 2019.

<sup>144</sup> I. Roberts et al, 2019, Effects of tranexamic acid on death, disability, vascular occlusive events and other morbidities in patients with acute traumatic brain injury (CRASH-3): a randomised, placebo-controlled trial. *The Lancet*, Volume 394, Issue 10210, P1713-1723, November 09, 2019

<sup>145</sup> A.Gayet-Ageron et al, 2018, Effect of treatment delay on the effectiveness and safety of antifibrinolytics in acute severe haemorrhage: a meta-analysis of individual patient-level data from 40 138 bleeding patients. *The Lancet*, Volume 391, Issue 10116, p125-132, January 13, 2018.



Source A.Gayet-Ageron et al, 2018, *Effect of treatment delay on the effectiveness and safety of antifibrinolytics in acute severe haemorrhage: a meta-analysis of individual patient-level data from 40 138 bleeding patients.*

#### Hyloris' product candidate: Tranexamic Acid Ready-To-Use

In order to optimize the injection of tranexamic acid and avoid unnecessary time wasted on pre-administration dilution manipulations and to avoid dosing errors, Hyloris has developed ready-to-use, prediluted solutions packed in infusion bottles with concentrations of 2.0g (10 mg/ml, 200ml), 1.0g (10mg/ml, 100ml) and 0.5g (5 mg/ml, 100ml). A ready-to-use injectable solution of tranexamic acid will bring the following advantages:

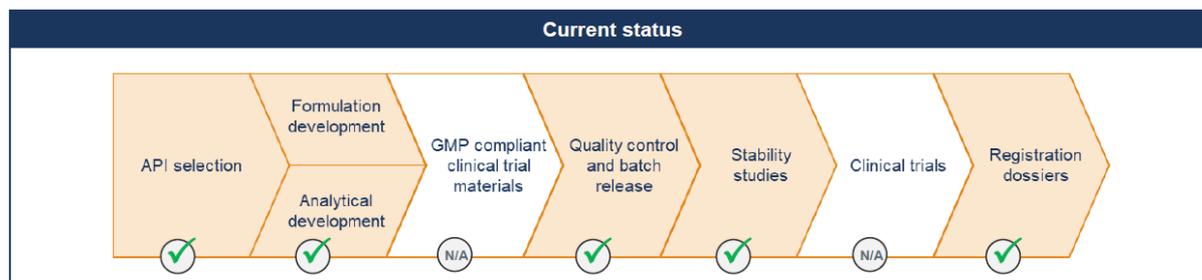
- facilitate the use of antifibrinolytic therapies for hemophilia patients and patients with trauma injuries; and
- save time for the healthcare administrators by eliminating the need of additional dilution procedures and manipulations before administration.

In April 2019, Exela Pharma Sciences LLC obtained approval of a 10 mg/ml version of tranexamic acid RTU in 100 ml sodium chloride. This competing product is substantially the same as one of the three strengths Hyloris is developing. Exela's product was launched in October 2019 at a WAC price of USD 21 per vial and gained 4.5%<sup>146</sup> of market share as of December 2019. Compared to the product of Exela Pharma Sciences LLC, Hyloris is proposing one additional strength of 5 mg/ml of Tranexamic Acid RTU in 100 ml, and an additional bottle volume of 200 ml for the 10 mg/ml Tranexamic acid RTU strength. As the infusion dosage depends on the body weight and varies from 10 mg/kg/h to 20 mg/kg/h, the additional strength and volume allow an improved coverage and convenience.

<sup>146</sup> IQVIA 2019

Hyloris expects that some hospitals will change to Tranexamic Acid RTU. Several other products have been transformed into an RTU formulation in the United States such as Esmolol IV and Dexmedetomidine IV, where the RTU version achieved market shares of 19.5% and 20.8% respectively, in 2018<sup>147</sup>.

Tranexamic acid RTU's clinical status, regulatory status and commercial strategy



No clinical studies were required for the NDA submission for Tranexamic Acid RTU. The FDA concluded that an in vivo bioequivalence study of an intravenous solution intended solely for administration by injection is self-evident<sup>148</sup>.

The product candidate will be manufactured in an FDA certified EU based CMO. Hyloris expects to submit the registration application to the FDA in early H2 2020 with approval expected in the second half of 2021. A launch is expected shortly thereafter.

Hyloris fully owns the IP and has a patent<sup>149</sup> application pending<sup>150</sup>, and intends to partner with a pharmaceutical company able to commercialize this product candidate to the relevant hospitals and buyers. Considering the presence of direct competitors (such as Exela Pharma Sciences LLC, generics manufacturers of the vials and possible additional entrants) pricing pressure is expected. This price pressure, together with deteriorating market conditions, might cause a significant decline in the revenues and profits from Tranexamic Acid RTU, which could result in the termination of the commercialization of Tranexamic Acid RTU in the future.

**B HY-REF-038**

Deficiency

HY-REF-038 references a pharmaceutical product that has been approved in its existing form for more than 30 years and which is very frequently administered to patients with a specific deficiency. More than two million people in the United States suffer from this condition. There are various formulations available to treat this deficiency, however the number of cases being treated with injections is growing due to several advantages of the injection as compared to alternative methods of treatment. For competitive reasons, Hyloris is unable to share further details on the specific deficiency.

<sup>147</sup> IQVIA

<sup>148</sup> Code of Federal Regulations Title 21

<sup>149</sup> Hyloris believes its patents may also cover Exela's formulation. Exela has no patents listed in the Orange Book for the moment. If/when they listed a patent it would be trigger a 30 month stay if generics companies file the product.

<sup>150</sup> See also Section 8.17.1 (Patents).

### Current standard of care

The current treatment consists of the administration of a drug in multi-dose and a single dose glass container. Sales in 2018 amounted to more than 20 million doses split between a multi-dose and a single dose container. The single dose container, which Hyloris' product is targeting, is primarily used in the retail market setting. Unit sales of the single dose container have grown with a CAGR of approximately 25% between 2016 and 2018<sup>151</sup> culminating to 10.6 million units sold in 2018 in the retail market. The cheapest generic version currently has a WAC of approximately USD 18.00 per unit, however this price is expected to be significantly discounted<sup>152</sup>. The IQVIA ex-factory sales for the current products are between USD 7.50 and USD 14.90.

The Company expects overall market growth with respect to HY-REF-038 to continue, albeit at a lower level, and expects to be able to command a premium price for the added convenience it provides.

### Limitations of the current standard of care

The currently marketed product is mainly sold in the retail sector and Hyloris believes it is to a large extent self-administered by the patient. The administration, which requires opening the container and loading a syringe before an injection can take place, is a cumbersome process for a non-healthcare professional.

### Hyloris' product candidate: HY-REF-038

In order to solve some of the limitations of the current standard of care, Hyloris is developing a prefilled syringe to allow administration of the drug. The most important advantages that prefilled syringes have over traditional packaging in glass containers are the ease of use and possible health economic benefit. Prefilled syringes essentially (i) eliminate the manipulations required for a drug in a glass container to be administered, (ii) increase the ease of use especially for non-healthcare professionals, and (iii) eliminate dosing errors because they contain the exact dose needed with no loss due to the withdrawal of drug from the container, which increases compliance and hence is expected to have an overall health economic benefit.

### HY-REF-038's clinical and regulatory status, and commercial strategy

In 2019, Hyloris entered into a development agreement with Generic Specialty Pharma (see Section 8.12.9.1 (Generic Specialty Pharma - Development Agreement)).

Hyloris does not expect to conduct any clinical trials for the product candidate. The FDA, through a controlled correspondence, has confirmed that HY-REF-038 should be filed via the ANDA regulatory pathway. The ANDA filing for HY-REF-038 is expected to take place in H2 2021.

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<sup>151</sup> IQVIA  
<sup>152</sup> PriceRX

Hyloris is primarily targeting the retail sector with this product candidate but does expect to be able to obtain a smaller market share in the hospital and the multi dose segment and at a lower premium price compared to the retail market.

Although promotional efforts focus mainly on creating product awareness, Hyloris intends to partner this product with a pharmaceutical company that is able to effectively commercialize the product to the relevant physicians.

#### **8.10.3.4 ORAL SOLID TO ORAL LIQUID CONVERSIONS**

Hyloris has several oral liquid product candidates in development aimed at improving patient compliance and easing administration to children and the elderly. The oral liquid product candidates are typically targeted at children, who Hyloris believes, in addition to a general discomfort and difficulties swallowing tablets and capsules, often have need for age-suitable dosing<sup>153</sup> or for drugs that need dose titration. Compared to liquid formulations, solid formulations may require manipulations from parents and caregivers. In a study by Fang et al., one third of participants reported having to manipulate solid medicines which could affect potential physicochemical effects and thus drug bioavailability and therapeutic responses<sup>154</sup>. Certain oral liquids could also have use in the elderly population, as 15%-22% of persons over the age of 50 suffer from dysphagia (difficulty swallowing)<sup>155</sup>.

The oral liquids may be formulated as either oral solutions, oral suspensions or powder for oral solution or suspension. This will typically be identified during the formulation trials and determined by the feasibility of making a stable solution.

##### **A *Atomoxetine Oral Liquid***

###### **Disorder: Attention deficit hyperactivity disorder (ADHD)**

ADHD is a chronic mental childhood-onset disorder characterized by developmentally inappropriate and impaired inattention, motor hyperactivity, and impulsivity, with difficulties often continuing into adulthood. Children and adolescents suffering from ADHD experience challenging key formative years. Because of impulsive behavior and slower rates of processing information, they perform poorly on standardized tests, score lower grades and are more likely to drop out of school. In addition, ADHD often presents itself with one or more comorbidities such as oppositional defiant disorder, major depressive disorder, and anxiety disorders, thus bestowing additional challenges on these individuals.

ADHD is among the most common neurobehavioral problems affecting children between the age of 6 and 17. Its prevalence in the United States ranges from 2% to 18% in this age group. About 60% to 80% of the symptoms of ADHD persist into adulthood. Thus, ADHD is not just a childhood disorder that

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<sup>153</sup> Fang Liu, et al. *Drugs*. 2014; 74(16): 1871–1889, Patient-Centered Pharmaceutical Design to Improve Acceptability of Medicines: Similarities and Differences in Paediatric and Geriatric Populations. *Drugs*. 2014; 74(16): 1871–1889

<sup>155</sup> Aslam M and Vaezi MF. Dysphagia in the elderly. *Gastroenterol Hepatol (N Y)*. 2013 Dec; 9(12): 784–795.)

resolves spontaneously after adolescence. It is estimated that about 4.0% to 4.5% of adults in the United States have ADHD<sup>156</sup>.

### Current standard of care

ADHD is treated by a variety of drugs. Stimulants are the most common type of medication prescribed which includes widely used drugs such as methylphenidate (brand name Ritalin), amphetamine, dexamphetamine and lisdexamfetamine. Stimulants are believed to work by increasing dopamine levels in the brain. Dopamine is a neurotransmitter associated with motivation, pleasure, attention and movement. For many people with ADHD, stimulant medications boost concentration and focus while reducing hyperactive and impulsive behaviors.

In addition to the traditional stimulant drugs, there are several other medications used to treat ADHD, including atomoxetine, atypical antidepressants and certain blood pressure medications. In most cases, non-stimulant medications are considered when stimulants haven't worked or have caused intolerable side effects<sup>157</sup>.

Strattera<sup>®</sup>, also known by its generic name atomoxetine, is the only non-stimulant medication approved by the FDA for ADHD treatment. Unlike stimulants, which affect dopamine, Strattera<sup>®</sup> boosts the levels of norepinephrine, a different brain chemical. Strattera<sup>®</sup> is longer-acting than the stimulant drugs as its effects last over 24 hours. Since it has some antidepressant properties, it's also a choice for those with co-existing anxiety or depression. In addition, it does not exacerbate tics or Tourette's Syndrome<sup>158</sup>.

Atomoxetine was approved by the FDA in 2002 for the treatment of ADHD and is currently manufactured, marketed, and sold in the United States under the brand name Strattera<sup>®</sup> as well as under generic names sold by several companies. Atomoxetine is currently marketed in the United States as capsules of 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg.

In 2019, atomoxetine had more than 2 million prescriptions<sup>159</sup> in the United States. The number of atomoxetine capsules sold over the past few years has grown from 88.5 million in 2016 to 93.6 million in 2018<sup>160</sup>.

### Limitations of the current standard of care

Administration of atomoxetine to pediatric patients can be challenging. The drug requires titration from 0.5 mg/kg increasing to 1.2 mg/kg and it is not always commercially available in appropriate dosage formulations and strengths. Furthermore, while a diagnosis of ADHD in children commonly occurs at around the age of six to seven, the current capsule formulation on the market exceeds 16 millimeters in

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<sup>156</sup> Sharma and Couture. A review of the pathophysiology, etiology and treatment of attention-deficit hyperactivity disorder (ADHD). *Ann Pharmacother*. 2014 Feb; 48(2):209-25.

<sup>157</sup> <https://www.helpguide.org/articles/add-adhd/medication-for-attention-deficit-disorder-adhd.htm>

<sup>158</sup> <https://www.helpguide.org/articles/add-adhd/medication-for-attention-deficit-disorder-adhd.htm>

<sup>159</sup> "The Top 300 of 2019". *clincalc.com*. Archived from the original on 21 November 2018. Retrieved 22 December 2018.

<sup>160</sup> IQVIA

length<sup>161</sup>, which is best avoided in children until the age of 11 years to prevent inadvertent inhalation or choking<sup>162</sup>.

Hyloris' product candidate: Atomoxetine Oral Solution

An oral solution of atomoxetine will provide significant clinical benefit to pediatric, adult and elderly patients by:

- Facilitating the use of atomoxetine in the pediatric, adult and elderly populations who are unable to tolerate or to swallow tablets. It is worth noting, that prevalence of ADHD in the elderly, a population with a higher occurrence of dysphagia, is approximately 3%<sup>163</sup>;
- Improving compliance and convenience during the therapy; and
- Facilitating the dose adjustment when the initial dosing is based on body weight, requiring the precise titration of the drug.

Most markets where the liquid formulation has been introduced have seen a significant increase in the market share of the oral liquid, showing that there is a need for this formulation <sup>164</sup>.

Table 5: Liquid penetration outside the United States (markets with more than one million USD sales).

	2016 (CU = doses)	2017 (CU = doses)	2018 (CU = doses)
Japan	8.3%	7.8%	6.8%
Germany	8.5%	9.5%	9.2%
UK	10.0%	17.9%	21.1%
Sweden	9.7%	11.8%	13.4%
Spain	7.8%	32.8%	38.9%
Mexico	0.0%	22.4%	40.7%
Turkey	0.0%	2.8%	7.2%
Romania	12.5%	36.8%	44.6%
Norway	4.4%	5.9%	8.2%
Switzerland	1.6%	8.8%	12.5%
Austria	14.7%	20.0%	23.1%
Ireland	13.4%	21.4%	24.7%
Hungary	51.8%	52.7%	49.3%

Source: IQVIA

<sup>161</sup> <https://www.drugs.com/pro/strattera.html>

<sup>162</sup> Van Riet-Nales DA et al. Oral medicines for children in the European paediatric investigation plans. PLoS One 2014; 9(6): e98348.

<sup>163</sup> Kooij JJ, Michielsen M, Kruithof H, Bijlenga D. ADHD in old age: a review of the literature and proposal for assessment and treatment. Expert Rev Neurother. 2016 Dec;16(12):1371-1381. Epub 2016 Jul 4.)

<sup>164</sup> IQVIA



Similarly, the U.S. market has shown receptivity to oral liquid formulations of other ADHD drugs with market shares varying from 3% – 60% as shown in the table below:

Table 6: Market shares of different forms in the U.S. market 2018 (CU = doses).

	IR Tablets	Capsules (IR)	Chewable tablets (IR)	SR tablets	SR capsules	Oral liquid (IR)	SR oral liquid	Patch (SR)	WAC range liquids
Atomoxetine	n/a	100%	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Lisdexamfetamine	n/a	98.4%	1.6%	n/a	n/a	n/a	n/a	n/a	n/a
Methylphenidate	36.3%	n/a	0.5%	44.1%	9.0%	6.4%	3.1%	0.6%	5 mg/ml: 70 – USD 376 10 mg/5 ml: USD 100 - USD 536 5-7 generic products
Amphetamine	19.0%	n/a	n/a	21.0%	n/a	n/a	60.0%	n/a	USD 577 – USD 678 in a market 1 generic product
Dexamphetamine	53.9%	n/a	n/a	n/a	34.3%	11.9%	n/a	n/a	USD 719 – USD 800 3 generic products.
Dexmethylphenidate	34.9%	n/a	n/a	n/a	65.1%	n/a	n/a	n/a	n/a
Modafinil	100.0%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Armodafinil	100.0%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Methamphetamine	100.0%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

Source: IQVIA and PriceRX for WAC (Actual sales prices, are believed to be below WAC, especially for the genericized products). IR = immediate release (an immediate-release drug breaks down immediately allowing an immediate release of the drug in the body). SR = sustained release (a sustained-release drug is designed to release the drug at a predetermined rate in order to maintain a constant drug concentration for a specific period of time with minimum side effects).

### Atomoxetine Oral Solution's clinical status, regulatory status and commercial strategy

Hyloris licensed a formulation of an oral solution from Taho Pharmaceuticals, an independent third party, along with two granted patents in the United States (reference is made to Section 8.12.10 (Atomoxetine Oral Liquid) for further information on this license agreement). This is a different formulation from the Strattera<sup>®</sup> liquid that is currently available in some countries. Taho Pharmaceuticals has performed two studies on the product candidate, one study compared it to the Japanese capsule formulation in 42 healthy people (since Taho is mainly active in Asia) and a pilot bioequivalence study was successfully performed on a slightly modified formulation in Malaysia comparing their Atomoxetine Oral Solution with the Japanese Strattera<sup>®</sup> liquid (Atomoxetine liquid as sold in Japan by the innovator) in 10 healthy volunteers. These studies illustrated the pharmacokinetics of Hyloris' atomoxetine product candidate, enabling the Company to design its clinical program more easily. As part of the in-licensing arrangement, Hyloris obtained access to all communication with the FDA, which established the pathway for approval. Hyloris will need to manufacture submission batches as well as perform a pharmacokinetic trial before compiling the dossier that will be submitted to FDA. Hyloris expects to initiate the pharmacokinetic study in H2 2020, submit the 505(b)(2) application to the FDA towards the end of H2 2021, to price the product at the level of existing liquid drugs in the same therapeutic category, and expects that the product will be approved and subsequently launched in H1 2023. Hyloris expects to develop Atomoxetine in a bottle equivalent to 23 40 mg doses. Full product development and commercial manufacturing will be performed by a U.S. based CMO.

Strattera<sup>®</sup> liquid has been developed and commercialized in several countries, but it is not commercialized in the United States. Hyloris' Atomoxetine Oral Solution is not an improvement, but a different formulation which was patented by our partner Taho. Considering there is a clear need for this product, potential competitors may be developing it and Hyloris may potentially not be first to market or might experience an impact on the expected registration or launch date. Although expected sales would be impacted, Hyloris believes the market is sufficiently large and that there is room for multiple players. Note that Hyloris has an approved patent and that the patent landscaping has not indicated other players yet.

Hyloris intends to partner Atomoxetine Oral Liquid with a pharmaceutical company active in pediatrics, neurology, or already active in the ADHD segment.

### **B HY-REF-029**

#### Viral infections

HY-REF-029 is an antiviral drug, which treats numerous conditions that affect adults as well as children. These conditions can be treated with different drugs, however the active ingredient of HY-REF-029 has several advantages over the key competitor, mainly in frequency and duration of dosing.

### Current standard of care

The current product has been marketed as an oral solid for more than 20 years and is not available in liquid form in the United States. In 2019, the product had more than four million prescriptions<sup>165</sup> and sold more than 400 million single units in 2018 growing at a CAGR of 9% from 2016 to 2018<sup>166</sup>.

In the same therapeutic category, there are a number of other molecules that have been made available in liquid form for which the market shares over the 2016-2018 period are shown below:

*Table 7: Market shares of liquid forms 2016-2018 for all major molecules in the U.S. market for the therapeutic category of HY-REF-029 as well as CAGR for the molecule. Both calculated on basis of SU = single units, all strengths considered equal). WAC for the liquid forms.*

	2016	2017	2018	CAGR	WAC range <sup>(1)</sup>
Molecule A	39.2%	38.1%	33.4%	78.0%	USD 70 – USD 190
Molecule B	7.6%	7.8%	7.5%	4.2%	USD 800 – USD 1,280 <sup>(2)</sup>
Molecule C	2.9%	3.2%	2.9%	-3.0%	USD 350 – USD 580 <sup>(2)</sup>
Molecule D	No liquid existing				N/A
Molecule E (HY-REF-029)	No liquid existing				

Source: IQVIA for 2016-2018 data, PriceRX for WAC

#### Note:

- (1) Recent IQVIA analysis shows, on average, the first generic company prices its product at 70-80% of the brand price<sup>167</sup>.
- (2) The IMS ex-factory price for molecule B and C was below the range of WAC prices.

### Limitations of the current standard of care

Administration of the product to pediatric patients can be challenging as it requires the appropriate dosage forms and strengths, which are often not commercially available. The product requires dose adjustments based on weight, which makes treatment with current oral solid formulations difficult. Furthermore, the oral solid formulation is avoided in the elderly and young children to prevent inadvertent inhalation or choking as the units are quite large (18 – 23 mm long).

### Hyloris' product candidate: HY-REF-029

The commercialization of Hyloris' product will meet a currently unmet need in pediatric patients, allowing a more accurate and more easily titrated treatment and, therefore, providing a superior clinical benefit over the solid oral form. Additionally, the easy-to-administer form (oral liquid) will also be available for

<sup>165</sup> <https://clincalc.com/DrugStats/Top300Drugs.aspx>

<sup>166</sup> IQVIA data 2018

<sup>167</sup> U.S. generics market – evolution of Indian players, IQVIA February 2019; <https://payorsolutions.cvshealth.com/insights/a-new-agenda-for-the-fda>

adults and elderly patients who have difficulties tolerating or swallowing the oral solid form. The Company believes that the fact that the Hyloris product will require fewer daily intakes than competing liquid formulations or the solid oral drug will encourage patients to convert to the Hyloris product.

#### HY-REF-029's clinical status, regulatory status and commercial strategy

Hyloris is currently in final negotiation with an FDA certified EU based company for in-licensing a formulation for the United States. This company will perform the product development and commercial manufacturing of the product, whereas Hyloris will manage the clinical work. Hyloris will collaborate with a development partner that already has prior experience with the product. Hyloris expects that the product formulation (based on the in-licensed IP) is expected to be finalized in the course of H2 2020. Hyloris has not held a pre-IND, since the development plan is comparable to other liquid products for which a pre-IND has been submitted and because the final study protocol will be submitted for approval by FDA during the IND process in the course of H2 2020. Hyloris plans to conduct an open-label, randomized, two-period, two-sequence, crossover bioavailability study to assess the pharmacokinetic and safety profile of HY-REF-029 liquid formulation versus the marketed oral solid formulation in healthy subjects between 18 and 45 years old under fasting condition.

The primary objective of the study is to characterize the pharmacokinetics profile of HY-REF-029 in healthy subjects and compare the bioavailability. The secondary objective of the study is to assess the safety and tolerability of HY-REF-029. Safety assessments are adverse events, laboratory examination, physical examination, ECG examination and vital signs. The first patient in the study is expected in Q2 2021 with FDA filing taking place in 2022. Hyloris expects the FDA's approval and subsequent commercialization in the course of 2023.

Hyloris intends to partner this product with a pharmaceutical company active in pediatrics, which it expects to capture a market share in line with the lower market shares of the oral liquid drugs in the therapeutic category. The WAC prices are expected to be in line with molecule A in Table 7 above.

Compared to its key competing molecule which exists also in a liquid form, HY-REF-029 has a better bioavailability which allows less frequent dosing which may improve the patient compliance and treatment.

### **C      *HY-REF-075***

#### Coronary Heart Disease

HY-REF-075 is a pharmaceutical product that has been approved in the United States for many decades and which is still commonly administered to patients with specific cardiovascular diseases. There are more than 7 million people in the United States on blood thinners, of which approximately 1.3 million people were using this drug in 2016<sup>168</sup>. The condition being treated is characterized by a substantial number of patients being subject to swallowing abnormalities.

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<sup>168</sup> Matthew Alcusky et al. 2019, Changes in Anticoagulant Utilization Among United States Nursing Home Residents With Atrial Fibrillation From 2011 to 2016, J Am Heart Assoc.

### Current standard of care

The drug in its current form is currently used to treat this cardiovascular disease is amongst the 100 most prescribed drugs in the United States and was used to treat 1.3 million patients in 2016<sup>169</sup> (a 23% decrease in usage from 2014 to 2016).

### Limitations of the current standard of care

Compliance and (potentially very regular) dose adjustments are very important to properly address the targeted disease, hence having the possibility of changing and adjusting doses in an easy manner to avoid unnecessary side effects and hospitalizations is key. However, the current marketed product is a solid form, which does not allow to easily change and adjust dosing.

### Hyloris' product candidate: HY-REF-075

HY-REF-075 is a reformulation of the existing cardiovascular drug of which generic versions are available in the United States. It aims to significantly improve the ease of use of the drug, which is administered to elderly patients, and occasionally children, and requires frequent dosage changes and adjustments.

Hyloris Developments and Nordic Specialty Pharma (NSP) (a member of the Alter Pharma group) entered into an "Asset Purchase and Development Agreement", whereby NSP assigned to Hyloris Developments its rights and interests relating to HY-REF-075 (see Section 8.12.12 (HY-REF-075) for more information on this agreement).

The Company expects some patients will be converted from the existing market to HY-REF-075.

### HY-REF-075's clinical status, regulatory status and commercial strategy

The development partner of this product is Nordic Specialty Pharma BV, a fully owned subsidiary in the Alter Pharma group<sup>170</sup>.

Hyloris expects that the product formulation will be finalized in the course of H2 2020 and to conduct a pharmacokinetic study with the objective to assess the pharmacokinetic profile crossed with the same single dose oral solid dosage to document and compare systemic bioavailability of HY-REF-075 to the approved oral solid dosage form in healthy subjects. The primary pharmacokinetic endpoints will be the maximum drug concentration in the blood and the total patient exposure to the drug. Additional pharmacokinetic parameters will be measured. The recruitment of the first subject is scheduled to take place in H1 2021. Furthermore, Hyloris expects to submit the 505(b)(2) application to the FDA in the course of 2022.

The manufacturing will be performed by an identified U.S. based CMO. Hyloris intends to partner the product, which is intended for the retail market, with a pharmaceutical company that has an appropriate

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<sup>169</sup> Matthew Alcusky et al. 2019, Changes in Anticoagulant Utilization Among United States Nursing Home Residents With Atrial Fibrillation From 2011 to 2016, J Am Heart Assoc.

<sup>170</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

commercial presence. Marketing and promotional efforts will focus on pediatric, geriatric and specific general physicians, specific generalists and hospitals through targeted promotion and commercial support. Hyloris expects that the product can be commercialized at a pricing level that should be above 200.00 USD/bottle<sup>171</sup>.

Hyloris expects that final approval and commercialization of the product will start in the beginning of 2024.

#### **8.10.4 THE ESTABLISHED MARKET PORTFOLIO (HIGH-BARRIER GENERICS)**

Although Hyloris' core focus is not on established market product candidates (high barrier generics), the Company may, in certain cases, and on an opportunistic basis, evaluate and selectively initiate development of established market products where the barrier to entry is high due to requirements for clinical trials. As of the date of this Prospectus, Hyloris has two such high-barrier generics in its product candidate portfolio.

Compared to the development of most generic products these high-barrier generics require the conduct of large multicenter pharmacodynamics (clinical) trials which involve the recruitment of larger patient sample sizes (typically from 180 to 450 patients). The management of pharmacodynamics (clinical) trials require specific competencies in several domains such as data management, medical writing, pharmacovigilance and monitoring which are not required for the development of general generic products.

##### **8.10.4.1 HY-EMP-016**

The original brand of HY-EMP-016 is currently marketed as a topical gel in the United States, where it was approved in 1997<sup>172</sup>. It is an antimicrobial gel used to treat an infectious disease. Symptoms include itching, bleeding, burning and severe discomfort. Recurrences are common, as treatments do not sufficiently focus on the underlying disease. The branded topical gel is expensive and accounted for 24% of the total market of that drug in units but 83% of the total market in value.

The active ingredient exists as a cream and lotion in many countries, whereas the gel is only sold in the United States, Puerto Rico and a few countries in Latin America. The most common side effects of the drug relate to burning sensations and to the erosion of healthy skin at the application site. To avoid the occurrence of these side effects, patients are instructed to apply the drug in small amounts and to avoid applying it on normal skin. These safety measures are easier to follow using a thick gel instead of a liquid lotion.

The drug was discovered in the 19th century in the United Kingdom and approved in the United States in 1990, in a period when the pharmaceuticals companies were not internationally deployed as they are

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<sup>171</sup> Indicative management pricing assumption; For reference and only for highly indicative purposes, please find herewith the WAC pricing (*i.e.*, pre discounting) for four other oral liquids in the cardiovascular space: (i) Enalapril (USD 537/150 ml), (ii) Lisinopril (USD 540/150 ml), (iii) Sotalol (USD 446/240 ml, USD 856/480 ml), and (iv) Spironolactone (USD 320/118 ml, USD 1,154/473 ml) (Source: PriceRX). In addition, depending of the dosing, the bottle will last typically between 30 and 60 days, with a large minority of patients lasting 30 days with one bottle.

<sup>172</sup> [https://www.accessdata.fda.gov/scripts/cder/ob/results\\_product.cfm?Appl\\_Type=N&Appl\\_No=020529#18741](https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=020529#18741)

today. Different products using the active ingredient have been commercialized by different pharmaceuticals companies throughout the world.

There are currently no generics in the gel formulation in the United States, which Hyloris believes is due to the high clinical entry barrier that requires a sizeable placebo-controlled trial

The current U.S. market for the drug comprises of a liquid topical solution (lotion) and a topical gel.

Table 8: U.S. market for the drug 2016 – 2018.

	Sales packs 2016 (1,000)	Sales packs 2017 (1,000)	Sales packs 2018 (1,000)	Sales USD 2016 (1,000)	Sales USD 2017 (1,000)	Sales USD 2018 (1,000)
0.5% topical gel – <u>brand</u>	37	35	29	14,377	15,153	13,670
<b>0.5% topical gel - Total</b>	<b>37</b>	<b>35</b>	<b>29</b>	<b>14,377</b>	<b>15,153</b>	<b>13,670</b>
0.5% topical lotion – # 1	53	53	50	1,967	1,990	1,867
0.5% topical lotion – # 2	49	48	42	1,222	1,115	950
0.5% topical lotion – # 3 ( <u>brand</u> )	0	0	0	35	18	0
0.5% topical lotion – # 4	0	0	0	8	0	0
<b>0.5% topical lotion – Total</b>	<b>103</b>	<b>100</b>	<b>92</b>	<b>3,231</b>	<b>3,123</b>	<b>2,817</b>

Source IQVIA.

As seen in the table above, there are multiple generics of the lotion, which does not require a clinical trial, but no generics on the gel. The size of the gel market in 2018 was USD 13.7 million. Despite a 20% decrease in volume of the gel from 2016 to 2018 the overall market size has only declined by 5% due to price increases. While Hyloris does not expect to capture the full market, generic versions of the lotion had captured more than 98% of market share before the branded version was discontinued as set out in the table above. The current WAC of the branded gel 0.5% is USD 633.34<sup>173</sup>.

Hyloris expects to be the first company to launch a generic HY-EMP-016 through its partner Perrigo. Due to the size of the market and the clinical requirement, Hyloris does not expect additional generic players to develop the product. Hyloris believes it will grasp a majority of the market share, in line with what generic versions of the lotion captured before the discontinuation of the branded version. Recent IQVIA analysis shows, on average, the first generic company prices its product at 70% - 80% of the branded product price<sup>174</sup>.

Hyloris has partnered with Perrigo on the development of HY-EMP-016 (see Section 8.12 (Partnerships and Collaborations)). Perrigo is a market leading pharmaceutical company in dermatology with global turnover of USD 4.7 billion (70% from the United States)<sup>175</sup>. Perrigo completed the development of the

<sup>173</sup> PriceRx

<sup>174</sup> U.S. generics market – evolution of Indian players, IQVIA February 2019

<sup>175</sup> <https://www.macrotrends.net/stocks/charts/PRGO/perrigo/revenue>

formulation and CMC requirements of the ANDA and submitted the filing. Hyloris performed the clinical trial required by FDA.

The clinical trial conducted by Hyloris has been completed under the supervision of the Hyloris team and met all required parameters. A total of 413 subjects were recruited in a multi-center (17 located in 3 countries), randomized, double-blind, parallel group, placebo-controlled study of Hyloris' HY-EMP-016 0.5% compared to the reference listed drug (RLD) gel 0.5% and placebo in male and female patients with the specific infectious disease. The primary endpoint of the clinical study was the proportion of subjects in the per protocol (PP) population with "treatment success" defined as "total disappearance of the complication within all treated areas". Study visits occurred on the seventh (7) day of each treatment cycle: on Day 7 (Week 1), Day 14 (Week 2), Day 21 (Week 3), and Day 28 (Week 4). The primary endpoint (total disappearance of the complication within all treated areas) was evaluated during each of these visits. The mean responder rates (meant as total disappearance of the complication within all treated areas) were 64.52% for Hyloris' HY-EMP-016 subjects<sup>176</sup>, 66.67% for RLD gel subjects<sup>177</sup> and 23.21% for the placebo group. The study concluded that HY-EMP-016 topical gel 0.5% is bioequivalent to the RLD Gel 0.5% and superior to placebo.

Perrigo submitted the ANDA to the FDA in the first quarter of 2020. Upon approval (expected in 2021), Perrigo plans to launch the product that is manufactured in its Minneapolis, Minnesota-based facility.

#### **8.10.4.2 FUSIDIC ACID CREAM**

Fusidic acid is an antibiotic derived from the fungus *Fusidium coccineum* and was developed by Leo Pharma in Denmark in the 1960s. It is available in many forms (creams, ointment, tablets, IV, and eyedrops) both alone and in combination with corticosteroids. The cream is used locally to treat skin infections. It is indicated for the treatment of non-severe, superficial, non-extensive, primary skin infections caused by microorganisms that are sensitive to fusidic acid, especially for infections caused by bacteria called Staphylococcus. The primary skin infection for which fusidic acid is applied topically is impetigo.

Fusidic acid has been launched in many countries in the world typically where the innovator (Leo Pharma) had a commercial presence at the time of launch. The product is not available in the United States and, due to the requirement for a clinical trial with the Canadian product as a reference product, there is currently no generic equivalent to the brand (Fucidin® cream 2%) in Canada in contrast with most other countries. Hyloris believes that there are no existing patents since the product was developed in the 1960s and launched in Canada only in 1984. It sold approximately 690,000 packs in 2018 equating to EUR 9.7 million in sales<sup>178</sup>.

Table 9: Canadian market for Fusidic Acid cream 2016 – 2018.

	<b>Sales packs 2016 (1,000)</b>	<b>Sales packs 2017 (1,000)</b>	<b>Sales packs 2018 (1,000)</b>	<b>Sales EUR 2016 (1,000)</b>	<b>Sales EUR 2017 (1,000)</b>	<b>Sales EUR 2018 (1,000)</b>

<sup>176</sup> subjects treated with HY-EMP-016 Topical Gel 0.5%

<sup>177</sup> subjects treated with Reference Listed Drug (RLD) Gel 0.5%

<sup>178</sup> IQVIA

<i>Fusidic acid 15% 30 g cream – Leo</i>	689	694	687	10,050	10,152	9,700
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Source IQVIA.

Hyloris licensed the exclusive Canadian marketing rights to the product candidate from Stasisport NV (a subsidiary of the Alter Pharma group<sup>179</sup> – see Section 12.6 (Business Agreements)), who, together with Basic Pharma Manufacturing from the Netherlands, had developed the generic cream for commercialization in Europe, where it was launched in 2012 through various clients of Stasisport and Basic Pharma Manufacturing. However, the Canadian Marketing Approval Application requires a pharmacodynamics clinical study demonstrating the equivalence of Hyloris' Fusidic Acid Cream and Fucidin® cream from Leo Pharma as marketed on the Canadian market, in the treatment of patients with impetigo. The study will be conducted in several countries and is expected to start in Q2-Q3 2020 and submitted to the Canadian Health Authority by the end of 2022. The Company believes that the licensing of the product candidate is a good fit to its diversified portfolio as it has extensive experience in managing clinical trials and the product will face limited competition due to the level of investment required in the clinical trial which can be used for registration of a generic in Canada only. In 2016-2017, the average time for approval of a generic drug by the Canadian Health Authority was approximately fifteen months<sup>180</sup>.

Once the product candidate is approved, Hyloris intends to find a local marketing partner to commercialize the product candidate on a distribution or profit share basis with Hyloris keeping the majority of the profit. The product will be manufactured by Basic Pharma Manufacturing in the Netherlands.

The table below displays market shares of other dermatological products in the Canadian market with one generic competitor.

<sup>179</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

<sup>180</sup> <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/access-to-generic-drugs.html>

Table 10: Other products on the Canadian market with 1 generic 2016 – 2018.

	Sales packs 2016 (1,000)	Sales packs 2017 (1,000)	Sales packs 2018 (1,000)	Sales USD 2016 (1,000)	Sales USD 2017 (1,000)	Sales USD 2018 (1,000)	Price% of brand 2016	Price% of brand 2017	Price% of brand 2018
<b>Betamethasone 0,1% lotion 75 ml total</b>	<b>205</b>	<b>277</b>	<b>259</b>	<b>965</b>	<b>1,343</b>	<b>1,257</b>			
Taro Pharmaceuticals	191	277	259	900	1,343	1,257	100%	N/A	N/A
Valeant Pharmaceuticals	14	0	0	65	0	0			
Generic market share	93%	100%	100%						
<b>Mometasone 0,1% cream 50 g total</b>	<b>274</b>	<b>306</b>	<b>272</b>	<b>5,718</b>	<b>6,481</b>	<b>5,892</b>			
Taro Pharmaceuticals	231	275	219	4,663	5,682	4,569	81%	81%	82%
Merck Canada	42	31	52	1,055	799	1,323			
Generic market share	84%	90%	81%						
<b>Mometasone 0,1% cream 15 g total</b>	<b>262</b>	<b>296</b>	<b>258</b>	<b>1,667</b>	<b>1,920</b>	<b>1,714</b>			
Taro Pharmaceuticals	209	248	189	1,276	1,555	1,201	83%	83%	85%
Merck Canada	53	48	69	391	365	513			
Generic market share	80%	84%	73%						
<b>Mometasone lotion 0.1% 75 ml total</b>	<b>101</b>	<b>106</b>	<b>120</b>	<b>2,083</b>	<b>2,194</b>	<b>2,469</b>			
Taro Pharmaceuticals	82	93	106	1,558	1,825	2,079	69%	70%	73%
Merck Canada	19	13	14	525	369	390			
Generic market share	81%	88%	88%						
<b>Mometasone lotion 0.1% 30 ml total</b>	<b>101</b>	<b>106</b>	<b>120</b>	<b>2,083</b>	<b>2,194</b>	<b>2,469</b>			
Taro Pharmaceuticals	48	47	49	354	360	373	71%	71%	72%
Merck Canada	10	9	3	103	94	27			
Generic market share	47%	44%	41%						
<b>Mometasone 0,1% ointment 50 g total</b>	<b>92</b>	<b>89</b>	<b>122</b>	<b>1,385</b>	<b>1,389</b>	<b>1,882</b>			
Teva Canada	85	80	113	1,197	1,155	1,648	56%	55%	56%

Merck Canada	7	9	9	187	234	234			
Generic market share	92%	90%	93%						
<b>Mometasone 0,1% ointment 15 g total</b>	63	74	83	303	361	424			
Teva Canada	54	65	72	241	294	346	61%	59%	64%
Merck Canada	9	9	10	62	67	78			
Generic market share	86%	88%	87%						
<b>Fluocinonide 0,05% cream 60 g total</b>	<b>93</b>	<b>98</b>	<b>105</b>	<b>997</b>	<b>1,073</b>	<b>1,184</b>			
Taro Pharmaceuticals	91	95	102	973	1,043	1,150	95%	95%	96%
Valeant Pharmaceuticals	2	3	3	25	30	34			
Generic market share	98%	97%	97%						
<b>Fluocinonide 0,05% ointment 60 g total</b>	57	57	63	780	803	889			
Taro Pharmaceuticals	55	56	62	755	777	866	95%	95%	92%
Valeant Pharmaceuticals	2	2	1	25	26	23			
Generic market share	97%	97%	98%						
<b>Fluocinonide 0,05% gel 60 g total</b>	12	12	12	162	173	176			
Taro Pharmaceuticals	11	12	12	154	170	171	96%	92%	94%
Valeant Pharmaceuticals	1	0	0	7	4	5			
Generic market share	96%	98%	97%						

Source IQVIA

Hyloris is currently preparing the pharmacodynamics study to demonstrate the equivalence of Fusidic acid cream and Fucidin® cream in the treatment of adult and pediatric patients with impetigo, of which the submission expected in 2022. Based on Hyloris' pricing expectation, Fusidic Acid Cream is expected to cost ca.40% less compared to the current price of Fucidin® cream (taking into account that a generic, by law, needs to have a lower price compared to the brand product and that, if additional generics would enter, the price would decrease further). Hyloris expects to gradually acquire a significant part of this stable and substitution driven market.

### 8.11 FACILITIES

Hyloris and its subsidiaries operate out of a leased office in Liège, Belgium.

## 8.12 PARTNERSHIPS AND COLLABORATIONS

This Section 8.12 (Partnerships and Collaborations) describes the material business agreements relating to Hyloris' product(s) (candidates). The below table provides an overview of the different material product (candidates) of Hyloris:

Product (candidate)	IP	Pathway	Development partner	Development partner compensation	CMO location	API supplier selected	Commercialization	Commercial fee	Section describing business agreements	Section describing the product (candidate)
<b><u>Cardiovascular products</u></b>										
Sotalol IV	Owned	505(b)(2)	AltaThera <sup>(1)</sup>	Commercialization rights and reimbursement of part of the development costs <sup>(2)</sup>	EU	Yes	AltaThera	Sales-related commission and one-time payment	8.12.1	8.10.2.1
Dofetilide IV	In-licensed	505(b)(2)	Academic Pharmaceuticals	Sales-related commission and development milestone payments <sup>(3)</sup>	U.S.	Yes	Own sales team	N/A	8.12.2	8.10.2.1
Metolazone IV	In-licensed	505(b)(2)	Academic Pharmaceuticals	Sales-related commission and development milestone payments <sup>(3)</sup>	TBD	Yes	Own sales team	N/A	8.12.3	8.10.2.2
HY-CVS-073	In-licensed	505(b)(2)	Academic Pharmaceuticals	Sales-related commission and development milestone payments <sup>(3)</sup>	TBD	No	Own sales team	N/A	8.12.4	8.10.2.3
HY-CVS-074	In-licensed	505(b)(2)	Academic Pharmaceuticals	Sales-related commission and development milestone payments <sup>(3)</sup>	TBD	No	Own sales team	N/A	8.12.5	8.10.2.3

<b><u>Other Reformulation Portfolio</u></b>										
Maxigesic® IV	Co-owned / In-licensed	505(b)(2)	AFT Pharmaceuticals/ Neogen <sup>(6)</sup>	Commercialization rights <sup>(4)</sup>	EU	Yes	AFT Pharmaceuticals	Sales-related commission	8.12.6	8.10.3.1
HY-REF-004	Owned	505(b)(2)	None	N/A <sup>(5)</sup>	U.S.	Yes	Third party	TBD	8.12.7	8.10.3.2
Tranexamic Acid RTU	Owned	505(b)(2)	None	N/A	EU	Yes	Third party	TBD	8.12.8	8.10.3.3A
HY-REF-038	Owned	ANDA	Generic Specialty Pharma <sup>(6)</sup>	Sales-related commission and a one-time payment <sup>(3)</sup>	TBD	Yes	Third party	TBD	8.12.9	8.10.3.3B
Atomoxetine Oral Liquid	In-licensed	505(b)(2)	None	N/A <sup>(7)</sup>	U.S.	Yes	Third party	TBD	8.12.10	8.10.3.4A
HY-REF-029	Owned	505(b)(2)	TBD	TBD	TBD	No	Third party	TBD	8.12.11	8.10.3.4B
HY-REF-075	Owned	505(b)(2)	Nordic Specialty Pharma <sup>(6)</sup>	Sales-related commission and a one-time payment <sup>(3)</sup>	U.S.	Yes	Third party	TBD	8.12.12	8.10.3.4C
<b><u>Established Market Portfolio (“high barrier generics”)</u></b>										
HY-EMP-016	Owned	ANDA	Perrigo	Commercialization rights and reimbursement of part of the development costs	U.S.	Yes	Perrigo	Profit-related commission	8.12.13	8.10.4.1
Fusidic Acid Cream	Owned / In-licensed	Generic	None	N/A	EU	Yes	Third party	TBD	8.12.14	8.10.4.2

**Notes:**

- (1) AltaThera has subcontracted the development work to Academic Pharmaceuticals.
- (2) Hyloris has acquired the rights to the product from Academic Pharmaceuticals and must pay, in consideration thereof, *inter alia*, a sales-related commission (see Section 8.12.1.1 (Academic Pharmaceuticals – Asset purchase agreement)).
- (3) Hyloris also compensates the development partner for all development related expenses.
- (4) Hyloris in-licenses certain rights to the product from Neogen Developments (part of the Alter Pharma group, which is a related party (see also Section 12 (Related Party Transactions))), and must pay, in consideration thereof, *inter alia*, a sales-related commission (see Section 8.12.6.1 (Neogen Developments – Patent know-how and license agreement)).
- (5) Hyloris has acquired the rights to the product from Kiel Laboratories and Codadose, and must pay, in consideration thereof, *inter alia*, a sales-related commission (see Section 8.12.7 (HY-REF-004)).
- (6) Part of the Alter Pharma group. The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).
- (7) Hyloris in-licenses certain rights to the product from Tahoe Pharmaceuticals, and must pay, in consideration thereof, *inter alia*, a sales-related commission (see Section 8.12.10 (Atomoxetine Oral Liquid)).

- (8) Hyloris has subcontracted certain parts of the development to Neogen NV and will pay Neogen NV a share of its profit. Neogen NV is part of the Alter Pharma group. The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

For an overview of the rights, patents, patent applications, provisional patents filed and the licenses that Hyloris holds with respect to its product (candidate) portfolio, reference is made to Section 8.17.1 (Patents and Licenses).

## **8.12.1 SOTALOL IV**

### **8.12.1.1 ACADEMIC PHARMACEUTICALS – ASSET PURCHASE AGREEMENT**

Sotalol IV, was approved by the FDA in 2009. The product was initially out-licensed by Academic Pharmaceuticals to Bioniche, who subsequently became part of Mylan. In December 2014, Hyloris Developments entered into an “Asset Purchase Agreement” with Academic Pharmaceuticals whereby the latter assigned to Hyloris Developments all rights, titles and interests in Sotalol IV, including the relevant NDA, all other authorizations, approvals and regulatory findings (INDs) and all data and other relevant information and know-how relating to Sotalol IV.

In exchange, Hyloris Developments agreed to pay to Academic Pharmaceuticals (i) an upfront payment of USD 400,000, as well as (ii) a fee on Hyloris Developments’ aggregate net profits received from distribution of the products in the United States, during the period in which it receives such net profits (except in the event of prior termination of the agreement due to a material breach of Academic Pharmaceuticals) (the “term”) and (iii) a fee on any other revenues (derived other than from the direct sale of Sotalol IV), for a period of ten years following the first receipt of such “other revenues”. The upfront payment of USD 400,000 has been made (*i.e.*, fifty percent at closing and fifty percent one year thereafter).

Each party may terminate the agreement early in the event the other party commits a material breach. In the event Academic Pharmaceuticals terminates the agreement due to a material breach of Hyloris Developments, Academic Pharmaceuticals may elect to have the NDA transferred back to it, in order to assume, at its discretion, any agreements with third parties with respect to the NDA or with respect to Sotalol IV. In such case, Hyloris Developments shall be entitled to a fee based on Academic Pharmaceuticals’ aggregate net profits received from distribution of the product in the United States, during the period in which it receives such net profits.

Hyloris out-licensed the rights for Sotalol IV to AltaThera in December 2014 (see Section 8.12.1.2 (AltaThera – Licensing, development and supply agreement)). Sotalol IV was launched in the United States in 2015. A label extension for Sotalol IV, filed by AltaThera was approved by the FDA in March 2020.

### **8.12.1.2 ALTATHERA – LICENSING, DEVELOPMENT AND SUPPLY AGREEMENT**

In December 2014, Hyloris Developments and AltaThera entered into an agreement, whereby Hyloris Developments granted AltaThera the right to market, distribute, commercialize and sell Sotalol IV in the United States and whereby AltaThera is responsible for the subsequent commercialization and distribution of Sotalol IV in the United States. AltaThera has subcontracted the regulatory and development work to Academic Pharmaceuticals.

The agreement provides that Hyloris Developments is responsible for all regulatory affairs and for the manufacturing, testing, packaging and labelling of Sotalol IV. Hyloris Developments shall ensure the manufacturing of one full batch of Sotalol IV for AltaThera every 12 to 18 months as ordered by AltaThera.

It was initially agreed that Hyloris Developments would be the exclusive supplier of Sotalol IV to AltaThera, even though the actual manufacturing and supply of Sotalol IV would be performed by a third-party supplier. However, in November 2019, AltaThera informed Hyloris Developments that it had directly entered into a six-year supply agreement with the existing supplier of Sotalol IV, and that the obligations of Hyloris Developments under the licensing, development and supply agreement in relation to the supply of Sotalol IV to AltaThera are suspended until the supply agreement between AltaThera Pharmaceuticals and the aforementioned third party is terminated (for whatever reason), at which point in time the obligations of Hyloris Developments in relation to the supply of Sotalol IV under the licensing, development and supply agreement with AltaThera Pharmaceuticals will revive.

The parties have also agreed to jointly (further) develop line extensions for Sotalol IV. All rights, titles and interests in jointly developed inventions shall be jointly owned by both parties. AltaThera is entitled to sublicense any such inventions in the United States, while Hyloris Developments may do so outside the United States.

The costs incurred pursuant to the agreement are borne jointly by both parties (approximately each 50%).

At the closing of the agreement, AltaThera paid Hyloris Developments a lump sum license fee. During the course of the agreement, AltaThera must pay sales-related fees to Hyloris Development on its annual net sales derived from Sotalol IV. In addition, AltaThera must also pay five one-time sales-related milestone payments of increasing amounts that become payable if a determined annual minimum net sales level is exceeded, with a total maximum aggregate of USD 18 million. The first milestone payment will materialize when annual net sales exceed USD 20 million.

The term of the agreement is (i) as long as Hyloris Developments continues to supply Sotalol IV to AltaThera, or (ii) until the 20<sup>th</sup> anniversary date of the first commercial sale of Sotalol IV, whichever is later. The parties may however immediately terminate the agreement in the event the other party (i) fails to remedy any breach of the agreement within a period of 90 days after receipt of a written request thereto and/or (ii) the other party is confronted with insolvency issues. However, if AltaThera terminates the agreement due to one of the aforementioned events, the license granted to it shall survive indefinitely. AltaThera shall then pay reduced (by 20%) fees, as long as it sells Sotalol IV in the United States. In addition, AltaThera is entitled to terminate the agreement if (i) any adverse events occur whereby the distribution of Sotalol IV is significantly affected during three consecutive months or which necessitate a recall of Sotalol IV, and/or (ii) it is established by a court decision that Sotalol IV infringes third party intellectual property rights, affecting AltaThera's ability to sell Sotalol IV in the United States. During a period of five years following the termination of the agreement, Hyloris Developments and/or its affiliates are prohibited from selling or manufacturing competing products in the United States. Hyloris Developments has the contractual right not to pursue the Sotalol IV project with AltaThera, in which unlikely case the exclusive right to develop Sotalol IV would be transferred to AltaThera.

## **8.12.2 DOFETILIDE IV**

### **8.12.2.1 ACADEMIC PHARMACEUTICALS – BINDING TERM SHEET**

In April 2019, Hyloris Developments and Academic Pharmaceuticals signed a binding term sheet by way of which they agreed to enter into a research, development and license agreement, pursuant to which they will jointly perform research and development activities with regard to Dofetilide IV. In this context, Academic Pharmaceuticals undertook, among other things, to manage (pre-)clinical studies, perform data analysis, write product labels and provide assistance with the preparation of all required FDA applications and submissions. Once Dofetilide IV is (duly) developed and approved, Hyloris Developments shall be responsible for the commercialization and distribution thereof (by itself or by engaging a third party). For this purpose, Academic Pharmaceuticals shall grant Hyloris Developments an exclusive and worldwide license to import, develop, label, use, store, package, register, make applications, sell, offer for sale, distribute and commercialize Dofetilide IV.

In consideration of the development services and the granted license, Hyloris Developments shall pay various (development) milestone payments to Academic Pharmaceuticals for a total amount of USD 525,000. Hyloris Developments shall also reimburse Academic Pharmaceuticals for all agreed development costs incurred to obtain (and maintain) NDA approval. USD 125,000 of the total of USD 525,000 milestone payments has already been paid (*i.e.*, USD 50,000 at signing and USD 75,000 at acceptance of the clinical pathway).

In the event Hyloris Developments engages a third party to commercialize and distribute Dofetilide IV, parties agreed upon a specific profit split schedule. In the event Hyloris Developments undertakes to commercialize and distribute the product itself, parties shall negotiate in good faith a profit share “*at arm’s length*” compensation for Hyloris Development. No payment shall take place unless and until Hyloris Developments has recovered any and all investments, external costs and expenses incurred or payments made in connection with the product (other than internal project management expenses).

The duration / period of validity of the binding term sheet is not specified. The binding term sheet is governed by Belgian law, and all disputes in relation thereto shall be submitted to the International Chamber of Commerce, residing in Brussels.

### **8.12.2.2 EXCITE PHARMA SERVICES – CLINICAL TRIAL MANUFACTURING AGREEMENT**

In March 2020, Hyloris Developments accepted a written contract proposal by Excite Pharma Services titled “Analytical Development/Tech Transfer, Formulation Development, Process Development and Clinical Trial Manufacturing with Stability for Dofetilide for Injection”. Pursuant to the agreement, Excite Pharma Service shall develop and manufacture a clinical trial batch of Dofetilide IV and Hyloris Developments is entitled to request the execution of a formal supply agreement at industry customary terms, ensuring support for the NDA application as well as to ensure long term commercial supply. The agreement provides that if Hyloris Developments requests such a supply agreement, the commercial terms of such supply agreement are expected to include five years exclusivity from the date of commercial launch, subject to certain safeguards for Hyloris Developments (including, but not limited

to, non-exclusivity in the event of failure to supply or non-compliance by Excite Pharma Services) and a right for either party to terminate the relationship with two years' notice.

Hyloris Developments is responsible for all regulatory filings, the supply of Dofetilide active ingredient and supporting documentation, whereas Excite Pharma must provide all required CMC data and, generally, perform all development work required to obtain final approval of the NDA. Hyloris shall own all rights to the regulatory filings and all data generated under the agreement.

In consideration of the services provided by Excite Pharma Services, Hyloris Developments shall pay an amount estimated to be USD 867,491 in total, payable in different agreed installments. Costs associated with regulatory required changes are to be borne solely by Hyloris Developments, excluding facility related changes not specific to Dofetilide IV. As of the date of this Prospectus, no payments to Excite Pharma Services in this respect have been made yet.

The costs for the work required for additional CMC work required for registration and validation (including analytical work, registration, and validation batches and stability testing services) in relation to future production (if requested by Hyloris Developments) are estimated to amount to USD 882,100 in total.

### **8.12.3 METOLAZONE IV**

#### **ACADEMIC PHARMACEUTICALS – BINDING TERM SHEET**

In March 2019, Hyloris Developments and Academic Pharmaceuticals signed a binding term sheet by way of which they agreed to enter into a research, development and license agreement, pursuant to which they will jointly perform research and development activities with regard to Metolazone IV. Hyloris and Academic Pharmaceuticals are currently in a final stage of negotiating such research, development and license agreement that is expected to be executed in Q3 2020. In this context, Academic Pharmaceuticals undertook, among other things, to manage (pre-)clinical studies, perform data analysis, write product labels and provide assistance with the preparation of all required FDA applications and submissions.

Once Metolazone IV is (duly) developed and approved, Hyloris Developments shall be responsible for the commercialization and distribution thereof (as the case may be, by engaging a third party). For this purpose, Academic Pharmaceuticals shall grant Hyloris Developments an exclusive and worldwide license to import, develop, label, use, store, package, register, make applications, sell, offer for sale, distribute and commercialize Metolazone IV, whereby Hyloris Developments shall have sole discretion to determine the commercialization strategy and have the sole right and authority to make decisions regarding whether and when to launch the product in a particular country or region and the level of efforts to be expended in any particular country or region.

In consideration of the development services and the granted license, Hyloris Developments shall pay various development milestone payments to Academic Pharmaceuticals for a total amount of USD 550,000, of which USD 50,000 has been paid at signing of the binding term sheet and another USD 50,000 has been paid at acceptance of the clinical pathway. Sales milestones of USD 100,000,

USD 200,000 and USD 1,000,000 will be due when Hyloris will receive net sales of respectively USD 15 million, USD 20 million and USD 25 million.

Hyloris Developments shall also reimburse Academic Pharmaceuticals for all agreed development costs and expenses incurred.

In the event Hyloris Developments engages a third party to commercialize and distribute Metolazone IV, parties agreed upon a specific profit split schedule. In the event Hyloris Developments undertakes to commercialize and distribute the product itself, parties shall negotiate in good faith a profit share “*at arm’s length*” compensation for Hyloris Development. In any event, no profit split shall take place unless and until Hyloris Developments has recovered any and all investments, external costs and expenses incurred or payments made in connection with the product (other than internal project management expenses).

#### **8.12.4 HY-CVS-073**

##### **8.12.4.1 ACADEMIC PHARMACEUTICALS – BINDING TERM SHEET**

In October 2019, Hyloris Developments and Academic Pharmaceuticals Inc. signed a binding term sheet by way of which they agreed to enter into a research, development and license agreement, pursuant to which they will agree to jointly perform research and development activities with regard to HY-CVS-073. In this context, Academic Pharmaceuticals undertook, among other things, to manage (pre-)clinical studies, perform data analysis, write product labels and provide assistance (on a best efforts basis) with the preparation of all required FDA applications and submissions. Once HY-CVS-073 is (duly) developed and approved, Hyloris Developments shall be responsible for the commercialization and distribution thereof (by itself or by engaging a third party). For this purpose, Academic Pharmaceuticals grants Hyloris Developments an exclusive and worldwide license to import, develop, label, use, store, package, register, make applications, sell, offer for sale, distribute and commercialize HY-CVS-073.

In consideration of the development services and the granted license, Hyloris Developments shall pay development milestone payments to Academic Pharmaceuticals for a total amount of USD 650,000 of which USD 25,000 has been paid at signing of the binding term sheet. Hyloris Developments shall also reimburse all development costs incurred by Academic Pharmaceuticals including the cost to obtain (and maintain) NDA approval.

In the event Hyloris Developments engages a third party to commercialize and distribute HY-CVS-073, parties agreed upon a specific profit split schedule. In the event Hyloris Developments undertakes to commercialize and distribute the product itself, parties shall negotiate in good faith an additional “*at arm’s length*” compensation for Hyloris Development. In any event, no profit split shall take place unless and until Hyloris Developments has recovered any and all product related investments, external costs and expenses incurred or payments made in connection with the product (other than internal project management expenses).

The duration of the binding term sheet is not specified. The binding term sheet is governed by Belgian law, and all disputes in relation thereto shall be submitted to the International Chamber of Commerce, residing in Brussels.

#### **8.12.5 HY-CVS-074**

##### **ACADEMIC PHARMACEUTICALS – BINDING TERM SHEET**

In December 2019, Hyloris Developments and Academic Pharmaceuticals signed a binding term sheet by way of which they agreed to inter into a research, development and license agreement, pursuant to which they will jointly perform research and development activities with regard to HY-CVS-074. In this context, Academic Pharmaceuticals undertook, among other things, to manage (pre-)clinical studies, perform data analysis, write product labels and provide assistance with the preparation of all required FDA applications and submissions. Once HY-CVS-074 is (duly) developed and approved, Hyloris Developments shall be responsible for the commercialization and distribution thereof (by itself or by engaging a third party). For this purpose, Academic Pharmaceuticals grants Hyloris Developments an exclusive and worldwide license to import, develop, label, use, store, package, register, make applications, sell, offer for sale, distribute and commercialize HY-CVS-074.

In consideration of the development services and the granted license, Hyloris Developments shall pay various (development) milestone payments to Academic Pharmaceuticals for a total amount of USD 350,000 of which USD 25,000 has been paid at signing of the binding term sheet. Hyloris Developments shall also reimburse Academic Pharmaceuticals for all agreed development costs incurred to obtain (and maintain) NDA approval.

In the event Hyloris Developments engages a third party to commercialize and distribute Dofetilide IV, parties agreed upon a specific profit split schedule. In the event Hyloris Developments undertakes to commercialize and distribute the product itself, parties shall negotiate in good faith a profit share “*at arm’s length*” compensation for Hyloris Development. No payment shall take place unless and until Hyloris Developments has recovered any and all investments, external costs and expenses incurred or payments made in connection with the product (other than internal project management expenses).

The duration / period of validity of the binding term sheet is not specified. The binding term sheet is governed by Belgian law, and all disputes in relation thereto shall be submitted to the International Chamber of Commerce, residing in Brussels.

#### **8.12.6 MAXIGESIC® IV**

##### **8.12.6.1 NEOGEN DEVELOPMENTS – PATENT KNOW-HOW AND LICENSE AGREEMENT**

On 22 May 2012, Hyloris Pharmaceuticals and Neogen Developments (Neogen) (a member of the Alter Pharma group<sup>181</sup>), signed a “Patent and know-how license agreement”, pursuant to which Neogen granted to Hyloris Pharmaceuticals a worldwide, exclusive, irrevocable and sub-licensable license to manufacture, have manufactured, use, import, supply, sell or otherwise commercialize any

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<sup>181</sup> The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

pharmaceutical product containing paracetamol and ibuprofen in in approximately a 3.3:1 ratio in all appropriate dosages and in a formulation appropriate and intended for intravenous delivery and related patents.

In exchange for the grant of the aforementioned license, Hyloris Pharmaceuticals must pay to Neogen a percentage on all net revenue received by Hyloris derived from any sales (or licensing) of Maxigesic® IV, less any overhead costs and expenses incurred by Hyloris Pharmaceuticals in connection with the development and commercialization of Maxigesic® IV.

The agreement remains in force until all licensed patent applications regarding Maxigesic® IV, registered in the name of Neogen, shall have expired (which shall, based on the currently registered patents, at least be until august 2029 but which may be extended pursuant to the filing of new patent (applications) by Neogen). Neogen is however entitled to terminate the agreement at an earlier time in the event Hyloris Pharmaceuticals (i) suspends (or threatens to suspend) any payments due or is deemed unable to pay, (ii) is confronted with certain financial difficulties and/or (iii) suspends or ceases to carry on all (or substantially all) of its business. Upon such termination, all outstanding sums shall immediately become due, and all granted rights and licenses shall terminate, and Hyloris Pharmaceuticals shall have to cease the exploitation of the licensed patent (applications) and know-how.

Under the agreement, Neogen is not liable for any damages, costs or losses arising from the exercise of the granted rights. Hyloris Pharmaceuticals has agreed to indemnify Neogen in the event of loss or damages arising from any exploitation of the license. The liability of Hyloris Pharmaceuticals is not subject to a liability cap.

#### **8.12.6.2      AFT PHARMACEUTICALS – DEVELOPMENT COLLABORATION AGREEMENT**

In May 2012 and following the license agreement with Neogen Developments, Hyloris Pharmaceuticals and AFT Pharmaceuticals entered into a “Development collaboration agreement” whereby both parties agreed to jointly perform (further) research and development activities with regard to “Maxigesic® IV”. Hyloris is primarily responsible for the research and development with respect to the development of an appropriate stable IV formulation (which development was subcontracted to and completed by Neogen as described below), whereas AFT Pharmaceuticals is primarily responsible for the pre-clinical and clinical development. The vast majority of development costs for Maxigesic® IV have already been incurred, as the clinical trials have been completed or are soon to be completed. Each party bears its own internal costs. External costs are generally shared. All intellectual property rights that are jointly developed by both parties are held in co-ownership. The agreement also provides for reciprocal licenses to the parties’ respective relevant intellectual property rights for purposes of the development collaboration.

In addition, the parties agreed that, in the event the collaborative research and development activities are successful, AFT Pharmaceuticals shall be responsible for the effective manufacturing and commercialization of the products developed under the agreement. For this purpose, AFT Pharmaceuticals has agreed to enter into (various) agreements with third party pharma companies active in the different countries in which parties wish to distribute Maxigesic® IV. In that context, AFT

Pharmaceuticals has entered into various subsequent development, license and supply agreements for the distribution of Maxigesic® IV in over 80 countries.

The agreement provides for a profit sharing mechanism. Hyloris Pharmaceuticals is entitled to a share on any revenues, such as license fees, royalties, milestone payments (or other net considerations) received by AFT Pharmaceuticals under any such manufacturing, license and supply agreements. Such “other net considerations” include, for example, any amount exceeding the “fair market value” in the event AFT Pharmaceuticals would sell its business. This however excludes any profit generated from Australia and New Zealand (as contractually agreed with AFT Pharmaceuticals).

The agreement with AFT Pharmaceuticals shall expire upon termination of AFT Pharmaceuticals’ payment obligations due to (i) the termination of all concluded manufacturing, license and supply agreements, (ii) the expiration of the applicable intellectual property rights and/or (iii) the cessation of the distribution of Maxigesic® IV by either party or by a third party pharma company. Upon such termination, AFT Pharmaceuticals is granted a non-exclusive license to further manufacture and commercialize Maxigesic® IV on its own behalf. AFT Pharmaceuticals may also terminate the agreement prematurely in the event Hyloris Pharmaceuticals (or its affiliates) initiate legal proceedings against AFT Pharmaceuticals to annul any registered patent (applications). Up to a period of four months following the expiration or termination of the agreement, the collaboration between the parties shall “remain exclusive” with respect to Maxigesic® IV.

#### **8.12.6.3            NEOGEN DEVELOPMENTS – DEVELOPMENT SUBCONTRACT**

Hyloris Pharmaceuticals has subcontracted certain parts of the development work (such as formulation, submission batches, stability and process validation) under the development and collaboration agreement with AFT Pharmaceuticals (as described above) to Neogen Developments. This subcontract started on 2012 and is still in force. As of the date of this Prospectus a total amount of EUR 580,000 has been paid by Hyloris Pharmaceuticals to Neogen Developments under this subcontract.

#### **8.12.7    *HY-REF-004***

#### **KIEL LABORATORIES AND CODADOSE – ASSET PURCHASE AGREEMENT**

In December 2012, Kiel Laboratories and Codadose assigned and transferred to Hyloris Pharmaceuticals, on the basis of an “Asset Purchase Agreement”, all their respective rights, titles and interests in HY-REF-004, including all intellectual property rights, proprietary information, authorizations and approvals related to HY-REF-004 for a total of EUR 420 thousand. Pursuant to the agreement, Hyloris Pharmaceuticals agreed to pay various development milestone payments up to a total amount of USD 400,000. An amount of USD 175,000 has already been paid (*i.e.*, an upfront payment of USD 125,000 and a payment of USD 50,000 for the submission of the IND filing).

In addition, Hyloris Pharmaceuticals agreed to pay a fee on aggregate net profits received out of any sales of HY-REF-004 realized by Hyloris. The aforementioned payment obligation shall terminate, on a country-by-country basis, when a period of fifteen years following the first (commercial) sale of HY-REF-

004 in the concerned country has expired (the “term”). The agreement shall remain in effect until termination of the term in each country.

However, each party may terminate the agreement early in the event (i) the other party breaches any of its obligations under the agreement and/or (ii) the other party is confronted with certain insolvency issues. Hyloris Pharmaceuticals may further terminate the agreement if it intends to cease the development and/or commercialization of HY-REF-004 in which case the transferred assets are however transferred back to the sellers. The agreement includes a non-compete clause, prohibiting the parties to (directly or indirectly) sell, develop or commercialize HY-REF-004 in the United States for a period of ten years following the end of the term.

### **8.12.8 *TRANEXAMIC ACID RTU***

#### **8.12.8.1 S.M. FARMACEUTICI - MANUFACTURING AGREEMENT**

In October 2019, RTU Pharma and S.M. Farmaceutici concluded a “Manufacturing agreement”, whereby S.M. Farmaceutici undertook to manufacture and supply Tranexamic Acid RTU to (any indicated client of) RTU Pharma. RTU Pharma shall however first deliver the drug substance of Tranexamic Acid RTU to S.M. Farmaceutici. RTU Pharma must purchase at least 30% of its total requirements of Tranexamic Acid RTU from S.M. Farmaceutici. RTU Pharma becomes the exclusive owner of all intellectual property rights related to Tranexamic Acid RTU and the entire dossier thereof (including patent (applications), inventions, data, writings and other property in any form whatsoever, and including any and all improvements and developments of the foregoing).

S.M. Farmaceutici charges RTU Pharma a price per purchased unit of Tranexamic Acid.

The term of the agreement is for an initial period of five years following the launch of Tranexamic Acid RTU by any (client of) RTU Pharma. Upon expiring of the initial term, the agreement may be extended for successive periods of two years. Each party may terminate the agreement upon prior notice of minimum one year. Further, each party may, immediately and without prior notice, terminate the agreement (i) in the event the other party breaches any of the terms of or of its obligations under the agreement without remedying such breach within a period of seven days after receiving notice thereto, (iii) the other party is confronted with insolvency issues, (iv) the organization or capital control of the other party changes in such a way that the continuation of the manufacturing agreement is no longer possible.

The agreement is governed by Belgian law, and all disputes in relation thereto shall be submitted to the courts of Brussels.

#### **8.12.8.2 HUNANG DONGTING PHARMACEUTICAL CO. - SUPPLY AGREEMENT**

In March 2017, RTU Pharma and Hunan Dongting Pharmaceuticals Co. entered into a supply agreement pursuant to which Hunan Dongting Pharmaceuticals Co. agrees to supply to RTU Pharma the API for Tranexamic Acid RTU.

The term of the agreement is for an initial period of ten years. The agreement shall automatically be renewed for consecutive periods of five years, unless either party terminates the agreement upon prior written notice of 24 months.

Hunan Dongting Pharmaceuticals Co. charges RTU Pharma a price per kg on a “cost, insurance and freight” basis (if transport takes place by sea) or on a “carriage and insurance paid to” basis (if transport takes place other than by sea).

The agreement is governed by the laws of Switzerland, and all disputes in relation thereto shall be submitted to the courts of Geneva.

### **8.12.9 HY-REF-038**

#### **8.12.9.1 GENERIC SPECIALTY PHARMA - DEVELOPMENT AGREEMENT**

On 28 June 2019, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group<sup>182</sup>) entered into a “Development agreement” with Dermax, pursuant to which GSP agreed to carry out all development activities required for (the acquisition/ registration of ANDA/NDA approval for) HY-REF-038. Following the development of HY-REF-038, GSP shall be responsible for the filing of a patent application in the name of Dermax. In general, all intellectual property rights developed by GSP in relation to HY-REF-038 shall exclusively belong, and are assigned, to Dermax.

Dermax may request to terminate the development of HY-REF-038 (or ask to reformulate the product) in the event a third party registers or launches a HY-REF-038 PFS on the U.S. market. In consideration for the development services, Dermax shall pay a (lump sum) development fee of EUR 2,000,000 (which has already been paid) and a variable price (due on a yearly basis) amounting to (i) 25% of the net margin (*i.e.*, of the total turnover derived from the (worldwide) sales of the product as invoiced by Dermax, minus a fixed percentage of 40% for marketing and distribution costs), in the event the product is granted an “orphan drug designation”, or to (ii) 12.5% which of the net margin is significantly lowered if the product is not granted such status. Hyloris does not expect HY-REF-038 to be granted the “orphan drug status”.

In the event the supply of the product is managed by GSP, GSP shall be entitled to take a 13% margin on the (direct) development costs, prior to the profit split. Dermax is entitled to take over the supply of the product at any time. In the event the development costs exceed an amount of EUR 1,600,000, Dermax shall reimburse the excessing amount to GSP. Before any variable payment is made, Dermax may deduct the cost for its key-investments as made for the product development, increased with EUR 1 million.

The duration of the agreement is not specified. Dermax may however at any time request to terminate the development of HY-REF-038 (or ask to reformulate the product) in the event a third party registers or launches a HY-REF-038 PFS on the U.S. market.

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<sup>182</sup> The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

The agreement is governed by Belgian law, and all disputes in relation thereto shall be submitted to the courts of Brussels.

#### **8.12.9.2 ALTER PHARMA - ASSET PURCHASE AGREEMENT**

On 2 February 2020, Dermax and Alter Pharma (a subsidiary of the Alter Pharma group<sup>183</sup>) entered into an “Asset Purchase Agreement” whereby Dermax assigned to Alter Pharma all (intellectual property) rights, title and interest in the product HY-REF-038 in vial form. Dermax has retained the ownership of HY-REF-038 in the form of prefilled syringes and the Development Agreement with GSP (see Section 8.12.9.1 (Generic Specialty Pharma - Development Agreement)) was amended as to clarify that its scope is limited to the development of HY-REF-038 in the form of prefilled syringes.

In consideration of the transferred intellectual property rights described in the Development Agreement, Dermax has received EUR 1,400,000 (*i.e.*, repayment of prepaid R&D expenses).

#### **8.12.10 ATOMOXETINE ORAL LIQUID**

##### **TAHO PHARMACEUTICALS – LICENSE AGREEMENT**

In November 2019, Hyloris Developments and Tahoe Pharmaceuticals entered into a “license agreement” pursuant to which Tahoe Pharmaceuticals granted Hyloris Developments an exclusive, perpetual and irrevocable license to manufacture, register, sell, offer, import and/or otherwise commercialize the product Atomoxetine Oral Liquid in the United States. Further, Tahoe Pharmaceuticals assigned the U.S. patents US9,855,228 and US9,993,445 as well as any other patents in the United States that relates to Atomoxetine Oral Liquid that is owned by Tahoe Pharmaceuticals, or which is licensed to it, with the right to sublicense the concerned patent, to Hyloris Developments. Hyloris Developments agreed to use commercially reasonable efforts to develop, file for, obtain and maintain (by itself or through sublicensees) the required regulatory approvals to use Atomoxetine Oral Liquid in the United States. Tahoe Pharmaceuticals shall provide Hyloris Developments with all information (including all inventions, data, protocols, plans, works of authorship, instructions, results etc.) and all biological, chemical or physical materials useful for Hyloris Developments to register Atomoxetine Oral Liquid in the United States. Hyloris Developments shall own all registration documentation and registration approvals, provided that it shall make such registration documentation and approvals available to Tahoe Pharmaceuticals to sell Atomoxetine Oral Liquid outside the United States.

Hyloris shall have the exclusive right to commercialize Atomoxetine Oral Liquid inside the United States (by itself or by a third party). If, as per first full quarter following the commercial launch of Atomoxetine Oral Liquid, Hyloris Developments does not sell any Atomoxetine Oral Liquid for a period of four consecutive years, parties will discuss in good faith the appointment of a new distributor for the United States.

In consideration of any and all rights granted by Tahoe Pharmaceuticals to Hyloris Developments, Tahoe Pharmaceuticals shall be entitled to development milestone payments for a total amount of USD 350,000 of which USD 100,000 has already been paid at signing of the license agreement. In

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<sup>183</sup> The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

addition, Taho Pharmaceuticals shall be entitled to a low single digit percentage fee on all net sales of Atomoxetine Oral Liquid in the United States.

The agreement remains in force until either (i) 20 November 2039 or (ii) the expiry date of the last patent relating to Atomoxetine Oral Liquid assigned to Hyloris Developments, whichever occurs the latest. Both parties may however immediately terminate the agreement in the event the other party (i) fails to remedy any material breach of the agreement within a period of 90 days after receipt of a written request thereto and/or (ii) the other party is confronted with insolvency issues. Hyloris Developments may also terminate the agreement for convenience upon a 12 months prior written notice to Taho Pharmaceuticals. Upon termination of the agreement, Hyloris Developments shall retransfer the Taho patents back to Taho Pharmaceuticals. Such retransfer shall however not prejudice the granted (perpetual) license, except in the event Taho Pharmaceuticals terminates the agreement due to a material breach of the contract by Hyloris Developments, or due to insolvency issues of the latter (in which event the granted licenses shall terminate).

#### **8.12.11 HY-REF-029**

To date, Hyloris has not entered into any business agreements relating to HY-REF-029.

#### **8.12.12 HY-REF-075**

##### **NORDIC SPECIALTY PHARMA - ASSET PURCHASE AND DEVELOPMENT AGREEMENT**

On 21 December 2018, Hyloris Developments and Nordic Specialty Pharma (NSP) (a subsidiary of the Alter Pharma group<sup>184</sup>) entered into an “Asset Purchase and Development Agreement”, whereby NSP assigned to Hyloris Developments its rights and interests relating to the medicine HY-REF-075 for the United States market. The transfer includes all intellectual property rights and development data. In addition, the parties agreed that NSP would remain responsible for further developing the (patentable) HY-REF-075, as well as for the filing of a patent application in name of Hyloris Developments. In exchange for the aforementioned transfer of intellectual property rights, Hyloris Developments must pay NSP (i) a fixed price of USD 500,000 (of which USD 400,000 has already been paid and USD 100,000 will become payable upon completion of the formulation), and a royalty amounting to (i) 25% of the net profit of the sales within the United States in the event HY-REF-075 is granted an orphan drug designation or (ii) 12.5% if no such status is granted. Hyloris does not expect HY-REF-038 to be granted the “orphan drug designation”.

NSP explicitly provides no warranty whatsoever that the execution of the agreement shall not result in an infringement of any third-party patents or other intellectual property rights. On the contrary, it is explicitly agreed that Hyloris Developments shall indemnify and hold harmless NSP for any patent legal costs, it being understood that such cost can be deducted from the net profits for purposes of calculating the aforementioned royalty payments. The agreement is governed by Belgian law, and all disputes in relation thereto shall be submitted to the International Chamber of Commerce, residing in Brussels.

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<sup>184</sup> The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

In a subsequent “special agreement” with NSP of 21 December 2018, it was agreed that (i) if the total development costs exceed EUR 500,000, NSP is entitled to invoice these additional costs to Hyloris Developments; and that (ii) if Hyloris Developments would have no further interest in the development of the product, the parties will discuss in good faith the replacement of HY-REF-075 by another product and the fee already paid and the costs already incurred will be reallocated to such replacement product.

### **8.12.13 HY-EMP-016**

#### **8.12.13.1 HYLORIS DEVELOPMENTS - ASSET PURCHASE AGREEMENT**

On 28 February 2018, Hyloris Developments and Dermax (*i.e.*, before Dermax was acquired on 31 December 2019 by Hyloris Pharmaceuticals<sup>185</sup>) signed an “Asset Purchase Agreement” whereby Hyloris Developments transferred and assigned to Dermax all of its (intellectual property) rights and interests relating to the product HY-EMP-016. The transfer included, among other things, all rights and obligations of Hyloris Developments under the “Product development and commercialization collaboration agreement” regarding HY-EMP-016 entered into with Paddock Laboratories LLC (a wholly owned subsidiary of Perrigo) and under the agreement relating to the performance of clinical research activities entered into with Biorasi LLC.

The intellectual property rights are assigned to Dermax (i) in exchange for a fixed price of EUR 2,008,473 and (ii) upon compensation of all related costs incurred by Hyloris Developments in relation to HY-EMP-016 after the date of assignment. Due to the acquisition of Dermax by Hyloris Pharmaceuticals, Hyloris reobtained the rights relating to HY-EMP-016.

The agreement is governed by Belgian law, and all disputes in relation thereto shall be submitted to the courts of Brussels.

#### **8.12.13.2 PADDOCK LABORATORIES - PRODUCT DEVELOPMENT AND COMMERCIALIZATION AGREEMENT**

On 16 November 2015, Hyloris Developments and Paddock Laboratories concluded a “Product development and commercialization collaboration agreement”, with the purpose to cooperate in the development and commercialization of HY-EMP-016 in the United States. Upon obtaining FDA approval of the ANDA for HY-EMP-016, Paddock Laboratories is responsible for manufacturing, packaging, selling and distributing HY-EMP-016 in the United States. Paddock Laboratories is also responsible for obtaining all required (regulatory and other) approvals and authorizations to manufacture and commercialize HY-EMP-016 in the United States.

Up to a period of five years following the termination of the agreement, the parties may not directly or indirectly sell, develop, or commercialize competing products of HY-EMP-016 in the United States. If a party acquires (a portfolio of assets of a) company including a product that competes with HY-EMP-016, that party will transfer all rights and interests in HY-EMP-016 to the other party.

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<sup>185</sup> In December 2019, the Issuer has acquired all shares in Dermax (see Section 12.4 (Dermax Acquisition)) such that it again indirectly owns the rights relating to HY-EMP-016.

Hyloris shall own all rights, titles and interests to any developed inventions, know-how and technical information relating to HY-EMP-016, except for the ANDA which is held by Paddock Laboratories.

Hyloris Developments is entitled to more than half of the gross profits derived from all sales of HY-EMP-016 in the United States by Paddock Laboratories. The costs incurred to develop and commercialize HY-EMP-016 in the United States shall be shared between both parties.

The term of the agreement is for an initial period of twenty years but may be renewed, upon mutual agreement by both parties, for additional periods of two years. Paddock Laboratories shall have the right to terminate the agreement upon a thirty days' prior notice in the event a third party makes a patent claim. Further, either party may terminate the agreement in the event (i) the other party commits a material breach without remedying such breach within a period of thirty days after receiving a notice request thereto, (ii) in the event the other party files for bankruptcy, dissolves, liquidates or discontinues all or a significant part of its business or threatens to cease such business, (iii) the other party is confronted with other solvability issues and/or (iv) HY-EMP-016 appears not commercially viable. In the event Paddock Laboratories terminates the agreement due to a material breach of Hyloris Developments, the latter shall transfer to Paddock Laboratories all its rights and assets in HY-EMP-016, at no costs or expenses. Equally, all Paddock Laboratories' rights and assets in HY-EMP-016 shall be transferred to Hyloris Developments in the event the agreement is terminated due to a material breach of Paddock Laboratories.

The agreement is governed by the laws of New York. All disputes in relation thereto shall be referred to a joint development committee. If parties are unable to resolve the dispute within 15 business days, any method of dispute resolution may be selected.

#### **8.12.14 FUSIDIC ACID CREAM**

##### **8.12.14.1 STASISPORT PHARMA - LICENSE AGREEMENT**

On 8 June 2019, Dermax entered into a "License and distribution agreement" with Stasisport Pharma (a subsidiary of the Alter Pharma group<sup>186</sup>), pursuant to which the latter granted Dermax a personal, sub-licensable and exclusive right to use all available development data and registration documents (which shall be compiled by Stasisport Pharma and updated with the clinical trials and/or comparative studies) concerning Fusidic Acid Cream, in order to obtain (one or multiple) marketing authorizations for Fusidic Acid Cream in Canada, and to subsequently market, sell and distribute Fusidic Acid Cream in that territory. The clinical trial results generated under the agreement are the (exclusive) property of Dermax, but Stasisport Pharma retains a perpetual, royalty-free license to use such clinical data generated outside Canada. Further, the agreement stipulates that Dermax must exclusively purchase its total requirements for Fusidic Acid Cream in Canada from Basic Pharma Manufacturing and that Dermax may not register, market, sell or manufacture any competing products in Canada.

The license has been granted to Dermax in exchange for a one-time lump-sum license fee of up to EUR 975,000 of which EUR 500,000 already has been paid. However, if the costs of the required clinical trials are below EUR 800,000, Stasisport Pharma shall reimburse the difference between EUR 800,000

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<sup>186</sup> The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

and the amount of the actual costs of the clinical trials (hence, if no clinical trials are required by the Canadian health authorities, the full amount of EUR 800,000 would be reimbursed in the form of a credit that can be used as a set-off against any payment due by Dermax or any of its affiliates in any other projects with Stasisport Pharma or any of its affiliates).

The agreement is entered into by the parties for an initial period of twenty years, but shall automatically be extended for an indefinite period, unless (and until) terminated by either party providing at least twenty-four months' prior written notice. Both parties are however entitled to immediately terminate the agreement in the event the other party (i) commits a material breach which is not (or cannot be) remedied within sixty days following receipt of a written request thereto, and/or (ii) is confronted with insolvency issues or liquidation. Dermax may further terminate the agreement upon prior written notification to Stasisport Pharma in the event Dermax' applications for the (Canadian) market authorizations for Fusidic Acid Cream are rejected due to reasons clearly attributable to Stasisport Pharma.

In the event Stasisport Pharma (and/or Basic Pharma Manufacturing) decides to commercialize the concerned product in Canada itself after termination of the agreement, Stasisport Pharma will refund to Dermax the amount of the license fee of EUR 975,000 paid in relation to the clinical costs, but the (intellectual property) rights related to results of the clinical trial shall be transferred to Stasisport Pharma upon refund.

The agreement is governed by Belgian law, and all disputes in relation thereto shall be submitted to the courts of Brussels.

The patent regarding Fusidic Acid Cream that was obtained after conclusion of the License Agreement is registered in the name of, and owned by, Dermax.

#### **8.12.14.2      BASIC PHARMA MANUFACTURING – SUPPLY AGREEMENT**

On 13 March 2020, Dermax and Basic Pharma Manufacturing entered into a "Supply Agreement", pursuant to which Basic Pharma Manufacturing agreed to supply Fusidic Acid 2% Cream 30g to Dermax. Dermax (or its appointed distributor) must purchase its total requirement of Fusidic Acid 2% Cream 30g for Canada exclusively from Basic Pharma Manufacturing or from a third party appointed by it. Dermax agreed to launch, and thereafter continue to market and sell, Fusidic Acid 2% Cream 30g in Canada. Basic Pharma Manufacturing is entitled to have the product manufactured by a third party and may add or change API suppliers.

Dermax must purchase Fusidic Acid 2% Cream 30g at an agreed price per pack. If there are extra requirements needed for Canada, these costs shall be borne by Dermax. After a period of five years following the launch of the product, the supply price may annually be adjusted in accordance with the evolution in the Dutch consumer price index of that time. In the event the net profit margin realized by Dermax does not reach an agreed threshold, the supply price may be adjusted to ensure that Dermax realizes that threshold margin. However, the agreement contains a minimum price per pack below which the supply price will in no event fall.

The agreement shall continue, on a regional basis, for a period of 20 years following the launch of Fusidic Acid 2% Cream 30g in the concerned region within Canada. However, the agreement shall automatically be extended for an indefinite period, unless (and until) terminated by either party providing at least twelve months' prior notice. Either party may immediately terminate the agreement in the event the other party (i) commits a material breach which is not (or cannot be) remedied within sixty days following receipt of a written request thereto, and/or (ii) is confronted with insolvency issues or liquidation.

The agreement is governed by Belgian law, and all disputes in relation thereto shall be submitted to the courts of Brussels.

### **8.13 COMMERCIAL OPERATIONS**

Hyloris intends to maximize the value of its current portfolio by applying different commercialization strategies for each of the three categories.

#### **8.13.1 *IV CARDIOVASCULAR PORTFOLIO***

For the IV cardiovascular product candidates, Hyloris expects to build its own commercial department for marketing, sales and distribution in the United States. Hyloris will create and leverage a lean and effective team of dedicated sales reps and medical science liaisons. Based on the number of hospital cardiologists, Hyloris believes that it can effectively target the relevant audience in the United States by establishing an internal sales force. In addition, Hyloris expects to engage an experienced third-party logistics company specialized in pharmaceuticals to manage the inventory, logistics, and sales reconciliation of its commercial products. Although Hyloris focus lies on the United States for its IV Cardiovascular Portfolio, Hyloris believes that HY-CVS-073 and HY-CVS-074 can potentially also be commercialized outside of the United States.

Hyloris currently has one IV cardiovascular product in an early stage of commercialization.

Hyloris chose to out-license the commercial rights for Sotalol IV to AltaThera before it had developed its other IV Cardiovascular Portfolio product candidates and therefore had not yet defined its strategy to establish its own commercial team in the United States for its IV Cardiovascular Portfolio.

#### **8.13.2 *OTHER REFORMULATION PORTFOLIO***

Hyloris will frequently review its commercial strategy to assess whether it is utilizing its resources efficiently.

For the product candidates in its Other Reformulation Portfolio, Hyloris intends to remain flexible and plans to selectively out-license or seek a marketing partner with specialized outreach specific to its products' respective indications on a case-by-case basis. Typically, such out-licensing deals involve both an upfront payment and milestones linked to development progress, clinical trial results and market approval, as well as participation in future commercial upside with fees on sales, margin or profits.

In relation to the possible commercialization of its product candidates in geographies other than the United States, Hyloris may exploit the use of existing regulatory data to obtain approval outside the United States for selected product candidates. Outside the United States, Hyloris may use a different commercialization strategy.

For product candidates in its Other Reformulation Portfolio, the formulation of the product is key. The technology and approach required for the formulation often differ per product candidate. Certain products need extensive formulation work and require specialized equipment. Having this knowledge and expertise is key to develop stable and bioequivalent reformulations. Hyloris typically requires three months (accelerated) stability on its candidate formulations before moving to upscaling and producing registration batches on which the FDA requires a minimum 12 months of stability data for filing.

Hyloris currently has one other reformulation product in an early stage of commercialization: Maxigesic<sup>®</sup> IV. Maxigesic<sup>®</sup> IV has been launched in Australia and New Zealand in June 2020 and is expected to be launched in the United Arab Emirates in the summer of 2020. As per contractual terms Hyloris will receive worldwide profit participation except for profit generated on sales in Australia and New Zealand. Hyloris' partner, AFT Pharmaceuticals, is responsible for the commercialization of Maxigesic<sup>®</sup> IV.

#### **8.13.3 ESTABLISHED MARKET PORTFOLIO (“HIGH-BARRIER GENERICS”).**

For its established market product candidates, Hyloris also intends to maintain flexibility and selectively out-license or seek a marketing partner on a case-by-case basis. Typically, such partnering deals are based on sharing net margin.

#### **8.14 RESEARCH AND DEVELOPMENT, CLINICAL TRIALS**

Hyloris has an experienced team with the ability to bring its product candidates to market in an efficient fashion by relying on strong reformulation development capabilities, its extensive product development experience, significant clinical development experience and a robust network of reliable, high quality subcontractors. Hyloris develops, co-develops or outsources part of the development of its product candidates to third parties. The overall product development however always occurs for the account and under the (financial) responsibility of Hyloris.

Hyloris' research and development (R&D) team has full end-responsibility for the development and manufacturing of product candidates, including the selection and qualification of services providers hereby directing the development and manufacturing of product candidates. Hyloris' R&D team ensures the quality of the validation protocols and reports of analytical methods and of analytical tests. It manages the project proactively by ensuring that project timelines are met and delays are managed. Hyloris' team is responsible for planning and negotiation of project budgets and assessment of appropriate project scopes. For more information about the composition of Hyloris' R&D team, reference is made to Section 8.20 (Human Resources).

Hyloris' clinical team is in charge of ensuring that the clinical trials are properly conducted, including the selection of qualified services providers. It monitors the quality and robustness of the clinical data and ensures that all clinical work is handled according to GCP. Hyloris' clinical team is also responsible for

the development of the clinical study protocols, investigators' brochures and other relevant study documents. It ensures that the clinical studies run as smoothly as possible by tracking the project and managing the investigator and ethical review board information, and patient recruitment activity. It is further responsible for the financial management of the clinical trial.

All Hyloris team members are responsible to allow an efficient information flow between internal and external teams involved in the development of the product candidates.

Hyloris' may outsource current research and development activities to specialized service providers. Formulation development activities can be outsourced to Contract Development Organization (CDO) who will perform the development of a stable formulation as well as the development and validation of the analytical methods of a product candidate. Once completed, the technology will be transferred to a Contract Manufacturing Organization (CMO) who will manufacture batches necessary for Hyloris' clinical trials as well as to enable Hyloris to generate all of the data and documentation necessary to submit a final application to the FDA, including all validation and stability studies.

Alternatively, Hyloris may choose to work with a Contract Development and Manufacturing Organization (CDMO) who will perform the complete development of the product, including formulation development, manufacturing of clinical and submission batches, as well as conduct the stability studies and all required validation work, enabling Hyloris to compile the final application to the FDA.

During the development of the formulation and following the manufacturing of clinical batches by the CMO or CDMO, Hyloris' clinical team will engage a Contract Research Organization (CRO) who will conduct and manage the clinical trials for the product candidate.

All research, formulation development, manufacturing and clinical work is performed on the basis of specific contracts, framework contracts, or, in special cases, purchase orders. Typically, these contracts contain clauses intended to ensure that Hyloris owns all intellectual property generated during the process and is granted a royalty-free, indefinite right to use any existing intellectual property owned by the service provider.

Hyloris expects that internal and external research, development and clinical expenditures will significantly increase as it progresses its programs.

#### **8.15 SUPPLY OF ACTIVE PHARMACEUTICAL INGREDIENTS AND MANUFACTURING OF FINISHED DOSAGE FORMS**

Hyloris does not own or operate any API or manufacturing facilities, nor does it have plans to acquire or set up any own manufacturing operations in the foreseeable future. Hyloris currently depends on third parties for all of its required API supply and for all manufacturing of product candidates and products.

Hyloris typically engages all API suppliers and all manufacturers through supply agreements. Such agreements are normally put in place during the development phase.

Each of the API suppliers currently used by Hyloris holds FDA approval of the relevant Drug Master File (DMF) or are willing to submit the same to the FDA for approval.

Each of the CDMOs and CMOs currently used by Hyloris is based in the United States or Europe and hold an existing FDA approval to manufacture products for the U.S. market, with the exception of Basic Pharma (as the product manufactured is not targeting the United States). Hyloris seeks to work with CDMOs and CMOs that have a strong history of quality and FDA compliance with no open 483 observations or warning letters. Hyloris currently employs internal resources and third-party consultants to manage and monitor its API suppliers and manufacturers.

For specific products such as Sotalol IV, HY-EMP-016 and Maxigesic® IV, Hyloris' commercial partner will be responsible for the manufacturing of the final product.

Hyloris believes that relying on external manufacturers significantly reduces the amount of capital required to be invested and allows the flexibility to pursue a broad range of opportunities beyond the specific capabilities of a single facility.

#### **8.16 QUALITY ASSURANCE AND REGULATORY AFFAIRS**

As of the date of this Prospectus, Hyloris' quality assurance function is fully outsourced. Hyloris hires external auditors to audit the third-party manufacturers of its APIs and finished dosage forms. However, Hyloris plans to establish an internal quality function in the future when management deems it is commercially efficient for it to do so.

Hyloris' regulatory affairs function is partially outsourced. Hyloris handles its own pre-IND consultations with the FDA for most products, but outsources the dossier writing and the submission of its applications to highly specialized consultants under Hyloris' management and supervision. Hyloris closely evaluates and monitors its contractors and intends to take steps to strengthen its regulatory affairs function in the coming years, bringing the majority of such tasks in-house.

#### **8.17 INTELLECTUAL PROPERTY**

Hyloris intends to protect and enhance the proprietary technologies which are of key importance to its business through patents, trademarks and protection of its trade secrets. Furthermore, Hyloris performs landscape reviews when it deems it relevant.

Hyloris also relies on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain its proprietary position in the fields targeted by its product candidates. Hyloris intends to vigorously defend its intellectual property to preserve its rights and gain and maintain the benefits of the significant technological investments it made.

Hyloris seeks to obtain and maintain patents in appropriate jurisdictions for patentable aspects of its product candidates, their methods of use and any other inventions that are important to its business model.

### 8.17.1 PATENTS AND LICENSES

As of the date of this Prospectus, Hyloris holds the rights to the following patents, patent applications and provisional patents filed and the following licenses with respect to its product (candidates) portfolio:

Project	Patents / patent applications						Title
	Description	Key Jurisdictions	Filing date	(Projected) Expiry date	Summary status	Grant number	
<b><u>IV Cardiovascular Portfolio</u></b>							
<b>Sotalol IV</b>	Ready to use pharmaceutical IV composition comprising sotalol	Belgium	27 Aug 2014	27 Aug 2034	Granted	BE1021328, BE1021320	Owned
<b>Dofetilide IV</b>	A method of initiating or escalating dofetilide dose and formulations therefor	United States	24 Jun 2019	24 Jun 2039	Pending	-	In-licensed from Academic Pharmaceuticals
<b>Metolazone IV</b>	Parenteral solutions containing metolazone	United States	17 Mar 2008 17 Dec 2012	18 May 2029	Granted	US7,923,447, US9,427,398	In-licensed from Academic Pharmaceuticals
	Metolazone emulsion formulation	United States	11 Sep 2018	11 Sep 2038	Pending	-	In-licensed from Academic Pharmaceuticals
<b>HY-CVS-073</b>	CONFIDENTIAL	United States	CONFIDENTIAL	CONFIDENTIAL	Granted	CONFIDENTIAL	In-licensed from Academic Pharmaceuticals
<b>HY-CVS-074</b>	-	-	-	-	-	-	Unregistered intellectual property rights in-licensed from Academic Pharmaceuticals

<u>Other Reformulation Portfolio</u>							
<b>Maxigesic® IV</b>	Method for preparing a composition with a low dissolved oxygen content, comprising acetaminophen, and optionally one or more NSAIDs, and a composition obtained thereof	Argentina; Taiwan; United Arab Emirates; Australia; Brazil; Canada; Chile; China; Colombia; Ecuador; European Patent Office; Indonesia; Israel; Japan; Republic of Korea; Mexico; Malaysia; New Zealand; Peru; Philippines; Russian Federation; Saudi Arabia; Singapore; U.S.; Vietnam; South Africa	20 Apr 2018	20 Apr 2038	Pending	-	Co-owned with / in-licensed from AFT Pharmaceuticals <sup>(1)</sup>
	Aqueous formulation comprising paracetamol and ibuprofen	Australia; Brazil; Canada; China; Hong Kong; European Patent Office (Albania, Austria, Bulgaria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany,	8 Mar 2017 (HK) 12 Dec 2019 (EP divisional) 13 Dec 2019 (JP divisional) 28 May 2019 (US divisional) 17 Jul 2015 (other jurisdictions)	17 Jul 2035	Granted (EPO, Australia, South Africa)  Pending (other jurisdictions)	EP3169307 (EPO) AU2015289035 (Australia) ZA2017/00380 (South Africa)	Co-owned with / in-licensed from AFT Pharmaceuticals <sup>(1)</sup>

		Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Macedonia, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland/Liechtenstein, Turkey, United Kingdom); Israel; Japan; Mexico; Malaysia; New Zealand; Saudi Arabia; Singapore; Tunisia; U.S.; South Africa					
	Storage-stable formulation of paracetamol in aqueous solution	Belgium; Switzerland; Germany; France; U.K.; Italy; Luxembourg; Netherlands; Australia; New Zealand; U.S.; Vietnam; South Africa	13 Aug 2010	13 Aug 2030 20 Nov 2030 (U.S.)	Granted	60 2010 030 905.3 (Germany) 502016000055272 (Italy) AU2010283717 (Australia) NZ598585 (New Zealand) US8404891 (U.S.)	In-licensed from Neogen Developments

						VN1-0021040-000 (Vietnam) ZA2012/01806 (South Africa) EP2464332 (other jurisdictions)	
<b>HY-REF-004</b>	CONFIDENTIAL	Belgium U.S.	9 Jan 2019	9 Jan 2039	Granted Pending	BE1025996 (Belgium)	Owned
<b>Tranexamic Acid RTU</b>	Tranexamic acid RTU IV solution	Belgium; U.S.	17 Jun 2019 (Belgium) 24 Apr 2019 (U.S.)	17 Jun 2039 (Belgium) 24 Apr 2039 (U.S.)	Pending	-	Owned
<b>HY-REF-038</b>	-	-	-	-	-	-	Unregistered intellectual property rights owned
<b>Atomoxetine Oral Liquid</b>	Oral Solution Comprising Atomoxetine HCl and Methods Thereof	U.S.	14 Dec 2016 29 Nov 2017	14 Dec 2036 14 Dec 2036	Granted Granted	US9,855,228 US9,993,445	In-licensed from Taho Pharmaceuticals
<b>HY-REF-029</b>	-	-	-	-	-	-	Unregistered intellectual property rights owned
<b>HY-REF-075</b>	-	-	-	-	-	-	Unregistered intellectual property rights owned
<b><u>Established Market Portfolio ("high barrier generics")</u></b>							
<b>HY-EMP-016</b>	Improved method for production of <b>HY-EMP-016</b>	Belgium	26 Dec 2018	26 Dec 2038	Granted	CONFIDENTIAL	Owned
<b>Fusidic Acid Cream</b>	Fusidic acid cream and method for the preparation thereof	U.S.	20 Apr 2016	20 Apr 2036	Granted	US10,420,779	Owned

	-	-	-	-	-	-	Unregistered intellectual property rights in-licensed from Stasisport Pharma
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Notes:

- (1) Granted by the European Patent Office (EP3169307) and in Australia (AU2015289035) and South-Africa (ZA2017/00380);

### **8.17.2 LANDSCAPE REVIEW**

As of the date of this Prospectus, no patent infringement claims have been made against Hyloris. Parallel to the development of Hyloris' own intellectual property, patent literature in general and, more specifically, patents of competing companies are continuously monitored and evaluated in order to avoid infringement and to explore the space of patentable subject matter. Hyloris will normally perform a landscape review prior to manufacturing clinical batches or have it as a part of the analysis for performing a patent application. The analysis will normally be performed towards the U.S. market only.

### **8.17.3 TRADEMARKS**

As of the date of this Prospectus, Hyloris does not hold any trademarks that are material to Hyloris, but intends to apply for trademarks when it becomes relevant. For example, potentially in connection with the planning stages of the launch of its IV Cardiovascular Portfolio. The trademark for Maxigesic® is held by AFT Pharmaceuticals, and for Hyloris' other licensed products, HY-EMP-016 and Sotalol IV, the products will likely not carry a trademark.

### **8.17.4 TRADE SECRETS AND KNOW-HOW**

Hyloris intends to protect the use of its trade secrets and know-how through an extensive use of confidentiality agreements with any third party it engages. Furthermore, Hyloris enters into commercial agreements with its CDOs, CDMOs, CMOs and CROs in an effort to ensure that the ownership of any data generated will lie with Hyloris. For all in-licensed intellectual property, Hyloris ensures it has rights to use any know-how as part of the contract.

## **8.18 INSURANCE**

Hyloris maintains insurance to cover its potential exposure for a number of claims and losses, including product liability insurance, to help pay for the defense of product liability lawsuits and clinical study insurance, to help cover defense of lawsuits costs relating to products which are the subject of clinical studies. Hyloris believes that the insurance coverage that it has is adequate in light of the risks that it faces.

## **8.19 REGULATIONS**

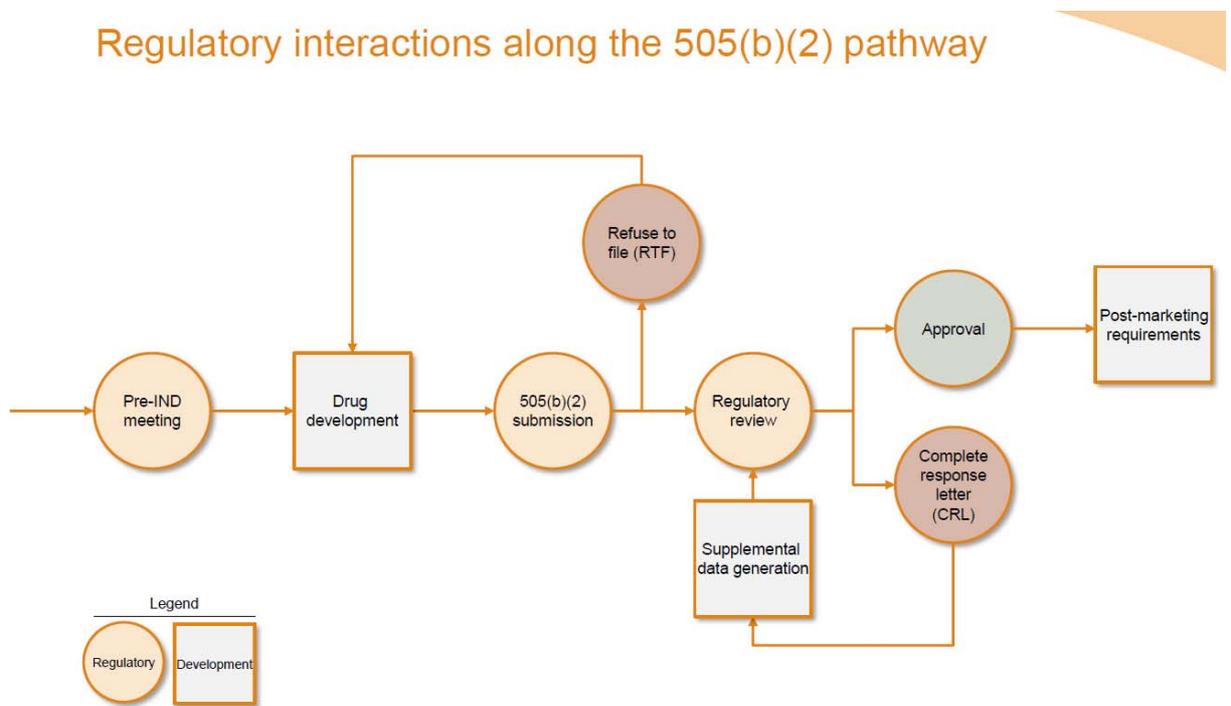
Pharmaceutical companies are subject to extensive regulation in the United States by federal, state and local agencies, such as the FDA. Outside the United States, they are subject to regulation by local European and non-European regulatory authorities. The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation. Additionally, Hyloris must follow rules and regulations established by the authorities requiring the presentation of data indicating that its products are safe and efficacious and are manufactured in accordance with so called cGMP regulations. If Hyloris does not comply with applicable requirements, Hyloris may be fined, the government may refuse to approve its marketing applications or allow it to manufacture or market its products, and Hyloris may be criminally prosecuted. Hyloris, its manufacturers, CDOs and CROs may also be subject to regulations under other foreign, federal, state and local laws, including, but not limited to, the U.S.

Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. The U.S. government has increased its enforcement activity regarding illegal marketing practices domestically and internationally. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

These regulatory requirements impact Hyloris' operations and differ from one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval of another country. The approval procedures involve significant investments and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

### 8.19.1 THE FDA MARKET APPROVAL PROCESS

The chart below is a depiction of the steps generally required to be taken before a new drug can be marketed in the United States:



Source: Camargo (amended)

These steps include:

- start of development and pre-clinical laboratory testing and submission of a pre-IND allowing Hyloris to interact with the FDA, to determine the FDA's clinical requirements for a product;
- completion of development and pre-clinical laboratory testing;

- completion of required CMC testing;
- submission to the FDA of an IND, the application for which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical studies;
- submission and approval of an NDA; and
- agreement with FDA of the language on the package insert.

Clinical studies are conducted in accordance with protocols detailing, among other things, the objectives of the study, the type of patients, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND process.

Clinical trials are usually conducted in three phases. Phase 1 clinical trials are normally conducted in small groups of healthy volunteers to assess safety of various dosing regimens and pharmacokinetics. In Phase 2 clinical trials the drug is administered to small populations of sick patients to look for initial signs of efficacy in treating the targeted disease or condition and to continue to assess safety and the correct dose. Phase 3 clinical trials are usually multi-center, double-blind controlled trials in hundreds or even thousands of subjects at various sites to assess as fully as possible both the safety and effectiveness of the drug. In certain cases, where the FDA will accept a pharmacokinetic study (PK study), such study is considered a Phase 3 trial as a PK study is considered a pivotal study, meaning that the NDA approval is mainly based on the data which will be generated from that study. A pivotal trial is typically considered to be a Phase 3 clinical trial.

Clinical trials must be conducted in accordance with the FDA's good clinical practices requirements. The FDA may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points, based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA increases as clinical studies progress. Hyloris and the third-party manufacturers on which it relies for the manufacture of API and its product candidates and their respective components are subject to

requirements that drugs be manufactured, packaged and labelled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labelling and packaging, quality control, recordkeeping and other requirements.

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of a new drug application (**NDA**), requesting approval to market the product, together with payment of a user fee. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the CMC and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA.

If an NDA submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Prescription Drug User Fee Act (**PDUFA**), the FDA's goal is to complete its initial review and respond to the applicant within ten months of submission, unless the application relates to an unmet medical need, or is for a serious or life-threatening indication, in which case the goal may be within six months of NDA submission. However, PDUFA goal dates are not legal mandates and the FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA requests or the sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved.

The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and inspects manufacturing facilities where the product candidates and/or its API will be produced, it will either approve commercial marketing of the drug product with prescribing information for specific indications or issue a CRL (complete response letter) indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the CRL requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug.

If the FDA approves one of Hyloris' product candidates, Hyloris will be required to comply with a number of post-approval regulatory requirements. Hyloris would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of its products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If Hyloris seeks to make certain changes to an approved product, such as certain manufacturing changes, it will need FDA review and approval before the change can be implemented. For example, if Hyloris changes the manufacturer of a product or its API, the FDA may require stability or other data from the new manufacturer, and such data will take time and are costly to generate, and the delay associated with generating these data may cause interruptions in Hyloris' ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the FDA, Hyloris may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

The FDA may also require post-marketing testing, or Phase 4 testing, as well as risk minimization action plans and surveillance to monitor the effects of an approved product or place conditions on an approval that could otherwise restrict the distribution or use of the product.

#### **8.19.2 505(b)(2) NEW DRUG APPLICATION**

Hyloris intends to submit applications for most product candidates via the 505(b)(2) NDA regulatory pathway. As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the FDCA, was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drugs that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the Section 505(b)(2) application. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to make certain certifications to the FDA concerning any patents listed for the approved product in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of an NCE, listed in the Orange Book for the reference product, has expired. If the Orange Book certifications outlined above are not accomplished, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. The molecule patent of the reference product for each of Hyloris' product candidates has either already expired or will expire prior to the relevant product candidate's approval by the FDA, and hence Hyloris expects there will be no restriction to enter the market with respect to any of its product candidates. However, certain of these reference products may have other patents that may limit Hyloris' freedom on formulation development, it being understood that Hyloris performs (or has performed) patent analysis prior to formulation development and hence does not expect any delays in approval due to patents.

On average, the 505(b)(2) approval process in practice takes about 12 to 15 months. For more information on the 505(b)(2) approval process, reference is made to Section 8.9 (Overview of the 505(b)(2) regulatory pathway).

### **8.19.3 505(J) ABBREVIATED NEW DRUG APPLICATION**

The Hatch-Waxman Act established abbreviated FDA approval procedures for drugs that are shown to be equivalent to proprietary drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by filing an ANDA with the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

Hyloris expects only in a few cases to utilize the ANDA regulatory pathway. In such cases, it will typically concern established market product candidates with high clinical barrier or products, where Hyloris would intend to switch container, for example from an ampoule to a vial or a vial to a prefilled syringe.

#### **8.19.4 *DESI PROGRAM***

Upon its enactment in 1938, the FDCA required new drugs to demonstrate that they were safe before they could be marketed. In 1962, the FDCA was amended to require that new drugs demonstrate that they were effective as well as safe. Following the 1962 amendments to the FDCA, the FDA adopted a program called the Drug Efficacy Study Implementation, or DESI, to review the efficacy of drugs approved between 1938 and 1962, and the drugs approved between 1938 and 1962 are commonly referred to as DESI drugs. DESI drugs were allowed to remain on the market until they were re-reviewed as long as they weren't substantially changed. The DESI program removed many products that were deemed to not be effective, but there was no comprehensive list of drugs approved and marketed at the time and not all drugs were re-reviewed. As a result, many DESI products remained marketed without a formal approval for effectiveness.

None of the product candidates in the portfolio of Hyloris are DESIs, however Hyloris may at a later stage attempt to convert DESI projects into approved NDA's, by generating sufficient data and clinical trial results to justify such a submission of a product candidate.

#### **8.19.5 *ORPHAN DRUGS***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation provides for seven years exclusivity, independent of patent protection, to Hyloris with orphan drug designation that brings a particular product to market. In addition, companies developing orphan drugs are eligible for certain incentives, including special protocol review for its clinical trials on the product candidate. In addition, an NDA for a product that has received orphan drug designation is not subject to a PDUFA fee unless the application includes an indication other than the rare disease or condition for which the drug was designated.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product may be entitled to the orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. Competitors, however, may receive approval of different active ingredients for the same indication or obtain approval for the same active ingredient for a different indication. In addition, doctors may prescribe products for off-label uses and undermine the exclusivity. Conversely orphan drug exclusivity could block the approval of one of Hyloris' products for seven years if a competitor obtains approval for the same active moiety for the same indication before Hyloris does, unless it is able to demonstrate that its product is clinically superior, or it may grant Hyloris additional protection on certain product candidates.

Hyloris is constantly investigating orphan drug opportunities and believe one may potentially be entitled to the orphan drug designation.

#### **8.19.6 CONTINUING REGULATION**

After a drug is approved for marketing and enters the marketplace, numerous regulatory requirements continue to apply. These include, but are not limited to:

- the FDA's cGMP regulations require API and finished product manufacturers, to follow stringent requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product;
- labeling regulations and the FDA prohibitions against the promotion of drugs for unapproved uses (known as off-label uses), as well as requirements to provide adequate information on both risks and benefits during promotion of the drug;
- approval of product modifications or use of a drug for an indication other than approved in an NDA;
- adverse drug experience regulations, which require us to report information on adverse events during pre-market testing;
- post-market testing and surveillance requirements, including Phase 4 trials, when necessary to protect the public health or to provide additional safety and effectiveness data for the drug; and
- the FDA's recall authority, whereby it can ask, or under certain conditions order, drug manufacturers to recall from the market a product that is in violation of governing laws and regulation. After a drug receives approval, any modification in conditions of use, active ingredient(s), route of administration, dosage form, strength or bioavailability, will require a new approval, for which it may be possible to submit a 505(b)(2) application, accompanied by additional clinical data necessary to demonstrate the safety and effectiveness of the product with the proposed changes. Additional clinical studies may be required for proposed changes.

#### **8.19.7 OTHER U.S. HEALTHCARE LAWS AND COMPLIANCE REQUIREMENTS**

For products distributed in the United States, Hyloris will also be subject to additional healthcare regulation and enforcement by the federal government and the states in which it conducts its business. Applicable federal and state healthcare laws and regulations include the following:

- The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order, or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- The Ethics in Patient Referrals Act, commonly referred to as the Stark Law, and its corresponding regulations, prohibit physicians from referring patients for designated health services (including outpatient drugs) reimbursed under the Medicare or Medicaid programs to entities with which the physicians or their immediate family members have a financial relationship or an ownership interest, subject to narrow regulatory exceptions, and prohibits those entities from submitting claims to Medicare or Medicaid for payment of items or services provided to a referred beneficiary;
- The federal False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- Health Insurance Portability and Accountability Act of 1996, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. This statute also prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items, or services; and
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government.

#### **8.19.8 CANADIAN HEALTHCARE LAWS AND COMPLIANCE REQUIREMENTS**

The Canadian requirements for approval, are fairly similar to the European requirements. Hyloris is currently developing one product for Canada (Fusidic Acid Cream), based on a product, that has recently been approved in several European countries.

#### **8.20 HUMAN RESOURCES**

On 31 March 2020, Hyloris employed 9.90 full-time equivalents, which included employees and consultants. The following table presents a break-down of Hyloris' full-time equivalents as at 31 March 2020, 31 December 2019, 31 December 2018 and 31 December 2017:

	31 March 2020	31 December 2019	31 December 2018	31 December 2017
<b>Research and Development</b>				
Management level	1.00 <sup>(1)</sup>	1.00	1.00	1.00
Staff	3.00	3.00	2.42	1.00
<i>Subtotal</i>	<i>4.00</i>	<i>4.00</i>	<i>3.42</i>	<i>2.00</i>

<b>General management and administration</b>				
Management level	4.20	3.20	3.00	3.00
Staff	1.71	1.53	1.63	1.30
<i>Subtotal</i>	5.91	4.73	4.63	4.30
<b>Total</b>	9.91	<b>8.73</b>	<b>8.05</b>	<b>6.30</b>

Note:

- (1) Mr. Passanisi (CCEO of the Issuer) will leave the Company on 3 July 2020 (i.e., shortly after the Offering) and is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

Hyloris intends to considerably increase the current number of its employees and/or consultants, both clinical and non-clinical, during the coming years in order to manage the expected increase in the size of its portfolio.

## 8.21 LEGAL AND ARBITRATION PROCEEDINGS

There are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which Hyloris is aware), during the previous 12 months which may have, or have had in the recent past, significant effects on Hyloris and/or Hyloris' financial position or profitability.

## 8.22 GRANTS AND SUBSIDIES

In July 2018, Hyloris was awarded grant support for an amount of EUR°1,952,500 as a refundable advance from the Walloon Region for its "Mucoz" research program (a mouthwash against oral mucositis based on allopurinol), of which it effectively received EUR 488,125, and of which it utilized EUR 78,638 in the context of the research program. However, the research program was abandoned by Hyloris due to unsatisfactory results. Hyloris is only required to repay the EUR 409,487 that it did not utilize in the context of the research program, and is not required to repay the balance of EUR 78,638, as long as it complies with the following three conditions: (i) transfer all rights *in rem* on the results of the program to the Walloon Region or another entity designated by it, (ii) refrain from using, exploiting, transferring or conceding part or all of those results and (iii) refrain, for a period of 72 months as from the decision to cancel the program, from conducting any research on behalf of a third party on part or all of the research object as described in the grant support contract. As of the date of this Prospectus Hyloris has transferred all rights *in rem* on the results of the program to the Walloon Region and respected, and intends to respect, the other conditions.

Grants are typically subject to certain obligations and in the instance that such obligations are not met, the grants could be suspended, reviewed or reclaimed. Further, under any future grant awarded to Hyloris, the Company will likely have the obligation to at all times be making reasonable efforts to progress the development of the relevant project. Terms of grants by the Walloon Region would typically provide that, in the instance that the relevant project is terminated or abandoned for any reason, Hyloris must return the rights to the results and the data generated during the project to the relevant granting authority (which, in the case of the pending request for grant support for its Metolazone IV product candidate, and in the hypotheses that such grant is granted, is the Société Publique Wallonne (SPW)), in which case Hyloris would not be required to repay the grant.

## **9 OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

*The following is a review of Hyloris' financial condition and results of operations as of and for the three-month periods ended 31 March 2020 and 2019 and the three years ended 31 December 2019, 2018 and 2017. This section should be read in conjunction with Section 6.1 (Selected Financial Information), Section 5.5 (Presentation of financial and other information) and the Financial Statements included elsewhere in this Prospectus. The figures used in this Section have been derived from the Financial Statements. The Financial Statements have been prepared in accordance with IFRS. Certain statements in this section are forward-looking and should be read in conjunction with Section 5.3 (Forward-Looking Statements) of this Prospectus.*

### **9.1 OVERVIEW**

Hyloris is an early-stage innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. The Company develops proprietary products it believes offer significant advantages compared to currently available alternatives, with the aim of addressing the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders in the healthcare system.

To date, Hyloris' operations have consisted primarily of the identification of product candidates to build its pipeline and the formulation, testing and development of its existing portfolio. During the three-month period ended 31 March 2020 and the years ended 31 December 2019, 2018 and 2017, Hyloris incurred research and development expenses of EUR 0.8 million, EUR 4.6 million (including an impairment loss of EUR 3.2 million as a result of the full impairment of one of Hyloris' product candidates), EUR 4.9 million and EUR 2.3 million, respectively, and general and administrative expenses of EUR 0.5 million, EUR 0.8 million, EUR 0.6 million and EUR 1.7 million, respectively. For the year ended 31 December 2019, Hyloris had revenue of EUR 91 thousand and a loss of EUR 5.8 million. For a more detailed analysis of Hyloris' revenues and expenses, please see Section 9.3 (Analysis of operating results).

### **9.2 KEY FACTORS AFFECTING RESULTS OF OPERATIONS**

Set forth below is a discussion of key factors that Hyloris believes have affected and will in the future affect Hyloris' results of operations.

#### **9.2.1 REVENUE**

Hyloris' revenue during the three-month period ended 31 March 2020 and the years ended 31 December 2019, 2018 and 2017 is comprised of royalties and a milestone payment paid by AltaThera, to which Hyloris has out-licensed the commercial rights of Sotalol IV in the United States.

As of the date of this Prospectus, in addition to its two early stage commercial products (Maxigesic® IV and Sotalol IV), Hyloris has twelve product candidates in various stages of development. Hyloris' products and product candidates are split into three portfolios, respectively the IV Cardiovascular, the Other Reformulation and the Established Market portfolios.

Hyloris' partner AltaThera obtained an expansion of the Sotalol IV product label in March 2020 and will start promoting the new label in the third quarter of 2020 (see Section 8.10.2.1E (Sotalol IV's clinical status, regulatory status and commercial strategy)).

Hyloris' other commercial product, Maxigesic<sup>®</sup> IV, has been launched by its collaboration partner AFT Pharmaceuticals in Australia and New Zealand in June 2020, and is expected to be launched in the summer of 2020 in the United Arab Emirates. Hyloris expects to receive (non-material) payments based on net profits from all sales generated by Maxigesic<sup>®</sup> IV in the United Arab Emirates from AFT Pharmaceuticals beginning in the second half of 2020. Hyloris will not receive such payments from sales of Maxigesic<sup>®</sup> IV in Australia and New Zealand as per its exclusive co-operation and profit-sharing arrangement, AFT Pharmaceuticals is entitled to all net profits for these two territories. Maxigesic<sup>®</sup> IV will require several years for approval and roll-out in all major territories and it is expected that Maxigesic<sup>®</sup> IV and Sotalol IV will remain important contributors to the growth of the company up until 2023 and decreasingly so thereafter.

Hyloris also expects to start generating revenue from 2023 onwards through its own commercial team for IV Cardiovascular products (other than Sotalol IV) it expects to establish in the United States. Hyloris intends to (i) create an internal sales and marketing function and (ii) establish a focused direct sales team for its IV Cardiovascular Portfolio (except for Sotalol IV) as it believes the prescribers can be addressed in a cost-efficient manner as they are typically grouped in specialized care facilities such as hospitals. For its other product candidates, Hyloris intends to remain flexible and assess the optimal commercialization strategy on a case-by-case basis (e.g., through selectively out-licensing or identifying appropriate distribution partners) in an effort to maximize its return on investment. See Sections 8.10 (Products) and 8.12 (Partnership and Collaborations) for an overview of Hyloris' business model for the commercialization of each of its products and product candidates.

Prior to 2024, eight product candidates are expected to be registered of which five belong to the Other Reformulation Portfolio (Maxigesic<sup>®</sup> IV (in additional territories), Tranexamic Acid RTU, Atomoxetine, HY-REF-038, and HY-REF-029), two to the Established Market Portfolio (HY-EMP-016 and Fusidic acid cream) and one to the IV Cardiovascular Portfolio (Dofetilide IV). As the Other Reformulation Portfolio product candidates are expected to be out-licensed and no significant further fixed expenses are expected to be incurred relating to their commercialization, this portfolio is expected to generate the majority of the revenues and profits during the first 3 to 5 years following the Offering.

As from 2024 onwards, three Cardiovascular IV product candidates are expected to be registered (Metolazone IV, HY-CVS-073 and HY-CVS-074). It is expected that the Other Reformulation Portfolio will still be the biggest contributor of sales but the relative importance of the IV Cardiovascular Portfolio will steadily increase. As the company intends to commercialize the IV Cardiovascular Portfolio using an own commercial team, the net profit contribution of the IV Cardiovascular Portfolio will be impacted, particularly during the first years following commercialization.

Based on Hyloris' existing product candidate pipeline and its current business plan (including the assumptions included therein), as from 2025, sales in IV Cardiovascular are expected to represent the main driver of overall sales growth with more than 70% of Hyloris' revenues by 2027. As the company will market and sell multiple IV Cardiovascular products (and ramp up sales) without significantly

(further) increasing its commercial infrastructure cost, the contribution of the portfolio is expected to become relatively more important than the contribution of the Reformulation Portfolio.

The Established Market Portfolio, consisting of two product candidates, is expected to remain the smallest portfolio with a sales contribution evolving towards a low single digit number by 2025 and will remain in that range for the following years. Typically, revenues in this portfolio will quickly erode once generic competitors enter the market as competition often leads to substantially lower prices.

The ability of Hyloris to increase its revenue will depend on a number of factors, including upon its, or its commercial partners', ability to (i) continue commercializing its two existing commercial products successfully, (ii) develop its current product portfolio and add new products to its pipeline, (iii) obtain regulatory approval and (iv) successfully commercialize additional product candidates. Among other factors, such success will depend upon the demand for Hyloris' products, which in turn will depend e.g. on their added value and pricing, the added value and pricing of competing products, including generics, the competitive environment more generally, the effectiveness of Hyloris' chosen route to market (whether through its own direct sales force or that of a third party) and regulatory environment in United States and other markets in which Hyloris is seeking to commercialize its products. In relation to product candidates to be added to its pipeline in the future, Hyloris' success will additionally rely on its ability to identify attractive product candidates for development and commercialization through the 505(b)(2) regulatory pathway or, to a lesser extent, ANDA regulatory pathway.

#### **9.2.2 COST OF SALES**

To date, the cost of sales is mainly comprised of the amortization expenses of the capitalized development costs of the product commercialized. At the end of March 2020, amortization expenses relate only to Sotalol IV. Cost of sales is also comprised of payments made to Academic Pharmaceuticals in connection with Sotalol IV. Hyloris pays to its development partner an agreed upon percentage of profits earned. Fixed contractual amounts due to the Sotalol IV development partner are determined based on the level of sales achieved by the product, which includes sales related royalties and milestone payments. Hyloris expects that its cost of sales will increase in line with sales increases of Sotalol IV. There are no anticipated cost of sales for Maxigesic<sup>®</sup> IV, as the expected revenues of the Company relating to Maxigesic<sup>®</sup> IV is the result of a profit split with Hyloris' partner, AFT Pharmaceuticals, which is in charge of appointing and supplying commercial partners.

Hyloris expects that its cost of sales will increase and expand with the approval and commercialization of additional product candidates. As Hyloris will start to source and supply products it will incur production related costs (including manufacturing costs and materials such as packaging and API) and pay, on several of its product candidates, product specific profit or sale-based payments to development partners.

It is estimated that based on Hyloris' existing product candidate pipeline and its current business plan (including the assumptions included therein) the overall cost of sales will remain at or below 20% of sales.

Between 2020 and 2023 most product launches will concern Other Reformulation Portfolio product candidates. It is expected that these product candidates will be commercialized through partners and that no significant further fixed commercialization expenses are incurred. In contrast, the company intends to build an own commercial team to commercialize the IV Cardiovascular Portfolio (except for Sotalol IV) from 2023 onwards. The Company expects to invest significant capital in order to build such team.

Due to this period of investment, Hyloris expects the margin contribution from its Other Reformulation Portfolio to be substantially greater than the IV Cardiovascular Portfolio.

In the period between 2025 and 2028, the Company expects significant revenue growth from its IV Cardiovascular Portfolio. During this period, Hyloris will be able to leverage its fully operational internal sales force to generate greater margin relative to other product categories. Over this period, the Company expects the IV Cardiovascular Portfolio to contribute over 50% of total profits.

### **9.2.3 RESEARCH AND DEVELOPMENT EXPENSES**

Hyloris directs, coordinates and monitors external service providers, who perform all operational activities to transform Hyloris product ideas into products that satisfy unmet clinical needs on behalf of Hyloris. This includes contracting an API supplier, a formulator, a GMP approved manufacturing site, a CRO and sometimes external advisors. Under certain of its development arrangements, Hyloris will be responsible for the associated research and development expenses and will be entitled to recoup all product related investments (including clinical study costs, formulation, manufacturing, API, patents, user fee costs and external advisor or consultant costs that have been assumed in the development budget) before proceeding with any profit split payment to the development partner.

Development costs differ on a product-by-product basis and are dependent on the current status of the product candidate and the requirements laid out by the regulatory bodies. There are no significant parts of the allocation of the net proceeds going to one product candidate. As a general rule, more expenses are allocated to projects that are earlier in the development process and still have relatively more work to be accomplished in order to prepare them for regulatory approval. In general product candidates that are conversions of approved tablet products (into IVs) also require higher investments compared to other reformulations (oral solids into oral liquids) mainly because of more expensive CMC work. Most CMC related activities are more expensive as IV product formulations often are more complex, require sterile manufacturing, potentially require more stability data (as vials need to be tested in all physical storage conditions) and have fewer service suppliers. Clinical requirements typically are also higher and more expensive. Therefore, the IV Cardiovascular Portfolio will typically have the most expensive product developments and particularly those with formulation challenges requiring specialized manufacturing methods. Also, PDUFA will be paid by Hyloris for its IV Cardiovascular Portfolio and not for its Other Reformulation Portfolio, which makes a significant difference in development costs.

Though Hyloris usually bears the Research and Development risks, under certain of these arrangements, Hyloris can decide at all times and in its sole discretion to discontinue the development and return the project to the development partners. In such cases, provided the project is launched commercially and a certain threshold of sales has been realized, a refund of the Hyloris investment will

be made. The products which Hyloris can return to its development partners are HY-REF-004, Metolazone IV, Dofetilide IV, HY-CVS-073 & HY-CVS-074.

These research and development expenses will principally take the form of:

- payments made to third-party CMOs, CROs, CDOs, CDMOs, contract laboratories and independent contractors;
- payments made to consultants who perform research and development on Hyloris' behalf and assist in the preparation of regulatory filings;
- payments made to third-party investigators who perform research and development on Hyloris' behalf; and
- payments for access to technology or to databases; and payments to purchase generics dossiers.

In connection with its product development activities, Hyloris sometimes outsources research and development activities to its development partners. In connection with those arrangements, Hyloris also makes certain upfront and milestone payments to those partners which are also part of research and development expenses.

Research and development expenses also include wages and salaries and other employee benefit expenses for Hyloris' development team, which as of the date of this Prospectus comprises four employees. Impairment losses on intangibles, when incurred, are also included in research and development expenses.

#### **9.2.4 GENERAL AND ADMINISTRATIVE EXPENSES**

General and administrative costs consist primarily of wages and salaries and other employee benefit expenses of Hyloris' staff other than its development team and other related costs, including share-based payments, finance, selling and operations personnel. General and administrative expenses also include office lease and related costs, professional fees for legal, consulting, tax and accounting services, insurance, depreciation and general corporate expenses. Hyloris expects that its general and administrative expenses will increase with the continued development and commercialization of its product candidates, particularly as it begins to commercialize its own products in the United States, as well as increased expenses associated with the listing of the Company.

#### **9.2.5 FINANCIAL EXPENSES**

Financial expenses principally comprise interest expenses on shareholders' loans from several shareholders, including a loan from Hyloris' CEO, Stijn Van Rompay (see Section 12.2 (Related Party Loans)). Going forward, Hyloris expects financial expenses to also include realized and unrealized exchange rate differences and interest expenses associated with the shareholder loans (to the extent they remain outstanding and have not been repaid in full).

## 9.2.6 TAXATION

Since its inception, Hyloris has not made profits and has only reported nominal amounts of current income tax which relates to taxes on certain employee benefits. Hyloris reports deferred tax income resulting from temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in Hyloris' consolidated financial statements under IFRS.

## 9.3 ANALYSIS OF OPERATING RESULTS

The following table presents Hyloris' consolidated statement of profit or loss and other comprehensive income for the three-month periods ended 31 March 2020 and 2019 and the years ended 31 December 2019, 2018 and 2017.

	For the three month period ended 31 March		For the year ended 31 December		
	2020	2019	2019	2018	2017
	(€ thousands)				
<b>CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME</b>					
Revenue.....	63	40	91	91	213
Other operating income.....	-	-	86	-	18
Cost of sales.....	(20)	(23)	(66)	(65)	(95)
<b>Gross profit.....</b>	<b>44</b>	<b>18</b>	<b>111</b>	<b>26</b>	<b>135</b>
Research and development expenses.....	(784)	(443)	(4,577)	(4,870)	(2,313)
General and administrative expenses.....	(523)	(136)	(808)	(622)	(1,657)
Other operating expenses.....	-	-	-	(3)	(31)
<b>Operating profit/(loss).....</b>	<b>(1,264)</b>	<b>(561)</b>	<b>(5,274)</b>	<b>(5,469)</b>	<b>(3,866)</b>
Financial income.....	9	99	10	7	257
Financial expenses.....	(325)	(223)	(518)	(597)	(174)
<b>Profit/(loss) before taxes.....</b>	<b>(1,579)</b>	<b>(685)</b>	<b>(5,782)</b>	<b>(6,059)</b>	<b>(3,783)</b>
Income taxes.....	(1)	-	14	20	66
<b>Profit/(loss) for the period.....</b>	<b>(1,580)</b>	<b>(685)</b>	<b>(5,768)</b>	<b>(6,039)</b>	<b>(3,717)</b>

### 9.3.1 OPERATING RESULTS FOR THE THREE MONTH PERIODS ENDED 31 MARCH 2020 AND 2019

#### Revenue

Hyloris' revenue for the three-month period ended 31 March 2020 increased by 57.5%, to EUR 63 thousand from EUR 40 thousand for the three-month period ended 31 March 2019 and are mainly related to the royalties received on sales of Sotalol IV.

#### Cost of sales

Hyloris' cost of sales for the three-month period ended 31 March 2020 decreased by 13.0% to EUR 20 thousand from EUR 23 thousand for the three-month period ended 31 March 2019. Hyloris' cost of sales corresponded to the amortization expenses of the development costs of Sotalol IV.

#### Gross profit

Reflecting the factors above, gross profit for three-month period ended 31 March 2020 increased by 144.4%, to EUR 44 thousand from EUR 18 thousand for three-month period ended 31 March 2019, which is primarily a result of the increase in revenue.

#### **Research and development expenses**

Research and development expenses for the three-month period ended 31 March 2020 increased by 77.0%, to EUR 784 thousand from EUR 443 thousand for the three-month period ended 31 March 2019 as a result of an increase in outsourced research and development expenses.

#### **General and administrative expenses**

Hyloris' general and administrative expenses for the three-month period ended 31 March 2020 increased by 284.6%, to EUR 523 thousand from EUR 136 for the three-month period ended 31 March 2019. The increase was principally driven by (i) the IFRS treatment of the ESOP Warrants (see Note 2.15 of the Financial Statements), (ii) additional headcount and (iii) an increase of fees associated with the IPO process such as audit, legal, and consultants' fees. See Section 12.4.3 (Warrants and Convertible Bonds) for a further discussion of the ESOP Warrants.

#### **Operating profit/(loss)**

Reflecting the factors discussed above, Hyloris' operating loss for the three-month period ended 31 March 2020 increased by 125.3%, to EUR 1,264 thousand compared to a loss of EUR 561 thousand for the three-month period ended 31 March 2019.

#### **Financial income**

Hyloris' financial income for the three-month period ended 31 March 2020 decreased by 90.9%, to EUR 9 thousand, from EUR 99 thousand for the three-month period ended 2019. This decrease was principally driven by realized and unrealized exchange rate differences.

#### **Financial expenses**

Hyloris' financial expenses for the three-month period ended 31 March 2020 increased by 45.7%, to EUR 325 thousand, from EUR 223 thousand for the three-month period ended 2019. Hyloris' financial expenses are mostly comprised of interest due on shareholders loans. The increase is due to an increase on interest due on shareholder loans, and the fair value adjustment on the convertible bond.

#### **Loss before taxes**

Reflecting the factors discussed above, Hyloris' loss before taxes for the three-month period ended 31 March 2020 increased by 130.5%, to EUR 1,579 thousand from EUR 685 thousand for the year three-month period ended 31 March 2019.

## **Income taxes**

Hyloris reported income taxes of EUR 1 thousand for the three-month period ended 31 March 2020 and nil thousand for the three-month period ended 31 March 2019.

## **Loss for the period**

Reflecting the factors discussed above, Hyloris' loss for the three-month period ended 31 March 2020 increased by 130.7%, to EUR 1,580 thousand from EUR 685 for the three-month period ended 31 March 2019.

### **9.3.2 ANALYSIS OF OPERATING RESULTS FOR THE YEARS ENDED 31 DECEMBER 2019, 2018, 2017**

#### **Revenue**

Hyloris' revenue remained constant at EUR 91 thousand for the years ended 31 December 2019 and 31 December 2018, reflecting royalties paid by AltaThera, to which Hyloris has out-licensed the commercial rights to Sotalol IV in the United States.

Hyloris' revenue decreased by 57%, to EUR 91 thousand for the year ended 31 December 2018 from EUR 213 thousand for the year ended 31 December 2017. Revenue for the year ended 31 December 2018 consisted solely of royalties paid by AltaThera to Hyloris in relation to sales of Sotalol IV in the United States. Revenue in the year ended 31 December 2017 beside royalties on sales also consisted of a EUR 176 thousand milestone payment made to Hyloris by AltaThera in relation to Sotalol IV.

#### **Other operating income**

Hyloris' other operating income was EUR 86 thousand, nil and EUR 18 thousand for the years ended 31 December 2019, 2018 and 2017, respectively. The other operating income in the years ended 31 December 2019 and 2017 reflected non-dilutive financing (recoverable cash advances) received from the Walloon Region, which was not applicable for the year ended 31 December 2018.

#### **Cost of sales**

Hyloris' cost of sales amounted to EUR 66 thousand for the year ended 31 December 2019 and remained constant compared to the same period in 2018. Cost of sales for the years ended 31 December 2019 and 2018 principally reflected amortization expenses of the development costs capitalized. Cost of sales are also composed of royalty payments made to Academic Pharmaceutical in relation to Sotalol IV.

In 2018, cost of sales decreased by 32%, to EUR 65 thousand, from EUR 95 thousand for the year ended 31 December 2017. In the year ended 31 December 2017, the royalty payments made to Academic Pharmaceutical in relation to Sotalol IV were higher due to the milestone payments received from AltaThera in that period. See Section 8.12.1.2 (AltaThera – Licensing, Development And Supply Agreement) for a discussion of Hyloris' commercial arrangements with AltaThera, including milestone payments.

## Gross profit

Reflecting the factors above, Hyloris' gross profit increased by EUR 85 thousand for the year ended 31 December 2019 from EUR 26 thousand for the year ended 31 December 2018. Gross profit amounted to EUR 135 thousand for the year ended 31 December 2017.

## Research and development expenses

The following table presents a breakdown of Hyloris' research and development expenses for the periods indicated, including the impairment of assets in 2019:

In € thousands	2019	2018	2017
Research and development costs	(1,374)	(4,870)	(2,313)
Impairment of assets	(3,203)	-	-
<b>Total R&amp;D costs</b>	<b>(4,577)</b>	<b>(4,870)</b>	<b>(2,313)</b>

The research and development strategy of the Company relies on outsourcing most of its projects and studies to recognized and experienced partners. Of the total research and development costs, EUR 0.3 million, EUR 0.2 million and EUR 0.2 million related to in-house research and development costs, as opposed to outsourced research and development, for the years ended 31 December 2019, 2018 and 2017, respectively.

Hyloris' research and development expenses decreased by 6.0%, to EUR 4.6 million for the year ended 31 December 2019 from EUR 4.9 million for the year ended 31 December 2018. Research and development expenses in 2019 included a EUR 3.2 million impairment charge related to the product candidate HY-REF-028 following unfavourable market information relating to that product candidate and Hyloris' decision to change its development focus towards other product candidates with higher expected profitability. Absent the EUR 3.2 million impairment charge, the decrease of the research and development expenses amounted to EUR 3.5 million, or 71.8%. This decrease was principally driven by higher research and development costs on 2018, and by the fact that three product candidates that were in the research phase in 2018 entered the development phase in 2019 (Maxigesic® IV, HY-EMP-016 and Tranexamic Acid RTU). In the year ending 31 December 2019, the Company capitalized development costs for a total of EUR 0.5 million. The Company did not capitalize development costs prior to 2019 because only when a product is moved to commercialization, development costs are capitalized.

Hyloris' research and development expenses increased by 110.5%, from EUR 2,313 thousand for the year ended December 31, 2017 to EUR 4,870 thousand for the year ended 31 December 2018. This increase resulted from higher development costs associated to the enlarged product portfolio of the Company.

## General and administrative expenses

Hyloris' general and administrative expenses increased by 29.9%, to EUR 808 thousand for the year ended 31 December 2019 from EUR 622 thousand for the year ended 31 December 2018. This increase

was principally driven by an increase in expenses in line with the growth of the business as well as one-time costs associated with the acquisition of Dermax in 2019.

Hyloris' general and administrative expenses decreased by 62.5%, to EUR 622 thousand for the year ended 31 December 2018 from EUR 1,657 thousand for the year ended 31 December 2017. This decrease was principally the result of the share-based payment expenses recognized in 2017 in connection with the issuance of the Transaction Warrants. See Section 13.4.1 (Transaction Warrants).

### **Operating (loss)**

Reflecting the factors above, Hyloris' operating loss decreased by 4%, to EUR 5.3 million for the year ended 31 December 2019 from EUR 5.5 million for the year ended 31 December 2018. Hyloris' operating losses increased by 41%, to EUR 5.5 million for the year ended 31 December 2018 from EUR 3.9 million for the year ended 31 December 2017.

### **Financial income**

Hyloris' financial income increased by 43%, to EUR 10 thousand for the year ended 31 December 2019 from EUR 7 thousand for the year ended 31 December 2018. This increase was driven by realized and unrealized exchange rate differences in relation to Hyloris' trade payables and shareholder loans denominated in U.S. dollars.

Hyloris' financial income decreased by 97.3%, to EUR 7 thousand for the year ended 31 December 2018 from EUR 257 thousand for the year ended 31 December 2017. This decrease was principally driven by realized and unrealized exchange rate differences.

### **Financial expenses**

Hyloris' financial expenses decreased by 13%, to EUR 518 thousand for the year ended 31 December 2019 from EUR 597 thousand for the year ended 31 December 2018. This decrease was principally driven by realized and unrealized exchange rate differences resulting from fluctuations in the Euro/U.S. dollar exchange rate, which was partially offset by higher average balances of shareholder loans.

Hyloris' financial expenses increased by 243%, to EUR 597 thousand for the year ended 31 December 2018 from EUR 174 thousand for the year ended 31 December 2017. This increase was principally driven by higher interest expenses resulting from higher average balances of shareholder loans and realized and unrealized exchange rate differences resulting from fluctuations in the Euro/U.S. dollar exchange rate.

### **Loss before taxes**

Hyloris' loss before tax decreased by 5% from EUR 6.1 million for the year ended 31 December 2018 to EUR 5.8 million for the year ended 31 December 2019. The loss before taxes was EUR 3.8 million for the year ended 31 December 2017.

## **Income taxes**

Hyloris reported a tax income of EUR 14 thousand, EUR 20 thousand and EUR 66 thousand for the years ended 31 December 2019, 2018 and 2017, respectively. In each year, this reflected deferred tax income resulting from temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in Hyloris' consolidated financial statements under IFRS.

## **Loss for the period**

As a result of the forgoing, Hyloris net loss for the period amounted to EUR 5.8 million ended 31 December 2019, a decrease of 4% compared to the same period ended 31 December 2018. At December 2018, the net loss of the period was EUR 6.0 million, an increase of EUR 2.3 million compared to 2017.

## **9.4 LIQUIDITY AND CAPITAL RESOURCES**

### **9.4.1 GENERAL**

Hyloris' primary uses of cash are to finance the development of its product portfolios.

As at 31 December 2019, Hyloris' primary sources of liquidity had been capital increases and loans from shareholders, which are principally denominated in Euros. In March and April 2020, Hyloris raised EUR 15.15 million in the form of Convertible Bonds from existing shareholders and other new investors. The Convertible Bonds (plus interest accrued at the rate of 6.0% per annum as of their issue date up to and including the date preceding the conversion date) will be converted into new Shares at a 30.0% discount to the Offer Price, upon consummation of the Offering. Hyloris has also sourced liquidity from a recoverable cash advance received from the Walloon Region and its limited revenue in the form of royalties under an out-licensing arrangement relating to Sotalol IV.

In 2020 (prior to the Offering), the Issuer will have repaid EUR 7.5 million of the outstanding shareholders loans. The remaining amount will be reimbursed the earlier of 31 December, 2022, or if and when Hyloris generates a positive EBIT (see also Section 12.2 (Related Party Loans) for more information on the shareholder loans).

Hyloris is not subject to financial covenants under the shareholders loans or under the recoverable cash advance from the Walloon Region. See Section 12 for additional information about the shareholder loans, Section 13.6 for additional information about the Convertible Bonds and Section 8.22 for additional information about the recoverable cash advance.

Hyloris had cash and cash equivalents of EUR 205 thousand as at 31 December 2019 and EUR 11.2 million as at 31 March 2020. Day-to-day treasury activities are handled by the Hyloris' management in accordance with its internal treasury policies.

For the year ended 31 December 2019, Hyloris recorded a loss for the period of EUR 5.8 million, resulting in an aggregate loss of EUR 15.5 million for the years ended 31 December 2019, 2018 and 2017, collectively. For three months ended 31 March 2020, Hyloris had a loss of EUR 1.6 million. The

financial statements have been prepared on a going concern basis, assuming we will have the ability to satisfy our obligations in the normal course of business. The Financial Statements do not include any adjustments that might be necessary if Hyloris is unable to continue as a going concern.

#### 9.4.2 CONSOLIDATED STATEMENT OF CASH FLOWS

The following table sets forth certain information regarding the principal items of the consolidated statement of cash flows for the periods and years indicated:

	Three month period ended 31 March		Year ended 31 December		
	2020	2019	2019	2018	2017
	(€ thousands)				
Net cash generated from/(used in) operating activities	(2,444)	(675)	(4,562)	(5,368)	(1,616)
Net cash provided by/(used in) investing activities	(240)	(32)	(1,228)	19	(2,736)
Net cash provided by/(used in) financing activities	13,691	533	3,308	7,765	4,398
Net increase/(decrease) in cash and cash equivalents	11,008	(175)	(2,482)	2,416	47
Cash and cash equivalents at beginning of period/year	205	2,687	2,687	271	224
Cash and cash equivalents at end of period/year	11,213	2,512	205	2,687	271

#### Net cash used in operating activities

Hyloris' net cash used in operating activities was EUR 2.4 million for the three-month period ended 31 March 2020, compared to net cash used in operating activities of EUR 0.7 million for the three-month period ended 31 March 2019. This change was principally driven by the increase of EUR 0.7 million of the operating expenses over the first quarter 2020 and the net payment of EUR 1.0 million of trade payables outstanding at year end 2019 (of which the payment of the invoice for pre-paid development expenses to GSP related to product candidate HY-REF-038 (prior to the transfer of the title and interest of the vial form of HY-REF-038 to Alter Pharma)).

Hyloris' net cash used in operating activities was EUR 4.6 million for the year ended 31 December 2019, compared to net cash used in operating activities of EUR 5.4 million for the year ended 31 December 2018. This variance was principally driven by a decrease of the operating loss (excluding non-cash expenses) of EUR 3.4 million, compensated by an increase of 2.6 million of the working capital requirements (mainly driven by the EUR 2.8 million prepayment of development expenses made to Generic Specialty Pharma (a subsidiary of the Alter Pharma group<sup>187</sup>) and related to the product candidate HY-REF-038) for EUR 2 million and to Stasisport for EUR 0.8 million and related to Fusidic Acid Cream product candidate.

Hyloris' net cash used in operating activities was EUR 5.4 million for the year ended 31 December 2018, compared to net cash used in operating activities of EUR 1.6 million for the year ended 31 December 2017. This variance was principally driven by an increase of the operating loss (excluding non-cash expenses) of EUR 2.9 million and a decrease of the working capital requirement of EUR 0.9 million.

<sup>187</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

### **Net cash provided by/(used in) investing activities**

Hyloris' net cash used in investing activities was EUR 248 thousand for the three-month period ended 31 March 2020, compared to net cash used in investing activities of EUR 32 thousand for the three-month period ended 31 March 2019. Investing activities during the first quarter of 2020 are related to the capitalization of the development expenses of the several products that have successfully reached the end of their respective clinical development.

Hyloris' net cash used in investing activities was EUR 1.2 million for the year ended 31 December 2019, compared to net cash provided by investing activities of EUR 19 thousand for the year ended 31 December 2018. Net cash used in investing activities in 2019 reflected (i) the acquisition of intangible assets related to a license agreement entered into with Stasisport Pharma (a subsidiary in the Alter Pharma group<sup>188</sup>) for the product candidate Fusidic Acid Cream, (ii) milestone payments relating to Hyloris' in-licensing arrangements for some of its IV Cardiovascular product candidate, (iii) the acquisition of new product candidate HY-REF-075 and (iv) the capitalization of development costs.

Net cash used in investing activities in 2018 related to the acquisition of a new product candidate, Tranexamic Acid RTU, which was made through the purchase of shares of RTU Pharma.

Hyloris' net cash used in investing activities was EUR 2.7 million for the year ended 31 December 2017. Net cash used in investing activities in 2017 principally reflected the acquisition of an intangible asset impaired in 2019 following unfavourable market information relating to that product candidate.

### **Net cash provided by financing activities**

Hyloris' net cash provided by financing activities was EUR 13.7 million for the three-month period ended 31 March 2020, compared to net cash provided by financing activities of EUR 0.5 million for the three-month period ended 31 March 2019. This change was principally driven by the financing initiatives made the Company by contracting the Convertible bonds and additional shareholders' loans over the first quarter of 2020.

Hyloris' net cash provided by financing activities was EUR 3.3 million for the year ended 31 December 2019, compared to net cash provided by financing activities of EUR 7.8 million for the year ended 31 December 2018. Net cash provided by financing activities in 2019 principally reflected additional shareholder loans made in 2019 as well as the receipt of a recoverable cash advance from the Walloon Region. Net cash provided by financing activities in 2018 principally reflected the proceeds of an EUR 6 million equity issuance and, to a lesser extent, additional shareholder loans.

Hyloris' net cash provided by financing activities was EUR 7.8 million for the year ended 31 December 2018, compared to net cash provided by financing activities of EUR 4.4 million for the year ended 31 December 2017. Net cash provided by financing activities in 2017 principally reflected additional shareholder loans.

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<sup>188</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

## 9.5 CONTRACTUAL OBLIGATIONS

The following table details Hyloris' remaining contractual maturity of its financial liabilities with agreed repayment periods as at 31 March 2020. The table is based on the undiscounted cash flows of financial liabilities based on the earliest date on which Hyloris can be required to pay. The figures presented in the table include both interest and principal cash flows.

31/03/2020 In € thousand	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
Borrowings					
Lease liabilities	43	12	-	-	55
Other financial liabilities					
Loans from shareholders	15,702	-	-	-	15,702
Other loans	409	-	-	-	409
<b>Total</b>	<b>16,154</b>	<b>12</b>	<b>-</b>	<b>-</b>	<b>16,166</b>

The Convertible Bonds in an aggregate nominal amount of EUR 10,800 thousand (fair valued at 31 March 2020 to EUR 10,671 thousand) are not presented in this table as completion of the Offering will result in the automatic conversion of all outstanding Convertible Bonds.

In the normal course of its business, Hyloris also enters into commercial agreements (including in relation to both in-licensing and out-licensing agreements) pursuant to which it will have obligations to make payments to third parties in the future. The nature and timing of those payments remains uncertain. These contractual obligations are summarized in Section 8.12 (Partnerships and Collaborations).

With respect to development and commercial partnerships and collaborations as referred in Section 8.12 (Partnerships and Collaborations), Hyloris estimates its contractual commitments as at 31 March 2020 at EUR 4.3 million (among which EUR 0.25 million and \$4.4 million converted to Euro at a rate of USD 1.0956 per Euro). The contractual commitments are due upon reaching certain milestones dependent on successful completion of development stages of the product candidate (including FDA approval) or on meeting specified sales targets, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted. The EUR 4.3 million of these commitments include the development and sales milestones and do not include profit split and royalties which percentage varies based on achieved profit (and for some only start once Hyloris recovered expenses and costs directly and exclusively made in connection with the product). Reference is made to Note 26 of the Annual Financial Statements.

## 9.6 DISCLOSURES ABOUT MARKET AND LIQUIDITY RISK

For information relating to Hyloris' market and liquidity risk, please see Note 5 to the Annual Financial Statements.

## **9.7 CRITICAL ACCOUNTING POLICIES**

For additional information regarding Hyloris' accounting policies, please see Note 3 to the Annual Financial Statements.

## **9.8 OFF-BALANCE SHEET ARRANGEMENTS**

As at 31 March 2020, Hyloris had no off-balance sheet arrangements related to guarantees of third party indebtedness; interests in assets transferred to an unconsolidated entity that serve as credit, liquidity or market risk support to such entity; and certain obligations under derivative instruments that are not reflected on its consolidated statement of financial position.

## **9.9 EVENTS AFTER THE BALANCE SHEET DATE**

Since 31 March 2020, the Company recorded additional subscriptions to the Convertible Bonds for a total principal amount of EUR 4.4 million, leading the total subscription of the Convertible Bonds to EUR 15.2 million. The Company also reimbursed part of the shareholders loans in April and June 2020 for a total of EUR 7.5 million.

On 11 March 2020 the World Health Organization declared the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. The length or severity of this pandemic cannot be predicted, but Hyloris anticipates that there may be a potential impact from COVID-19 on its planned product development activities.

With COVID-19 continuing to spread in Europe and in the United States, the business operations of Hyloris could be delayed or interrupted, particularly if a large portion of its employees become ill. COVID-19 may also affect employees of third-party organizations (such as CRO's and CMO's) located in affected geographies that Hyloris relies upon to carry out its preclinical and clinical trials. The spread of COVID-19, or another infectious disease, could also negatively affect the operations at its third-party suppliers, which could result in delays or disruptions in the supply of drug product used in its preclinical and clinical trials. In addition, Hyloris is taking temporary precautionary measures intended to help minimize the risk of the virus to its employees, including temporarily requiring all employees to work remotely, suspending all travel worldwide for its employees.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which have been adversely affected by the COVID-19 pandemic. Most of Hyloris' CRO's clinical trial sites are located in the United States, which is currently being afflicted by COVID-19.

Some factors from the COVID-19 outbreak that Hyloris believes will potentially affect enrollment in its trials at least on a temporary basis include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of physicians serving as clinical trial investigators, hospitals serving as its clinical trial sites and hospital staff supporting the conduct of its clinical trials;

- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product used in our trials; and
- employee absences that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

The impact of COVID-19 on the Company's business and operations are uncertain at the date of the Prospectus and will depend on future developments, which are highly uncertain and cannot be predicted. The Company is of the opinion that although there are lot of uncertainties, it does not materially impact the Company's ability to continue operations. As of the date of authorization for issue of the consolidated financial statements, we have encountered some delays in the development of our product-candidates (such as delayed patient enrollment in the current clinical trials), but we do not believe this will result in major deviation in our planned activities and in the assumptions of our business plan.

## 10 MANAGEMENT AND CORPORATE GOVERNANCE

This Section summarizes the rules and principles by which the Issuer's corporate governance will be organized, and which are contained in the Belgian Code of Companies and Associations (the **CCA**), other relevant legislation, and the Issuer's Articles of Association, corporate governance charter (the **GC Charter**) and dealing code (the **Dealing Code**), each entering into force subject to the completion of the Offering and with effect as from the Listing Date.

### 10.1 CORPORATE GOVERNANCE

The CG Charter is in line with the 2020 Belgian Code on Corporate Governance (the **CG Code 2020**), which the Issuer needs to apply, in accordance with a 'comply or explain' approach, as its corporate governance code pursuant to Article 3:6, §2, 1° CCA and the Royal Decree of 12 May 2019 specifying the corporate governance code to be complied with by listed companies.

The CG Charter describes the main aspects of the corporate governance of the Issuer, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics. The CG Charter must be read together with the Issuer's Articles of Association, which have been amended by the Extraordinary General Shareholders' Meeting of 8 June 2020.

The Issuer will apply the ten corporate governance principles contained in the CG Code 2020 and intends to comply with the corporate governance provisions set forth in the CG Code 2020, except in relation to the following:

- Provision 2.19: the powers of the members of the Executive Management other than the CEO are determined by the CEO rather than by the Board of Directors. This deviation is explained by the fact that the members of the Executive Management perform their functions under the leadership of the CEO, to whom the day-to-day management and additional well-defined powers were delegated by the Board of Directors.
- Provision 4.14: no independent internal audit function has been established. This deviation is explained by the size of the Issuer. The Audit Committee will regularly assess the need for the creation of an independent internal audit function and, where appropriate, will call upon external persons to conduct specific internal audit assignments and will inform the Board of Directors of their outcome.
- Provision 7.6: the non-executive members of the Board of Directors do not receive part of their remuneration in the form of Shares. This deviation is explained by the fact that the interests of the non-executive members of the Board of Directors are currently considered to be sufficiently oriented to the creation of long-term value for the Issuer, also considering the fact that some of them hold ESOP Warrants, the value of which is based on the value of the Shares (see Section 10.4.5 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management and/or senior management of the Issuer) and Section 13.4.4 (ESOP Warrants)). Therefore, the payment in Shares is not deemed

necessary. However, the Issuer intends to review this provision in the future in order to align its corporate governance with the provisions of the CG Code 2020.

- Provisions 7.9: no minimum threshold of Shares to be held by the members of the Executive Committee has yet been set. This deviation is explained by the fact that the interests of the members of the Executive Committee are currently considered to be sufficiently oriented to the creation of long-term value for the Issuer, also considering the fact that some of them hold ESOP Warrants, the value of which is based on the value of the Shares (see Section 10.4.5 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management and/or senior management of the Issuer) and Section 13.4.4 (ESOP Warrants)). Therefore, setting a minimum threshold of Shares to be held by them is not deemed necessary. However, the Company intends to review this in the future in order to align its corporate governance with the provisions of the CG Code 2020.

What constitutes good corporate governance will evolve with the changing circumstances of a company and with the standards of corporate governance globally and must be tailored to meet those changing circumstances. The Board of Directors intends to update the CG Charter as required to reflect changes to the Issuer's corporate governance.

The Articles of Association and the CG Charter will be made available on the Issuer's website ([www.hyloris.com](http://www.hyloris.com)). The Board of Directors shall, in accordance with Article 3:6, §2 CCA, include a corporate governance statement in its annual report for the financial year ending on 31 December 2020, to be published in 2021 (and any financial year thereafter).

Additionally, and in accordance with Article 3:6, §3 CCA, the corporate governance statement shall include a separate remuneration report, prepared by the Nomination and Remuneration Committee, for the financial year ending on 31 December 2020, to be published in 2021 (and any financial year thereafter).

The Annual General Shareholders' Meeting, deciding upon the Board of Director's annual report, shall also decide, by separate advisory vote, on the remuneration report. In addition, the General Shareholders' Meeting shall decide on the remuneration policy as further described below in Section 10.5.1 (Remuneration Policy).

## **10.2 BOARD OF DIRECTORS**

### **10.2.1 GENERAL**

The Issuer has opted for a "one tier" governance structure in accordance with Article 7:85 CCA and following, whereby the Board of Directors is the ultimate decision making body, with the overall responsibility for the management and control of the Issuer, and is authorized to carry out all actions that are considered necessary or useful to achieve the Issuer's purpose. The Board of Directors has all powers except for those reserved to the General Shareholders' Meeting by law. The Board of Directors acts as a collegiate body.

Pursuant to the Issuer's CG Charter, the role of the Board of Directors is to pursue sustainable value creation by the Issuer by setting the Issuer's strategy, putting in place effective, responsible and ethical leadership and monitoring the Issuer's performance. The Board of Directors decides on the Issuer's medium and long-term strategy based on proposals from the Executive Management and determines the risk appetite of the Issuer in order to achieve its strategic objectives.

The Board of Directors is assisted by a number of committees in relation to specific matters. The committees advise the Board of Directors on these matters, but the decision making remains with the Board of Directors as a whole.

The Board of Directors has the power to appoint and dismiss the Chief Executive Officer and other members of the Executive Management of the Issuer. When other members of the Executive Management of the Issuer than the CEO are being appointed or dismissed, the Board of Directors has to consult with the CEO thereon, and shall take into account the need for a balanced executive team.

Pursuant to the CCA and the Issuer's Articles of Association, the Board of Directors must consist of at least three directors. The Issuer's CG Charter provides that the composition of the Board of Directors should be (i) appropriate to the Issuer's purpose, its operations, phase of development, structure of ownership, (ii) on the one hand, small enough for efficient decision-making and, on the other hand, large enough for its board members to contribute experience and knowledge from their different fields and for changes to the board's composition to be managed without undue disruption and (iii) determined so as to gather sufficient expertise in the Issuer's areas of activity as well as sufficient diversity of skills, background, age and gender.

Pursuant to the CG Code 2020, the Board of Directors should be composed of a majority of non-executive directors, and should include an appropriate number of, and at least three, directors that can be qualified as independent directors. As stated below, there will be three independent directors on the Issuer's Board of Directors as of the date of this Prospectus. By 1 January 2026, at least one third of the members of the Board of Directors must be of the opposite gender. For further details on the criteria to be evaluated in order to be qualified as an independent director, reference is made to Section 10.2.3 (Independent Directors) of this Prospectus.

The term of the directors' mandates cannot exceed four years. Resigning directors can be re-elected for a new term, without limitation. Proposals by the Board of Directors for the appointment or re-election of any director must be based on a recommendation by the Remuneration and Nomination Committee. The directors are elected by the Issuer's General Shareholders' Meeting, casting a vote on each proposed appointment separately. However, in accordance with Article 7:88, §1 the CCA and the Articles of Association of the Issuer, when a director's seat becomes vacant, the remaining directors have the right to co-opt a new director, in which case the next General Shareholders' Meeting must confirm the co-opted director's mandate. If the mandate is confirmed by the General Shareholders' Meeting, and unless the General Shareholders' Meeting decides otherwise, the co-opted director will carry out the mandate of his predecessor for its remaining duration. In absence of such confirmation, the term of office of the co-opted director ends at the end of such General Shareholders' Meeting, without prejudice to the regularity of the composition of the Board of Directors up to that point in time.

The General Shareholders Meeting can dismiss the directors at any time.

A meeting of the Board of Directors is validly constituted if there is a quorum, consisting of at least a majority of the members present in person or represented at the meeting. If this quorum is not present, a new board meeting may be convened to deliberate and decide on the matters on the agenda of the board meeting for which a quorum was not present, provided that at least two members are present. Meetings of the Board of Directors are convened by the Chairperson of the Board whenever the interests of the Issuer so require or if at least two directors so request.

The Chairman of the Board of Directors shall not have a casting vote on matters submitted to the Board of Directors in the event of a tied vote.

The board should meet sufficiently regularly, and at least four times per year, to discharge its duties effectively. The Issuer may organize – where necessary and appropriate – board meetings using video, telephone or internet-based means. The number of board and board committee meetings and the individual attendance record of board members should be disclosed in the corporate governance statement. Non-executive directors should meet at least once a year in the absence of the CEO and the other executives.

#### **10.2.2 CHAIRPERSON**

The Issuer's CG Charter provides that the Board of Directors elects a chairperson from among its non-executive members on the basis of his or her knowledge, skills, experience and mediation strength. The chairperson of the Board of Directors and the CEO cannot be the same individual. The chairperson of the Board of Directors should be a person trusted for their professionalism, independence of mind, coaching capabilities, ability to build consensus, and communication and meeting management skills.

The chairperson of the Board of Directors is responsible for the leadership and the proper and efficient functioning of the Board of Directors. The chairperson of the Board of Directors ensures that there is sufficient time for consideration and discussion before decision-making. The chairperson of the Board of Directors sets the agenda of the board meetings, in consultation with the CEO and Company secretary, and ensures that procedures relating to preparatory work, deliberations, the passing of resolutions and the implementation of decisions are properly followed.

The chairperson of the Board of Directors, assisted by the Company secretary, ensures that board members are provided with accurate, concise, timely and clear information before the meetings and, where necessary, between meetings so that they can make a knowledgeable and informed contribution to board discussions. All board members should receive the same board information.

The chairperson of the Board of Directors establishes a close relationship with the CEO, providing support and advice, while respecting the executive responsibilities of the CEO, and ensures effective interaction between the Board of Directors and the Executive Management of the Issuer.

The chairperson of the Board of Directors ensures effective communication with shareholders and that board members develop and maintain an understanding of the views of the shareholders and other significant stakeholders.

The statutory auditor of the Issuer has direct and unrestricted access to the chairperson of the Board of Directors.

As of the date of this Prospectus, Mr. Stijn Van Rompay is the CEO and Mr. Stefan Yee is chairperson of the Board of Directors. If the Board of Directors envisages appointing a former chief executive officer as chairperson, it should carefully consider the positive and negative implications of such a decision and disclose in the CG Statement why such appointment will not hamper the required autonomy of the CEO.

### **10.2.3 INDEPENDENT DIRECTORS**

In accordance with Article 7:87, §1, subsection 1 CCA, a director in a listed company is considered to be independent if he/she does not have any relationship with the company or with an important shareholder of the company that compromises his or her independence (which is the general independence criterion), and that if a director is a legal entity, such independence must be assessed both on the part of the legal entity and on the part of its permanent representative.

Article 7:87, §1, subsection 2 CCA further states that in order to verify whether a candidate director meets this general independence criterion, the specific independence criteria set out in (provision 3.5 of) the CG Code 2020 are applied, and a candidate who meets these criteria is presumed to be independent, unless proven otherwise.

Provision 3.5 of the CG Code 2020 provides for the following criteria in order for a director to be able to be qualified as an independent director:

1. Not be an executive, or exercising a function as a person entrusted with the daily management of the Issuer or a related company or person, and not have been in such a position for the previous three years before their appointment. Alternatively, no longer enjoying stock options of the company related to this position;
2. Not have served for a total term of more than 12 years as a non-executive directors;
3. Not be an employee of the senior management (as defined in article 19,2° of the law of 20 September 1948 regarding the organization of the business industry) of the Issuer or a related company or person, and not have been in such a position for the previous three years before his or her appointment. Alternatively, no longer enjoying stock options of the Issuer related to this position;
4. Not be receiving, or having received during their mandate or for a period of three years prior to their appointment, any significant remuneration or any other significant advantage of a patrimonial nature from the company or a related company or person, apart from any fee they receive or have received as a non-executive directors;
5. (a) Not hold shares, either directly or indirectly, either alone or in concert, representing globally one tenth or more of the Issuer's capital or one tenth or more of the voting rights in the Issuer at the moment of appointment; (b) Not having been nominated, in any circumstances, by a shareholder fulfilling the conditions covered under (a);

6. Not maintain, nor have maintained in the past year before his or her appointment, a significant business relationship with the Issuer or a related company or person, either directly or as partner, shareholder, board member, member of the senior management (as defined in article 19,2° of the law of 20 September 1948 regarding the organization of the business industry) of a company or person who maintains such a relationship;
7. Not be or have been within the last three years before their appointment, a partner or member of the audit team of the Issuer or person who is, or has been within the last three years before his or her appointment, the external auditor of the Issuer or a related company or person;
8. Not be an executive of another company in which an executive of the Issuer is a non-executive directors, and not have other significant links with executive directors of the Issuer through involvement in other companies or bodies;
9. Not have, in the Issuer or a related company or person, a spouse, legal partner or close family member to the second degree, exercising a function as board member or executive or person entrusted with the daily management or employee of the senior management (as defined in article 19,2° of the law of 20 September 1948 regarding the organization of the business industry), or falling in one of the other cases referred to in 1. to 8. above, and as far as point 2. is concerned, up to three years after the date on which the relevant relative has terminated their last term.

When the Board of Directors submits to the General Shareholders' Meeting the appointment of an independent director who does not meet the aforementioned specific independence criteria of the CG Code 2020, it should explain the reasons why it assumes that the candidate meets the general independence criterion laid down in article 7:87 of the CCA.

The Board of Directors has not further quantified or specified the aforementioned criteria set out in provision 3.5 of the CG Code 2020.

The Issuer is of the view that the independent directors comply with each of the aforementioned criteria.

The Board of Directors will also disclose in its annual report which directors it considers to be independent directors. An independent director who ceases to satisfy the requirements of independence must immediately inform the Board of Directors thereof.

Mr. Marc Foidart (acting through Noshag Partners SCRL), Mrs. Carolyn Myers and Mr. James Gale are the Issuer's independent directors.

The Issuer is of the view that Mr. Marc Foidart (and Noshag Partners SCRL), Mrs. Carolyn Myers and Mr. James Gale meet the general independence criterion laid down in article 7:87 of the CCA and the specific independence criteria set out in (provision 3.5 of) the CG Code 2020. In particular with respect to Mr. Marc Foidart (and Noshag Partners SCRL) the Issuer believes that the independence criteria are met inter alia because the Convertible Bonds for which Noshag SA has subscribed (see Section 13.6

(Convertible Bonds)) (i) are expected to convert into a shareholding below 10% in the Issuer and (ii) are not considered a “significant business relationship” from the point of view of Noshaq SA.

#### 10.2.4 COMPOSITION OF THE BOARD OF DIRECTORS

##### 10.2.4.1 COMPOSITION

The Board of Directors consists of seven members (with a minimum set out in the Articles of Association of three), two of which are executive directors (as member of the Executive Management team) and five of which are non-executive directors, including three independent directors. The table below gives an overview of the members of the Issuer's Board of Directors and their terms as of the date of this Prospectus:

Name	Age	Position	Start of term	End of term
Mr. Stefan Yee	57	Non-executive director Chairman of the Board of Directors	2020	2024
Mr. Stijn Van Rompay <sup>(1)</sup>	44	Executive director	2020	2024
Mr. Thomas Jacobsen <sup>(2)</sup>	45	Executive director	2020	2024
Mr. Leon Van Rompay <sup>(3)</sup>	70	Non-executive director	2020	2024
Mr. Marc Foidart <sup>(4)</sup>	44	Independent director	2020	2024
Ms. Carolyn Myers	61	Independent director	2020	2024
Mr. James Gale	70	Independent director	2020	2024

Notes:

- (1) Acting through SVR Management BV.
- (2) Acting through Jacobsen Management BV.
- (3) Acting through Van Rompay Management BV.
- (4) Acting through Noshaq Partners SCRL.

The following paragraphs contain brief biographies of each of the Directors, or in the case of legal entities being director, their permanent representatives, with an indication of other relevant mandates as member of administrative, management or supervisory bodies in other companies during the previous five years.

#### Stefan Yee

Mr. Stefan Yee has more than 30 years of experience in audit, corporate law, mergers and acquisitions, corporate finance, investment banking and private equity with companies as KPMG, Linklaters, the Flemish investment bank Lessius, the Belgian Corporation for International Investment (SBI/BMI), Beluga (Euronext Brussels) and as the founder and CEO of the PE Group, a Belgian privately held

private equity firm. Stefan is, and has been an investor and/or board member of several listed and private companies such as, amongst others, Beluga, Encare group (Mensura), AXI, The Reference, Alro Holdings, Loomans Group, United Brands, Capco, Faseas International (Spacewell), HD Partners (Dekabo group), AED Rent, UnifiedPost Group, NRG New Generation, Axiles Bionics, including several healthcare companies (Docpharma (formerly Euronext Brussels), Uteron Pharma and Imcyse). Stefan holds Masters degrees in Law and Business Management from the Universities of Brussels (VUB and ULB Solvay Business School) and the University of Chicago (as a BAEF Fellow).

### **Stijn Van Rompay**

For a description of Mr. Stijn Van Rompay's Curriculum vitae, reference is made to Section 10.4.4 (Composition of the Executive Management).

### **Thomas Jacobsen**

For a description of Mr. Thomas Jacobsen's Curriculum vitae, reference is made to Section 10.4.4 (Composition of the Executive Management).

### **Leon Van Rompay**

Leon Van Rompay (70) has more than 40 years' experience in the pharmaceutical market. During his professional career he served in several positions including country & area manager (covering major territories) and board member of the Zambon Group. He was founder and CEO of Docpharma, a Belgian based generics company that was listed on Euronext and served on different boards including Ecodis and Uteron Pharmaceuticals. He was a founding member of BIGE/IBES (Belgian Institute for Health and Economics), the B.G.A. (Belgian Generic Association), BAPIE (Belgian Association of Parallel Import and Export) and was an executive committee member and board member of the Belgian Pharmaceutical Industry Association. He also was a member of the pharmaceutical deontological commission and responsible for this commission in the industry association executive committee

### **Marc Foidart**

Marc Foidart obtained a Master in Business Engineering from the University of Liège (1998). He is co-founder of EKLO ASBL, Member of the Executive Committee of Noshag SA in charge of the Life Sciences sector, CEO of B2H SA, the public company superseding the Liege life sciences ecosystem, and Investment Manager of Epimede SA, a EUR 50 million Belgian based private high-tech growth fund. He has more than 15 years of experience in strategic consulting and investment at all stages of development of small and medium high tech- high growth life sciences enterprises. He played a key role in several financing rounds at critical development stages of various Belgian young biotech companies among which: Mithra Pharmaceuticals SA, Imcyse SA, Uteron Pharma SA, PDC Line Pharma SA, Diagenode SA. As an entrepreneur, Marc Foidart is Co-Founder and past CEO of Arlenda SA, a spin-off company of the University of Liège providing expert statistical solutions to the pharmaceutical, chemical and environment industries. He is also Co-Founder and Executive Chairman of Eyed Pharma SA, a start-up company developing innovative controlled release microimplants in ophthalmology. Marc Foidart has been associate professor at the University of Liege since 2011.

### **Carolyn Myers**

Dr. Carolyn Myers is an accomplished senior executive with extensive experience creating, growing, and leading health care businesses. She is currently Principal of Bioensemble Ltd, a business strategy consulting firm that advises C-suite executives of small and medium size companies on a comprehensive range of drug development, commercial and business development services. Carolyn's experience comes from having led many businesses in their growth strategies. At Allergan (formerly Actavis), she was the Vice President of Global Business Development and Alliance Management with a focus on expanding product portfolios. At Forest Laboratories (acquired by Actavis), Carolyn was the Vice President of the CNS marketing group responsible for marketing and sales of established and new products. At Mylan she held two different leadership positions including President of Mylan Technologies, a division focused on developing generic transdermal systems and President of Dey Laboratories having full P&L responsibility to develop, manufacture and sell innovative respiratory products. Carolyn is also an advisor to several start-up organizations and capital investors.

Carolyn earned a PhD in Genetics from the University of British Columbia and an MBA from Rutgers University.

### **James Gale**

James (Jim) Gale is the founding partner of Signet Healthcare Partners. Jim has over 30 years of healthcare investing and finance experience.

Jim is a Managing Director in Signet Fund IV and is currently the Chairman of the Board of Alpex Pharma S.A., Knight Therapeutics Inc. (TSX: GUD), Teligent (NSDQ: TLGT, formerly IGI Laboratories), and also serves on the Board of Directors of Bionpharma, Chr. Olesen Synthesis A/S, CoreRx, Leon-Nanodrugs GmbH, Pharmaceuticals International (Pii), Advantice Health, and RK Pharma. Prior portfolio company boards include Arbor Pharmaceuticals, Amarin Corporation, eResearch Technologies Inc., and Valera Pharmaceuticals.

Prior to founding Signet, Jim was head of principal investment activities and head of investment banking for Gruntal & Co., LLC. While at Gruntal, he made a number of investments including Andrx Corporation, Royce Laboratories (merged with Watson Pharmaceuticals), Lifecell Corporation, Neurocrine Biosciences, and BML Pharmaceuticals (acquired by Endo Pharmaceuticals).

#### **10.2.4.2 ADDITIONAL INFORMATION ON THE MEMBERS OF THE BOARD OF DIRECTORS**

Reference is made to Section 10.7.2 (Statements concerning directors or their permanent representatives or members of the Executive Management) for the litigation statement concerning the members of the Board of Directors.

Reference is made to Section 10.7.3 (Other Mandates) for an overview of the names of all companies and partnerships in which the abovementioned members of the Board of Directors are, or have been in the previous five years, a member of the administrative, management or supervisory bodies or partner at any time (excluding any mandates held within the subsidiaries of the Issuer).

The business address of each of the members of the Board of Directors for the purpose of their mandate is Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium).

### 10.2.5 SHARES, WARRANTS, CONVERTIBLE BONDS AND OPTIONS ON SHARES HELD BY DIRECTORS

The table below provides an overview (as of the date of this Prospectus) of the Shares, warrants, Convertible Bonds and options on Shares held by the members of the Board of Directors. This overview must be read together with the notes referred to below.

Member of the Board of Directors	Shares owned before the closing of the Offering		Warrants <sup>(1)</sup> owned before the closing of the Offering		Convertible Bonds <sup>(2)</sup> owned before the closing of the Offering		Options on existing Shares owned before the closing of the Offering	
	Number (#)	Pct. (%) <sup>(3)</sup>	Number (#)	Pct. (%) <sup>(4)</sup>	Principal amount (€)	Pct. (%) <sup>(5)</sup>	Number (#)	Pct. (%) <sup>(6)</sup>
Mr. Stefan Yee	-	-	100,000 <sup>(7)</sup>	6.52%	-	-	-	-
Mr. Stijn Van Rompay (CEO) <sup>(8)</sup>	6,438,064	36.17%	920,096 <sup>(9)</sup>	60.02%	€ 1,000,000	6.60%	132,619 <sup>(10)</sup>	0.74%
Mr. Thomas Jacobsen <sup>(11)</sup>	3,437,760	19.31%	163,512 <sup>(12)</sup>	10.67%	-	-	66,329 <sup>(13)</sup>	0.37%
Mr. Leon Van Rompay <sup>(14)</sup>	-	-	-	-	-	-	-	-
Mr. Marc Foidart <sup>(15)</sup>	-	-	-	-	-	-	-	-
Mrs. Carolyn Myers	-	-	-	-	-	-	-	-
Mr. James Gale	-	-	-	-	-	-	-	-
<b>TOTAL</b>	<b>9,875,824</b>	<b>55.48%</b>	<b>1,183,608</b>	<b>77.21%</b>	<b>€ 1,000,000</b>	<b>6.60%</b>	<b>198,948</b>	<b>1.12%</b>

**Notes:**

- (1) Transaction Warrants and ESOP Warrants, in terms of number of shares to be issued upon exercise. The members of the Board of Directors do not own any other warrants with respect to Shares. Each of the Transaction Warrants entitles its holder to subscribe for 4 new Share (see Section 13.4.1 (Transaction Warrants)). Each of the ESOP Warrants entitles its holder to subscribe for one new Share (see Section 13.4.4 (ESOP Warrants)).
- (2) Each of the Convertible Bonds entitles its holder to subscribe for a number of new Shares dependent on the Offer Price (see Section 13.6 (Convertible Bonds) and Section 13.3.2 (Amount and composition upon Closing of the Offering)).
- (3) Percentage of all existing Shares before the closing of the Offering on a non-diluted basis *i.e.*, 17,801,768 Shares.
- (4) Percentage of shares to be issued upon exercise of all outstanding Transaction Warrants and ESOP Warrants (taken together) before the closing of the Offering.
- (5) Percentage of the aggregate principal amount of all Convertible Bonds before the closing of the Offering.
- (6) Percentage of all existing Shares before the closing of the Offering on a non-diluted basis
- (7) Which are all shares to be issued upon exercise of ESOP Warrants (which will have fully vested as of 1 January 2024).
- (8) Acting through SVR Management BV. All securities listed are held by Mr Stijn Van Rompay.
- (9) Shares to be issued upon exercise of 68,000 ESOP Warrants (which will have fully vested as of 1 January 2024) and 213,024 Transaction Warrants.
- (10) Pursuant to the Call Option.
- (11) Acting through Jacobsen Management BV. All securities listed are held by Mr Thomas Jacobsen.
- (12) Which are all shares to be issued upon exercise of Transaction Warrants.
- (13) Pursuant to the Call Option.
- (14) Acting through Van Rompay Management BV.
- (15) Acting through Noshag Partners SCRL.

For more information on the warrants, the Convertible Bonds and Share options, reference is made to, respectively, Section 13.4 (Warrants), Section 13.6 (Convertible Bonds) and Section 13.5 (Options on the Shares) of this Prospectus.

For the intentions of the members of the Board of Directors of the Issuer to participate in the Offering, reference is made to Section 14.4 (Intentions of the Shareholders, the members of the Board of Directors and the Executive Management of the Issuer) of this Prospectus.

## **10.2.6 WARRANTS**

The Issuer has issued warrants to the benefit of certain persons such as investors, employees, independent service providers and directors of Hyloris. For a description of these warrants, see Section 13.4 (Warrants) of this Prospectus.

## **10.2.7 PERFORMANCE REVIEW OF THE BOARD OF DIRECTORS**

The Board of Directors assesses its own performance and its interaction with the Executive Management, as well as its size, composition, functioning and that of its committees, on a continuous basis and at least every three years.

The Board of Directors reviews the Executive Management's performance and the realization of the Hyloris' strategic objectives annually against agreed performance measures and targets.

The evaluation assesses how the board of directors and its committees operate, checks that important issues are effectively prepared and discussed, evaluates each director's contribution and constructive involvement, and assesses the composition of the board of directors and its committees against the desired composition. This evaluation takes into account the members' general role as director, and specific roles as chairperson or member of a committee of the Board of Directors, as well as their relevant responsibilities and time commitment.

Non-executive directors assess their interaction with the Executive Management on a continuous basis.

## **10.3 COMMITTEES OF THE BOARD OF DIRECTORS**

### **10.3.1 GENERAL**

In accordance with Article 7:98 CCA, the Board of Directors may from among its members and under its responsibility establish one or more advisory committees, and shall define their composition and their mission. Such committees are advisory bodies only, and the decision-making remains the collegial responsibility of the Board of Directors.

Only "large" listed companies (as defined in Article 7:99, §3 CCA (Audit Committee) and Article 7:100, §4 CCA (Remuneration Committee) are legally obliged to establish a separate Audit Committee and a Remuneration Committee within their Board of Directors. The Issuer, as of the date of this Prospectus, does not qualify as a "large" listed company, but has nonetheless decided to establish a separate Audit Committee and a separate Remuneration Committee, subject to the completion of the Offering and with effect as from the Listing Date. As the Remuneration Committee will also performs the tasks of a nomination committee in accordance with the provisions 4.19 – 4.23 of the CG Code 2020, it is called the Remuneration and Nomination Committee.

The Issuer may decide to also establish a scientific committee (the "**Scientific Committee**").

The specialized board committees are responsible for assisting the Board of Directors and making recommendations in specific fields: the Audit Committee (in accordance with Article 7:99 CCA and

provision 4.10 – 4.16 of the CG Code 2020), the Remuneration and Nomination Committee (in accordance with Article 7:100 CCA and 4.17 – 4.23 of the CG Code 2020) and the Scientific Committee.

The terms of reference of these board committees are primarily set out in the CG Charter.

**10.3.2 AUDIT COMMITTEE**

The Audit Committee will consist of three directors.

According to Article 7:99, §2 CCA, all members of the Audit committee must be non-executive directors, and at least one member must be independent. The chairperson of the Audit Committee is to be appointed by the members of the Audit Committee. Subject to the completion of the Offering and with effect as from the Listing Date, the following directors will be the members of the Audit committee:

Name	Position
Mr. Marc Foidart <sup>(1)</sup>	Independent director Chairperson of the Audit committee
Mr. James Gale	Independent director
Mr. Stefan Yee	Non-executive director

Notes:  
(1) Acting through Noshag Partners SCRL.

The members of the audit committee must have a collective competence in the business activities of the Issuer, and at least one member of the Audit Committee must have the necessary competence in accounting and auditing. According to the Board of Directors, the members of the Audit Committee satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold (see also Sections 10.2.4 (Composition of the Board of Directors) and 10.7.3 (Other mandates) for more information on their curriculum vitae and mandates held in other companies). Both James Gale and Stefan Yee have been identified as having the necessary competence in accounting and auditing.

In accordance with Article 7:99, §4 CCA, the Audit Committee, without prejudice to the legal duties of the Board of Directors, has at least the following tasks:

- inform the Board of Directors of the result of the legal audit of the annual accounts and of the consolidated annual accounts and explain how the legal audit of the annual accounts and of the consolidated annual accounts contributed to the integrity of the financial reporting and what role the Audit Committee has played in this process;
- monitor the financial reporting process and make recommendations or proposals to guarantee the integrity of the process;

- monitor the effectiveness of the Issuer's internal control and risk management systems and monitor the internal audit and its effectiveness;
- monitor the statutory audit of the annual accounts and the consolidated annual accounts, including follow-up of the questions and recommendations formulated by the statutory auditor;
- assess and monitor the independence of the statutory auditor, in particular as to whether the provision of additional services to the Issuer is appropriate. In particular, the Audit Committee analyses, together with the statutory auditor, the threats to the statutory auditor's independence and the security measures taken to mitigate these threats when the total amount of fees exceed the criteria set out in Article 4, §3 of Regulation (EU) no. 537/2014; and
- make reasoned recommendations to the Board of Directors regarding the appointment of the statutory auditor of the Issuer in accordance with Article 16, §2 of Regulation (EU) No 537/2014.

The Audit Committee meets whenever it deems it necessary for the proper performance of its duties and at least four times a year. The Audit Committee regularly reports to the Board of Directors on the performance of its duties, and in any event when the Board of Directors prepares the annual accounts, the consolidated annual accounts and the condensed financial statements intended for publication.

The members of the Audit Committee have full access to the Executive Management and to any other employee to whom they may require access in order to carry out their responsibilities. The statutory auditor of the Issuer has direct and unrestricted access to the chairperson of the Audit Committee.

### **10.3.3 REMUNERATION AND NOMINATION COMMITTEE**

The Remuneration and Nomination Committee will consist of three directors.

According to Article 7:100, §2 CCA, all members of the Remuneration Committee must be non-executive directors, and the majority of its members have to be independent. The chairperson of the Board of Directors or another non-executive director is the chair of the Remuneration and Nomination Committee. Subject to the completion of the Offering and with effect as from the Listing Date, the following directors will be the members of the Remuneration and Nomination committee:

<b>Name</b>	<b>Position</b>
Mr. Stefan Yee	Non-executive director Chairperson of the Remuneration and Nomination committee
Carolyn Myers	Independent director

Marc Foidart<sup>(1)</sup>

Independent director

Notes:

(1) Acting through Noshag Partners SCRL.

The members of the Remuneration Committee must have the necessary expertise in terms of remuneration policy, which is evidenced by the experience and previous roles of its current members (see also Sections 10.2.4 (Composition of the Board of Directors) and 10.7.3 (Other mandates) for more information on their curriculum vitae and mandates held in other companies).

The CEO participates in the meetings of the Remuneration Committee in an advisory capacity each time the remuneration of another member of the Executive Management is being discussed.

The role of the Remuneration and Nomination Committee consists of making recommendations to the Board of Directors with regard to the appointment and remuneration of directors and members of the Executive Management and, and has in particular the following tasks:

1. Pursuant to its function as Remuneration Committee:
  - make recommendations to the Board of Directors on the remuneration policy and other remuneration proposals that the Board of Directors must submit to the General Shareholders' Meeting;
  - make recommendations to the Board of Directors in line with the remuneration policy approved by the General Shareholders' Meeting on the individual remuneration of the directors and members of the Executive Management, including variable remuneration and long-term performance bonuses, whether or not linked to Shares, in the form of stock options or other financial instruments, and severance pay, and, where applicable, the resulting proposals that the Board of Directors must submit to the General Shareholders' Meeting;
  - prepare the remuneration report, in line with the remuneration policy approved by the General Shareholders' Meeting, that the Board of Directors has to include in its corporate governance statement, which in turn forms a part of the Issuer's annual report; and
  - explain the remuneration report at the Annual General Shareholders' Meeting.
2. Pursuant to its function as Nomination Committee:
  - make recommendations to the Board of Directors with regard to the appointment of board members and members of the Executive Management;
  - prepare plans for the orderly succession of board members;
  - lead the re-appointment process of board members;

- ensure that sufficient and regular attention is paid to the succession of members of the Executive Management; and
- ensure that appropriate talent development programs and programs to promote diversity in leadership are in place.

The Remuneration and Nomination Committee shall meet whenever it deems it necessary for the proper performance of its duties and at least twice a year. The Remuneration and Nomination Committee shall regularly report to the Board of Directors on the performance of its duties.

At the end of each board member's term, the Remuneration and Nomination Committee shall evaluate the relevant board member's presence at the meetings of the Board of Directors or committee meetings, their commitment and their constructive involvement in discussions and decision-making, and shall also assess whether the contribution of each board member is adapted to changing circumstances. The Board of Directors shall act on the results of the performance evaluation, and shall, where appropriate, propose new board members for appointment, propose not to re-appoint existing board members or take any measure deemed appropriate for the effective operation of the Board of Directors.

#### **10.3.4 SCIENTIFIC COMMITTEE**

If and when the Scientific Committee is created, it shall consist of not less than three members (who may, but do not have to, be member of the Board of Directors), or such greater number as determined by the Board of Directors at any time.

The Scientific Committee will elect a chairperson from amongst its members.

Members of the Executive Management and the Board of Directors can be invited to attend meetings of the Scientific Committee.

The role of the Scientific Committee shall be to assist the Board of Directors with the following matters:

- providing strategic guidance for program development;
- providing a neutral view on the progress of technology and science;
- providing external validation of intellectual property or new technologies; and
- providing ad hoc advice on scientific matters at the request of the Board.

The Scientific Committee shall meet whenever it deems it necessary for the proper performance of its duties and at least twice a year. The Scientific Committee shall regularly report to the Board of Directors on the performance of its duties.

## **10.4 EXECUTIVE MANAGEMENT**

### **10.4.1 GENERAL**

Subject to the completion of the Offering and with effect as from the Listing Date, the Board of Directors has established an “Executive Management”, which is an advisory committee to the Board of Directors. The Issuer's Executive Management does not constitute a “*conseil de direction*” / “*directieraad*” within the meaning of Article 7:104 CCA.

The Board of Directors appoints the members of the Executive Management in consultation with the CEO, based on the recommendations made by the Remuneration and Nomination Committee. The Board of Directors will take into account the need for a balanced executive team.

### **10.4.2 THE EXECUTIVE MANAGEMENT**

The Executive Management will discuss and consult with the Board of Directors and advise the Board of Directors on the day-to-day management of the Issuer in accordance with the Issuer's values, strategy, general policy and budget, as determined by the Board of Directors.

Each member of the Executive Management has individually been made responsible for certain aspects of the day-to-day management of the Company and its business (in the case of the CEO, by way of a delegation from the Board of Directors; in the case of the other Executive Management members, by way of a delegation from the CEO).

Each member of the Executive Management is individually competent to decide on the matters delegated to him or her. However, each member of the Executive Management will ensure that any decision to be taken by that member in respect of the powers so delegated that could be material to the Company's day-to-day management (prior to taking such decision if possible, or otherwise after that decision has been taken) is presented and discussed at a meeting of the Executive Management.

The further tasks for which the Executive Management is responsible are described in greater detail in the terms of reference of the Executive Management as set out in the CG Charter.

### **10.4.3 CHIEF EXECUTIVE OFFICER**

The chief executive officer is charged by the Board of Directors with the day-to-day management of the Issuer and is therefore also managing director of the Issuer within the meaning of Article 7:121 CCA. He may be granted additional well-defined powers by the Board of Directors. He has direct operational responsibility for the Issuer. The chief executive officer is responsible for the execution and management of the outcome of all decisions of the board of directors.

The chief executive officer leads the Executive Management within the framework established by the Board of Directors and under its ultimate supervision. The chief executive officer is appointed and removed by the board of directors and reports directly to it.

The chief executive officer also has responsibility for other specific tasks, which are described in greater detail in the terms of reference of the chief executive officer, as set out in the CG Charter.

#### **10.4.4 COMPOSITION OF THE EXECUTIVE MANAGEMENT**

##### **10.4.4.1 COMPOSITION**

Subject to the completion of the Offering and with effect as from the Listing Date, the Executive Management will consist of the following members:

<b>Name</b>	<b>Position</b>
Mr. Stijn Van Rompay <sup>(1)</sup>	Chief Executive Officer
Ms. Astrid Heiremans <sup>(2)</sup>	Acting Chief Financial Officer
Mr. Thomas Jacobsen <sup>(3)</sup>	Executive Director <sup>(4)</sup>
Mr. Koenraad Van der Elst <sup>(5)</sup>	Chief Legal Officer
Mr. Edward Maloney <sup>(6)</sup>	Chief Business Development Officer

Notes:

- (1) Acting through SVR Management BV.
- (2) Acting through Finfactory BV.
- (3) Acting through Jacobsen Management BV.
- (4) Responsible for IP, regulatory and commercial partnerships.
- (5) Acting through Herauld BV.
- (6) Acting through Humara Kinetics LLC.

Hyloris expects to strengthen its Executive Management in the near future with a permanent Chief Financial Officer and the addition of a Chief Scientific Officer and a Chief Operating Officer. As of the date of this Prospectus, the Issuer is in advanced talks with potential candidates for the Chief Scientific Officer and Chief Operating Officer positions.

On 15 June 2020, Mr. Patrick Jeanmart (acting through PaJe SRL), Chief Financial Officer of the Issuer at that time, in common agreement resigned as CFO due to personal circumstances. Mr. Patrick Jeanmart will continue to provide transitional services to the Company during a transitional period. On 15 June 2020, Ms. Astrid Heiremans joined the Company as the acting Chief Financial Officer. The Company is actively looking for a definitive replacement and expects to hire a permanent CFO after the Offering.

#### **Stijn Van Rompay**

Mr. Stijn Van Rompay has over 20 years' of experience in leadership positions in the Pharmaceutical industry, and is the co-founder and CEO of the Issuer. Stijn also co-founded, and was CEO of, Alter Pharma, a high growth pharmaceutical company, focused on development of complex generics and sales of pharmacy related products. He was also co-CEO of Uteron Pharma, a company focused on

innovative female healthcare products. Prior to these positions, Stijn was CFO and afterwards CEO of Docpharma (formerly quoted on Euronext Brussels) a generics and medical device company. He also holds several non-executive director positions in the biotech sector and acts as an advisor to venture capital investors.

Stijn holds a Master in applied economics from the University of Antwerp.

Reference is also made to Section 8.6.5 (Management with significant track record of success) for more information on the professional track record of Stijn.

### **Astrid Heiremans**

Ms. Astrid Heiremans has more than 15 years' experience in various industries (production, consumer retail, business services) focusing both on compliance and on defining and implementing financial and operational strategies. Before joining the Issuer as CFO on 15 June 2020, Astrid, among other things, had a 10 year career at Deloitte serving as a Senior Audit Manager. She currently also serves as an independent non-executive director and chairperson of the audit committee at the House of HR NV.

Astrid holds a Master of Commercial Engineering from the University of Leuven (KULeuven).

### **Thomas Jacobsen**

Mr. Thomas Jacobsen has 20 years' experience in the pharmaceutical industry, focusing on operational management, business development, licensing as well as research and development, and is the co-founder and an executive director of the Issuer. He co-founded Alter Pharma and managed the generic division. Before joining Alter Pharma, Thomas worked at the Scandinavian based generics company Alternova, where he was, among other things, responsible for launching the company's first products as well as for building and registering the company's portfolio.

Thomas holds a Master in pharmacy from University of Copenhagen, as well as a business degree from Copenhagen Business School.

Reference is also made to Section 8.6.5 (Management with significant track record of success) for more information on the professional track record of Thomas.

### **Koenraad Van der Elst**

Mr. Koenraad Van der Elst has more than 30 years experience as in-house and external legal and general counsel of various listed companies, and was also involved in numerous capital market and M&A transactions worldwide.

Before joining the Issuer as CLO in January 2020, Koenraad served as General Counsel at Metris (currently Nikon Metrology) and acted as Secretary General & General Counsel of PUNCH INTERNATIONAL and PUNCH GRAPHIX plc, a company listed on the London Stock Exchange (AIM) and was President of the Supervisory Board ("Raad van Commissarissen") of PUNCH TECHNIX, a company listed on Euronext Amsterdam. Between 1995 and 2002, Koenraad was Director Legal

Documentation at the Investment Banking Department (corporate finance and capital markets) of Generale Bank/Fortis Bank. Koenraad was also an assistant Professor at the University of Brussels (VUB) in Financial Law.

Koenraad holds a Master of laws from the University of Brussels (VUB) and holds an MBA from EHSAL Brussels.

### **Edward Maloney**

Mr. Edward Maloney has 30 years' experience in the pharma industry in a variety of roles. Before joining the Issuer as Vice-President U.S. Operations in 2013, and since 1 January 2020 CBDO of the Issuer, he was President United States of Milla Pharmaceuticals, a subsidiary of the Alter Pharma group<sup>189</sup> a developer and distributor of generic and specialty pharmaceutical products, where he was responsible for U.S. Operations; Vice President Operations at Paddock Laboratories, a manufacturer of solid, liquid and semi-solid products, where he was responsible for manufacturing, supply chain and facilities; and Vice President Business Development at Paddock Laboratories, where he was responsible for in-licensing, out-licensing and joint venture deals.

Edward also served as a board member of the Generic Pharmaceutical Association (GPhA-US), which was the Generic Drug Lobby organization in the United States (since February 2017, the Generic Pharmaceutical Association was renamed to Association for Accessible Medicines (AAM)).

Reference is also made to Section 8.6.5 (Management with significant track record of success) for more information on the professional track record of Edward.

Edward holds a Bachelor of Science in Business Administration from the University of Minnesota.

#### **10.4.4.2 ADDITIONAL INFORMATION ON THE MEMBERS OF THE EXECUTIVE MANAGEMENT**

Reference is made to Section 10.7.2 (Statements concerning directors or their permanent representatives or members of the Executive Management) for the litigation statement concerning the members of the Executive Management.

Reference is made to Section 10.7.3 (Other Mandates) for an overview of the names of all companies and partnerships in which the abovementioned members of the Executive Management are, or have been in the previous five years, a member of the administrative, management or supervisory bodies or partner at any time (excluding any mandates held within the subsidiaries of the Issuer).

The business address of each of the members of the Executive Management for the purpose of their mandate is Boulevard Gustave-Kleyer 17, 4000 Liège (Belgium).

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<sup>189</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

#### 10.4.5 SHARES, WARRANTS, CONVERTIBLE BONDS AND OPTIONS ON SHARES HELD BY EXECUTIVE MANAGEMENT AND/OR SENIOR MANAGEMENT OF THE ISSUER

The table below provides an overview (as of the date of this Prospectus) of the Shares, warrants, Convertible Bonds and options on Shares held by the Executive Management of the Issuer. This overview must be read together with the notes referred to below.

Member of the Executive Management	Shares owned before the closing of the Offering		Warrants <sup>(1)</sup> owned before the closing of the Offering		Convertible Bonds <sup>(2)</sup> owned before the closing of the Offering		Options on existing Shares owned before the closing of the Offering	
	Number (#)	Pct. (%) <sup>(3)</sup>	Number (#)	Pct. (%) <sup>(4)</sup>	Principal amount (€)	Pct. (%) <sup>(5)</sup>	Number (#)	Pct. (%) <sup>(6)</sup>
Mr. Stijn Van Rompay (CEO) <sup>(7)</sup>	6,438,064	36.17%	920,096 <sup>(8)</sup>	60.02%	€ 1,000,000	6.60%	132,619 <sup>(9)</sup>	0.74%
Ms. Astrid Heiremans <sup>(10)</sup>	-	-	-	-	-	-	-	-
Mr. Edward Maloney (CBDO) <sup>(11)</sup>	428,828	2.41%	-	-	-	-	-	-
Mr. Koenraad Van der Elst (CLO) <sup>(12)</sup>	-	-	50,000 <sup>(13)</sup>	3.26%	€ 100,000	0.66%	-	-
Mr. Maurizio Passanisi (CCLO) <sup>(14)</sup>	190,524	1.07%	46,000 <sup>(15)</sup>	3.00%	-	-	-	-
Mr. Thomas Jacobsen (Executive director) <sup>(16)</sup>	3,437,760	19.31%	163,512 <sup>(17)</sup>	10.67%	-	-	66,329 <sup>(18)</sup>	0.37%
<b>TOTAL</b>	<b>10,495,176</b>	<b>58.96%</b>	<b>1,179,608</b>	<b>76.95%</b>	<b>€ 1,100,000</b>	<b>7.26%</b>	<b>198,948</b>	<b>1.12%</b>

##### Notes:

- (1) Transaction Warrants and ESOP Warrants, in terms of number of new Shares to be issued upon exercise. The members of the Board of Directors do not own any other warrants with respect to Shares. Each Transaction Warrant entitles its holder to subscribe for 4 new Shares (see Section 13.4.1 (Transaction Warrants)). Each ESOP Warrant entitles its holder to subscribe for one new Share (see Section 13.4.4 (ESOP Warrants)).
- (2) Each of the Convertible Bonds entitles its holder to subscribe for a number of new Shares dependent on the Offer Price (see Section 13.6 (Convertible Bonds) and Section 13.3.2 (Amount and composition upon closing of the Offering)).
- (3) Percentage of all existing Shares before the closing of the Offering on a non-diluted basis, i.e., 17,801,768 Shares.
- (4) Percentage of Shares to be issued upon exercise of all outstanding Transaction Warrants and ESOP Warrants (taken together) before the closing of the Offering.
- (5) Percentage of the aggregate principal amount of all Convertible Bonds before the closing of the Offering.
- (6) Percentage of all existing Shares before the closing of the Offering on a non-diluted basis
- (7) Acting through SVR Management BV. All securities listed are held by Mr Stijn Van Rompay.
- (8) Shares to be issued upon exercise of 68,000 ESOP Warrants (which will have fully vested as of 1 January 2024) and 213,024 Transaction Warrants.
- (9) Pursuant to the Call Option.
- (10) Acting through FinFactory BV.
- (11) Acting through Humara Kinetics LLC. All securities listed are held by Mr Edward Maloney.
- (12) Acting through Heralut BV. All securities listed are held by Mr Koenraad Van der Elst.
- (13) Which are all shares to be issued upon exercise of ESOP Warrants (which will have fully vested as of 1 January 2024).
- (14) Mr. Passanisi will leave the Company on 3 July 2020 (i.e., shortly after the Offering), and is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).
- (15) Which are all shares to be issued upon exercise of Transaction Warrants.
- (16) Acting through Jacobsen Management BV. All securities listed are held by Mr Thomas Jacobsen.
- (17) Which are all shares to be issued upon exercise of Transaction Warrants.
- (18) Pursuant to the Call Option.

For more information on the warrants, the Convertible Bonds and Share options, reference is made to, respectively, Section 13.4 (Warrants), Section 13.6 (Convertible Bonds) and Section 13.5 (Options on the Shares) of this Prospectus.

For the intentions of the members of the Executive Management of the Issuer to participate in the Offering, reference is made to Section 14.4 (Intentions of the Shareholders, the members of the Board of Directors and the Executive Management of the Issuer) of this Prospectus.

## **10.5 REMUNERATION AND BENEFITS**

### **10.5.1 REMUNERATION PRACTICES**

The Issuer's current remuneration practices are designed to:

- to attract, reward and retain the necessary talent;
- to promote the achievement of strategic objectives in accordance with the Issuer's risk appetite and behavioral norms; and
- to promote sustainable value creation.

The current remuneration practices in relation to the directors and members of the Executive Management are further described below in Section 10.5.2 (Directors) and section 10.4 (Executive Management) respectively.

The Issuer will prepare a remuneration policy pursuant to Article 7:89/1 CCA and intends to submit this policy to the General Shareholders' Meeting approving the annual accounts for the financial year ending on 31 December 2020. Upon every material change to the remuneration policy and in any case at least every four years, the remuneration policy will be submitted to the General Shareholders' meeting for approval. The Shareholders' vote on the remuneration policy is binding. The Issuer will only pay remuneration in accordance with the remuneration policy approved by the General Shareholders' Meeting. If the remuneration policy is not approved, remuneration will be paid in accordance with the most recently approved remuneration policy or, if there is no approved remuneration policy, the existing remuneration practices.

Until the approval of the remuneration policy pursuant to Article 7:89/1 CCA, the directors and members of the Executive Management will be remunerated pursuant to the current remuneration practices as described below in Section 10.5.2 (Directors) and section 10.4 (Executive Management) respectively.

### **10.5.2 DIRECTORS**

#### **10.5.2.1 GENERAL**

Upon recommendation and proposal of the Remuneration and Nomination Committee, the Board of Directors determines the remuneration of the directors to be proposed to the General Shareholders' Meeting.

Pursuant to Belgian law, the General Shareholders' Meeting approves the remuneration of the directors, including *inter alia*, each time as relevant:

- (i) in relation to the remuneration of executive (and non-executive directors), the exemption from the rule that Shares and Share options (or any other rights to acquire Shares) can only be acquired definitively or exercised after a period of at least three years as of their grant (Article 7:91, first subsection CCA);
- (ii) in relation to the remuneration of executive directors, the exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years (Article 7:91, second to fourth subsection CCA);
- (iii) in relation to the remuneration of non-executive non-independent directors, any variable part of the remuneration (independent directors can never receive a variable remuneration) (Article 7:92, fourth and fifth subsection CCA); and
- (iv) any service agreements to be entered into with executive directors providing for severance payments exceeding 12 months' remuneration (or, subject to a reasoned opinion by the remuneration and nomination committee, eighteen months' remuneration) (Article 7:92, first subsection CCA).

Notwithstanding point (i) and (ii) above, pursuant to the Issuer's Articles of Association, the Board of Directors is explicitly authorized to deviate from the provisions of Article 7:91 CCA.

#### **10.5.2.2 REMUNERATION AND COMPENSATION IN 2019 AND UP TO MAY 2020**

During 2019 and up to May 2020, no remuneration or compensation was paid to the members of the Board of Directors in that capacity, other than the reimbursement of travel and hotel expenses incurred by the members of the Board of Directors in connection with their attendance of the Board of Directors' meetings.

#### **10.5.2.3 REMUNERATION AND COMPENSATION AS OF JUNE 2020**

The remuneration and compensation of the non-executive directors that has been determined by the General Shareholders' Meeting as of June 2020, is as follows:

- Annual fixed fees:
  - o The non-executive directors will receive an annual fixed fee of EUR 12,500.
  - o The members of the Audit Committee, the Remuneration and Nomination Committee and the Scientific Committee (if and when created) will receive an additional annual fixed fee of EUR 5,000.

There are currently no plans to change the remuneration and compensation of the non-executive directors. However, the Issuer will continuously review the remuneration of its non-executive directors against market practice.

The Issuer also reimburses reasonable out of pocket expenses of directors (including travel expenses) incurred in performing the activity of director. Without prejudice to the powers granted by law to the General Shareholders' Meeting, the Board of Directors sets and revises the rules for reimbursement of directors' business-related out of pocket expenses.

The directors who will also be a member of the Executive Management will be remunerated for the Executive Management mandate, but not for their director mandate.

### **10.5.3 EXECUTIVE MANAGEMENT**

#### **10.5.3.1 GENERAL**

The remuneration of the chief executive officer and the other members of the Executive Management is based on recommendations made by the Remuneration and Nomination Committee. The chief executive officer participates in the meetings of the Remuneration and Nomination Committee in an advisory capacity each time the remuneration of another member of the Executive Management is being discussed.

The remuneration is determined by the Board of Directors in accordance with the current remuneration practices. After approval by the Issuer's General Shareholders' Meeting of a remuneration policy pursuant to Article 7:89/1 CCA, the remuneration will be determined by the Board of Directors in accordance with the remuneration policy.

As an exception to the foregoing rule, Belgian law provides that the General Shareholders' Meeting must approve, as relevant:

- (i) in relation to the remuneration of members of the Executive Management and certain other executives (if any), an exemption from the rule that Shares and Share options (or any other rights to acquire Shares) can only be acquired definitively or exercised after a period of at least three years as of their grant (Article 7:121, last subsection *jo*. Article 7:91, first subsection CCA);
- (ii) in relation to the remuneration of members of the Executive Management and certain other executives (if any), an exemption from the rule that (unless the variable remuneration is less than a quarter of the annual remuneration) at least one quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least two years and that at least another quarter of the variable remuneration must be based on performance criteria that have been determined in advance and that can be measured objectively over a period of at least three years (Article 7:121, last subsection *jo*. Article 7:91, second to fourth subsection CCA); and

- (iii) any service agreements to be entered into with members of the Executive Management and certain other executives (if any) (as the case may be) providing for severance payments exceeding 12 months' remuneration (or, subject to a reasoned opinion by the Remuneration and Nomination Committee, eighteen months' remuneration) (Article 7:121, last subsection *jo*. Article 7:92, first subsection CCA).

Notwithstanding point (i) and (ii) above, pursuant to the Issuer's Articles of Association, the Board of Directors is explicitly authorized to deviate from the provisions of Article 7:91 CCA.

An appropriate proportion of the remuneration package should be structured so as to link rewards to corporate and individual performance, thereby aligning the interest of the Executive Management with the sustainable value-creation objectives of the Issuer. The Board of Directors will determine whether the targets for the variable remuneration of the members of the Executive Management (if any), as set by the Board of Directors on the basis of the proposal made by the Remuneration and Nomination Committee, are met.

The remuneration of the Executive Management was amended in view of the contemplated Offering and currently consists of the following main remuneration components:

- annual base salary/fee (fixed); and
- participation in Share option plans.

The members of the Executive Management are not entitled to variable remuneration (i.e. remuneration linked to performance criteria) except for the CEO and CBDO (see Section 12.5 (Employment Services Agreements)).

Certain members of the Executive Committee hold ESOP Warrants (see Section 10.4.5 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management and/or senior management of the Issuer) and Section 13.4.4 (ESOP Warrants))

No member of the Executive Management is entitled to pension benefits.

The members of the Executive Management are also reimbursed for certain costs and expenses made in the performance of their function.

There are currently no plans to change the remuneration of the members of the Executive Management. However, the Issuer will continuously review the remuneration of the members of the Executive Management against market practice.

#### **10.5.3.2 REMUNERATION AND COMPENSATION IN 2019**

In 2019, the following remuneration and compensation was paid or accrued to the CEO (*i.e.*, Mr. Stijn Van Rompay) and the other members of the Executive Management who were engaged by Hyloris at

that time (i.e., Mr. Edward Maloney, Mr. Antoine Carlhian<sup>190</sup>, Mr. Maurizio Passanisi<sup>191</sup> and Mr. Thomas Jacobsen<sup>192</sup>):

	<u>CEO (EUR)</u>	<b>Other members of the Executive Management who were engaged by Hyloris at that time (EUR)</b>
Annual base salary .....	200,000	141,800
Supplementary pension plan (n° 016912 – defined contribution) .....	-	1,700 <sup>(1)</sup>
Car lease/transport allowance .....	-	7,500
Medical plan	-	1,000
Life insurance.....	-	500
Health insurance .....	-	500
<b>Total.....</b>	<b>200,000</b>	<b>152,000</b>

Note:

(1) The entitlement to pension benefits of Mr. Maurizio Passanisi (CLO of the Issuer until 3 July 2020)

### **10.5.3.3      PAYMENTS UPON TERMINATION**

#### **Mr. Stijn Van Rompay (CEO)**

The current services agreement with Mr. Stijn Van Rompay has been entered into between Mr. Stijn Van Rompay's Belgian incorporated management company SVR Management BV and the Issuer effective as from 1 September 2019, for an indefinite period. It can be terminated by both the Issuer upon six months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by SVR Management BV upon three months' notice or payment of a compensation equivalent to the fixed remuneration of such three-month period. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g., serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period (subject to certain exceptions) of 18 months after termination, against a payment of 100% of the fixed fee over such 18 months' period. However, SVR Management BV will not be entitled to this payment if it terminates the services agreement at its own initiative or if the Issuer terminates the services agreement for breach of contract imputable to SVR Management BV.

<sup>190</sup> Mr. Antoine Carlhian (former CFO) left the Company on 30 April 2020.

<sup>191</sup> Mr. Passanisi (CLO of the Issuer) will leave the Company on 3 July 2020 (i.e., shortly after the Offering) and is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

<sup>192</sup> Ms. Astrid Heiremans (Acting CFO) was engaged by Hyloris as of 15 June 2020. Mr. Koenraad Van der Elst (CLO) was engaged by Hyloris as of 1 January 2020.

#### **Mr. Thomas Jacobsen (Executive Director)**

The current services agreement with Mr. Thomas Jacobsen has been entered into between Mr. Thomas Jacobsen's Belgian incorporated management company Jacobsen Management BV and the Issuer effective as from 1 November 2019, for an indefinite period. It can be terminated by the Issuer upon six months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by Jacobsen Management BV upon three months' notice or payment of a compensation equivalent to the fixed remuneration of such three-month period. The agreement also provides for reasons for immediate termination because of breach of either party (e.g., serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period of 18 months after termination, against a payment of 100% of the fixed fee over that 18 months' period. However, Jacobsen Management BV will not be entitled to this payment if it terminates the services agreement at its own initiative or if the Issuer terminates the services agreement for breach of contract imputable to Jacobsen Management BV.

#### **Mr. Edward Maloney (CBDO)**

The current services agreement with Mr. Edward Maloney has been entered into between Mr. Edward Maloney's U.S. incorporated management company Humara Kinetics LLC and the Issuer effective as from 1 January 2020, for an indefinite period. It can be terminated by both the Issuer and Humara Kinetics LLC upon at least 120 days' notice. The agreement also provides for reasons for immediate termination because of breach of either party (e.g., gross misconduct affecting the Issuer's business, serious or repeated breaches of the services agreement, criminal convictions, negligence, insolvency, bankruptcy, incapacity for 60 days during a 52-week consecutive period, etc.).

In the event of termination of the services agreement, the agreement also provides for a non-compete period, and a non-solicitation period, of 12 and 18 months after, respectively.

#### **Ms. Astrid Heiremans (Acting CFO)**

The current services agreement with Ms. Astrid Heiremans has been entered into between Ms. Astrid Heireman's Belgian incorporated management company FinFactory BV and the Issuer effective as from 15 June 2020, for a fixed term of three months and after that automatically renewed for an indefinite term. It can be terminated by the Issuer and by FinFactory BV after the three-month fixed term, at any time upon one months' notice. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g. serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period of 12 months after termination, without any compensation.

#### **Mr. Koenraad Van der Elst (CLO)**

The current services agreement with Mr. Koenraad Van der Elst has been entered into between Mr. Koenraad Van der Elst's Belgian incorporated management company Herault BV and the Issuer effective as from 1 January 2020, for an indefinite period. It can be terminated by the Issuer upon six months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by Herault BV upon three months' notice period or payment of a compensation equivalent to the fixed remuneration of such three-month period. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g. serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period of 12 months after termination against a payment of 50% of the fixed fee over such 12 months' period. However, Herault BV will not be entitled to this payment if it terminates the services agreement at its own initiative or if the Issuer terminates the services agreement for breach of contract imputable to Herault BV.

#### **10.5.4 INDEMNIFICATION AND INSURANCE OF DIRECTORS AND EXECUTIVE MANAGEMENT**

The Issuer has implemented directors' and officers' insurance coverage in order to cover liability they may incur in the exercise of their mandates.

### **10.6 CONFLICTS OF INTEREST**

#### **10.6.1 GENERAL**

Each board member should place the Issuer's interests above their own. The board members have the duty to look after the interests of all shareholders on an equivalent basis. Each board member should act according to the principles of reasonableness and fairness (copy of provision 6.6 CG Code 2020).

The Board of Directors should act in such a manner that a conflict of interest, or the appearance of such a conflict, is avoided (copy of provision 6.9 CG Code 2020).

Each board member should, in particular, be attentive to conflicts of interests that may arise between the Issuer, its board members, its significant or controlling shareholder(s) and other shareholders. The board members who are proposed by significant or controlling shareholder(s) should ensure that the interests and intentions of these shareholder(s) are sufficiently clear and communicated to the Board of Directors in a timely manner (copy of provision 6.8 CG Code 2020).

When the board takes a decision, board members should disregard their personal interests. They should not use business opportunities intended for the Issuer for their own benefit (copy of provision 6.10 CG Code 2020).

The Issuer has put in place a number of procedures, pursuant to the CCA and the CG Code 2020, with a view to mitigating the risk of any adverse impact on the Issuer pursuant to conflicts of interest.

The Issuer will comply with the above mentioned corporate governance provisions set forth in the CG Code 2020 by applying the procedures under Section 10.6.2 (Conflicts of interest in relation to directors), 10.6.3 (Additional conflict of interest rules in relation to the directors and members of the Executive Management) and 10.6.4 (Conflicts of interest in relation to related parties) and 10.6.5(Corporate Opportunities). For the avoidance of doubt, these corporate governance provisions will also be applied if transactions will be entered into between the Issuer and related parties such as the Alter Pharma group (with which Mr. Stijn Van Rompay and Mr. Thomas Jacobsen have certain ties, see Risk Factor 2.1.4.2)<sup>193</sup>. See Section 2.1.4 (Risks related to conflicts of interest) for more information on the fact that certain of directors and members the Executive Management hold directorships or shareholdings in other pharmaceutical companies, which could create potential conflicts of interest.

#### **10.6.2 CONFLICTS OF INTEREST IN RELATION TO DIRECTORS**

Article 7:96 CCA provides for a special procedure within the Board of Directors in the event of a personal financial conflict of interest of one or more directors with one or more decisions or transactions by the Board of Directors, which the Board of Directors will apply.

In the event of such a conflict of interest, the director concerned must inform his or her fellow directors of his or her conflict of interest before the Board of Directors deliberates and takes a decision in the matter concerned. Furthermore, the conflicted director may not participate in the deliberation and voting by the Board of Directors on the matter that gives rise to the conflict of interest and will therefore not be taken into account for the calculation of the quorum and majority. The minutes of the meeting of the Board of Directors must contain the statement and explanation of the nature of this conflicting interest of the conflicted director.

The Board of Directors is not allowed to delegate decisions in respect of which one or more directors have a personal financial conflict of interest to, for example, special proxyholders in order to avoid the application of the procedure of Article 7:96 CCA. If all directors, or all but one, have a conflict of interest, the decision or transaction is submitted to the General Shareholders' Meeting; if the General Shareholders' Meeting approves the decision or transaction, the Board of Directors may execute it.

The minutes must also contain a justification by the Board of Directors for the decision or transaction, and a description of the financial consequences thereof for the Issuer. The relevant minutes must be included in the statutory annual report of the Board of Directors or, in the absence of such report, be deposited together with the statutory financial statements.

The conflicted director must also notify the Statutory Auditor of the conflict. The Statutory Auditor must describe the financial consequences of the decision or transaction that gave rise to the potential conflict in its statutory annual audit report.

Any person having an interest in this rule being complied with can request the annulment or suspension of the of the decision of the Board of Directors before the (president of the) enterprise court, and also the Issuer can request the annulment of the decision or the transaction that have taken place in breach

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<sup>193</sup> Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

of Article 7:96 CCA, if the counterparty to the decision or the transaction was, or should have been, aware of such breach.

This procedure does not apply to decisions or transactions in the ordinary course of business at customary market conditions. It also does not apply to transactions or decisions between companies of which one holds (directly or indirectly) at least 95% of the votes linked to the outstanding securities of the other, and transactions or decisions between companies whereby at least 95% of the votes linked to the aggregate outstanding securities of both companies are (directly or indirectly) held by another company.

The procedure applies to decisions concerning business agreements such as the ones described in section 12.6 (Business Agreements) of this Prospectus.

The procedure will be applied if Mr. Van Stijn Rompay or Mr. Thomas Jacobson has a personal financial conflict of interest in relation to decisions concerning business agreements with the Alter Pharma group.

### **10.6.3 ADDITIONAL FUNCTIONAL CONFLICT OF INTEREST RULES IN RELATION TO THE DIRECTORS AND MEMBERS OF THE EXECUTIVE MANAGEMENT**

The Issuer imposes on each member of the Board of Directors and of the Executive Management that he/she must try to avoid as much as possible the creation of conflicts of interest.

To protect the interests of the Issuer and its shareholders, the Board of Directors has furthermore decided, on a voluntary basis, through the CG Charter, to apply a conflict of interest procedure for functional conflicts of interest of members of the Board of Directors or of the Executive Management with respect to matters falling within the competence of the Board of Directors or the Executive Management. This procedure is without prejudice to procedures of Articles 7:96 and 7:97 CCA.

More specifically, there is a functional conflict of interest on the part of a member of the Board of Directors or of the Executive Management when:

- i. one of the close relatives of the member concerned has a personal financial interest that is in conflict with a decision or transaction that falls within the authority of the Board of Directors or the Executive Management; or
- ii. a company that does not belong to the group and in which the member or one of his or her close relatives holds a board or executive management position, has a personal financial interest that is in conflict with a decision or a transaction that falls within the authority of the Board of Directors or the Executive Management.

When such a functional conflict of interest arises with respect to a member of the Board of Directors, the member concerned shall inform his or her fellow directors of this at the beginning of the meeting of the Board of Directors. They will then decide whether or not the member concerned can vote on the matter to which the conflict of interest relates and whether or not he/she can participate in the discussion of this matter. The minutes of the Board of Directors shall describe how the procedure was applied. No publicity will be given to the application of the procedure.

When such a functional conflict of interest arises with respect to a member of the Executive Management, the matter is submitted to the Board of Directors.

#### **10.6.4 CONFLICTS OF INTEREST IN RELATION TO RELATED PARTIES**

The Board of Directors must comply with the procedure set out in Article 7:97, §3-4/1 CCA if it takes a decision or carries out a transaction that relate to a related party within the meaning of the International Accounting Standard 24, as adopted by the European Union (IAS 24), unless the exemptions of Article 7:97, §1, section 4 apply.

As per the date of this Prospectus, the Alter Pharma group is such a related party, and the procedure will be applied with respect to decisions and transactions that relate to the Alter Pharma group as long as it remains such a related party, unless any of the exemptions apply. As long as the Alter Pharma group is such a related party, the procedure will be applied with respect to decisions relating to business agreements with the Alter Pharma group such as the ones described in section 12.6 (Business Agreements) of this Prospectus.

The procedure set out in Article 7:97, §3-4/1 CCA also applies to the certain proposals the Board of Directors submits to the General Shareholders' Meeting. The procedure does not apply when the related party is a subsidiary of the Issuer, unless it concerns a subsidiary in which the natural or legal person who has direct or indirect control over the Issuer (if any) holds, directly or indirectly through other natural or legal persons than the Issuer, a participation representing at least 25% of the capital of the subsidiary in question or which entitles him to at least 25% of that capital in the event of a distribution of profits by that subsidiary.

In accordance with the procedure set out in Article 7:97, §3-4/1 CCA, all decisions or transactions to which the procedure applies must first be subject to the assessment of a committee of three independent directors, which, if it so chooses, shall be assisted by one or more independent experts of its choice. If the procedure is applied with respect to decisions and transactions that relate to the Alter Pharma group, the committee shall be assisted by one or more independent experts of its choice. The committee issues a written and reasoned opinion to the Board of Directors on the proposed decision or transaction, in which it addresses at least the elements set out in Article 7:97, §3, section 2 CCA.

After having taken note of the advice of the committee provided, and applying, where necessary the conflict of interest procedure set forth in Article 7:96 CCA, the Board of Directors shall deliberate on the intended decision or transaction. If a director is involved in the decision or operation, that director may not participate in the deliberation and voting. If all directors are involved, the decision or transaction is submitted to the General Shareholders' Meeting; if the General Shareholders' Meeting approves the decision or transaction, the Board of Directors may execute it. The board of directors confirms in the minutes of the meeting that the procedure described above has been complied with, and, if necessary, justifies why it deviates from the committee's opinion.

The statutory auditor assesses whether there are no material inconsistencies in the financial and accounting information included in the minutes of the Board of Director and in the committee's opinion

with respect to the information available to it within the scope of its mission. This opinion shall be attached to the minutes of the Board of Directors.

The Issuer will publicly announce the decisions or transaction in accordance with Article 7:97, §4/1 CCA.

Any person having an interest in this rule being complied with can request the annulment or suspension of the decision of the Board of Directors before the (president of the) enterprise court, and the Issuer can also request the annulment of the decision or the transaction that have taken place in breach of Article 7:97 CCA, if the counterparty to the decision or the transaction was, or should have been, aware of such breach.

This procedure does not apply to customary decisions and transactions at market conditions or to decisions and transactions the value of which is less than 1% of the net assets of the Issuer on a consolidated basis. In addition, decisions and transactions on the remuneration of the directors or the members of the Executive Management are exempted as are acquisitions or transfers of own shares, interim dividend payments and capital increases under the authorized capital without limitation or cancellation of the preferential subscription right of the existing shareholders.

The Issuer shall state in the annual report any material restrictions or burdens imposed on it by its controlling shareholder during the year under review, or of which it has requested the preservation.

#### **10.6.5 CORPORATE OPPORTUNITIES<sup>194</sup>**

Since the directors of the Issuer are appointed on the basis of their competencies and experience in the pharmaceutical industry and other adjacent areas of expertise, they may hold directorships in other pharmaceutical companies or in companies that control pharmaceutical companies, or they may exercise activities in the pharmaceutical industry as a natural person. See Section 10.7.3 (Other Mandates of the members of the Executive Management and/or senior management), in which are set forth the other mandates of the directors of the Issuer.

It may happen that a transaction submitted to the Board of Directors may arouse the interest of another company in which a director holds a mandate. For such cases the Board of Directors has decided, on a voluntary basis, through the CG Charter, to apply a procedure derived, to a certain extent, from the procedure of Article 7:96 CCA on conflicts of interest. This procedure is without prejudice to procedures of Articles 7:96 and 7:97 CCA. If such a situation arises, the director concerned informs the chairperson of the Board of Directors and the chief executive officer.

Once the risk has been identified, the director concerned and the chairperson of the Board of Directors shall examine together, taking into account the interest of the Issuer, whether or not the director concerned should withdraw from the deliberation and decision-making process concerning the transaction, in which case the preparatory notes shall not be sent to him or her and he or she shall withdraw from the meeting of the Board of Directors as soon as the matter in question is being discussed.

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<sup>194</sup> The procedure of Section 10.6.3 (Additional functional conflict of interest rules in relation to the directors and members of the Executive Management) relates to transactions to be entered into between the Issuer and the other party (with respect to which a director has a functional conflict of interest) and the procedure of Section 10.6.5 (Corporate Opportunities) relates to opportunities in which both the Issuer and that other party can be interested.

Compliance with this procedure does not of course release the director concerned from his or her obligation of confidentiality vis-à-vis the Issuer.

The minutes of the Board of Directors shall in such case establish, in general terms, the compliance with this procedure or explain, in general terms, the reasons why it was not applied. As soon as the risk no longer exists, this procedure shall no longer apply. No publicity will be given to the application of the procedure.

#### **10.6.6 SPECIFIC CONFLICTS OF INTERESTS**

As of the date of this Prospectus, as far as the Issuer is aware, none of the directors or the members of the Executive Management have a conflict of interest within the meaning of Article 7:96 CCA that has not been disclosed to the Board of Directors. Where such a conflict of interest has occurred (including with respect to all transactions (in particular those with the Alter Pharma group) set out in Section 12 (Related Party Transactions), save for the transactions in relation to the issue of Convertible Bonds, which are shareholder matters outside the scope of the statutory conflict of interest procedure of Article 7:96 CCA), Hyloris has applied (or ratified the application of) the statutory conflicts of interest procedure of Article 7:96 CCA.

Except for the fact that Mr. Leon Van Rompay (member of the Board of Directors of the Issuer) is the father of Mr. Stijn Van Rompay (CEO of the Issuer), none of the other members of the Board of Directors and the members of the Executive Management have a family relationship with any other of the members of the Board of Directors or the members of the Executive Management, as of the date of this Prospectus.

#### **10.7 OTHER INFORMATION**

##### **10.7.1 DEALING CODE**

With a view to preventing market abuse (insider dealing and market manipulation), and pursuant to the Market Abuse Regulation, the Board of Directors has established the Dealing Code. The Dealing Code describes amongst others the declaration and conduct obligations of directors and members of the Executive Management with respect to transactions in Shares and other financial instruments of the Issuer. The Dealing Code sets limits on carrying out transactions in Shares and other financial instruments of the Issuer, and allows dealing by the directors and the members of the Executive Management only during certain windows. The Dealing Code is attached to the Issuer's CG Charter.

##### **10.7.2 STATEMENTS CONCERNING DIRECTORS OR THEIR PERMANENT REPRESENTATIVES OR MEMBERS OF THE EXECUTIVE MANAGEMENT**

Each of the members of the Board of Directors (see Section 10.2.4 (Composition of the Board of Directors)) and each of the members of Executive Management, confirmed to the Issuer that neither he or she nor the company through which he or she acts (as the case may be) was subject to (i) any convictions in relation to fraudulent offenses during the past five years or (ii) any official public incrimination and/or sanctions of such members by statutory or regulatory authorities (including designated professional bodies), or disqualification by a court from acting as a member of the

administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer during the past five years. In addition, each of them has confirmed to the Issuer that neither he or she nor the company through which he or she acts (as the case may be) is or has been subject to any bankruptcies, receiverships or liquidations of any entities in which he, she or it held any office, directorships, or partner or senior management positions during the past five years, other than the following: Mr. Koenraad Van der Elst who acted as the liquidator in the voluntary liquidation of Garda srl, an Italian subsidiary of Nikon Metrology NV (in which he held the mandate as General Counsel and member of the Executive Committee before becoming CLO of the Issuer) until 31 May 2020; Mr. James Gale who was a director (and, indirectly through Signet Healthcare Partners, a minority shareholder) of Sancilio Pharmaceuticals, which went into receivership in June 2018 shortly after Mr. James Gale's mandate as director had terminated, and who is currently also a director of Spepharm BV, which is expected to be voluntarily liquidated in July 2020; and Ms. Astrid Heiremans, who was CFO/COO of Soficotex NV at the time of its voluntary liquidation in 2017.

**10.7.3 OTHER MANDATES OF THE MEMBERS OF THE EXECUTIVE MANAGEMENT AND/OR SENIOR MANAGEMENT**

In the five years preceding the date of this Prospectus, the directors (based on the membership before and after the completion of the Offering) and members of the Executive Management have held the following directorships (apart from their functions within the Issuer and its subsidiaries) and memberships of administrative, management or supervisory bodies and/or partnerships:

Name	Current	Past (5 years)
Mr. Stefan Yee (non-executive director and chairman of the Board of Directors)	<ul style="list-style-type: none"> <li>- Statutory manager of AS Partners BV</li> <li>- Managing director, acting through AS Partners BV, of PE Group NV</li> <li>- Board member, acting through AS Partners BV, of AED Rent NV</li> <li>- Board member, acting through AED Rent NV, of AED Display NV</li> <li>- Board member, through AED Rent NV, of AED Lease NV</li> </ul>	<ul style="list-style-type: none"> <li>- Managing director, acting through PE Group NV, of HD Partners NV</li> <li>- Statutory manager, acting through PE Group NV, of Dekabo BV</li> <li>- Statutory manager, acting through PE Group NV, of Fordibel SRL</li> <li>- Managing director, acting through PE Group NV, of Underground Solutions NV</li> <li>- Board member, through AS Partners BV, of SI2 Fund NV</li> </ul>

	<ul style="list-style-type: none"> <li>- Board member, acting through AED Display NV, of AED Studios NV</li> <li>- Managing director of PE Event Logistics NV</li> <li>- Board member, acting through AS Partners BV, of Heliventure FTO NV</li> <li>- Board member of UBLA VZW</li> <li>- Board member of MW Foundation ASBL</li> <li>- Chairman, acting through AS Partners BV, of UnifiedPost Group SA</li> <li>- Board member of UnifiedPost PaymentsNV</li> <li>- Board member of TrainM NV</li> <li>- Board member, acting through AS Partners BV, of Imcyse SA</li> <li>- Chairman of Axiles Bionics NV</li> <li>- Board Member of Marreyt International BV</li> <li>- - Board member, acting through Marreyt International BV, of Marreyt Classics BV</li> </ul>	<ul style="list-style-type: none"> <li>- Board member, acting through AS Partners BV, of FIT Franchise NV</li> <li>- Board member of Fitclass België VZW</li> <li>- Board member of Officenter Immo NV</li> <li>- Board member, acting through AS Partners BV, of Faseas International SA</li> <li>- Board member, acting through AS Partners BV, of PiroPro NV,</li> <li>- Board member of Action Reaction NV</li> </ul>
<p>Mr. Stijn Van Rompay (executive director and CEO)</p>	<ul style="list-style-type: none"> <li>- Director of SVR Management BV</li> <li>- Director of SVR Invest BV</li> </ul>	<ul style="list-style-type: none"> <li>- CEO and board member of Alter Pharma NV (until 10 January 2019) and a number of its subsidiaries (until February 2020)</li> </ul>

	<ul style="list-style-type: none"> <li>- Board member, acting through SVR Management BV, of Alter Pharma Group NV</li> <li>- Director of PE Group NV</li> <li>- Director, acting through SVR Invest, of Imcyse NV</li> <li>- Director of Exo Biologics NV</li> <li>- Managing representative in the civil-law partnership Uteron Pharma Invest</li> <li>- Director of Arcae NV</li> <li>- Director, through SVR Invest BV, of Silverline Properties BV</li> <li>- Director of Biogenesis NV</li> <li>- Sole managing partner of the civil-law partnership Burgerlijke Maatschap Eden</li> <li>- Board observer of Artic Fox Biomedical Inc.</li> <li>- Director of J.D.P. consult NV</li> <li>- Director of Acure Pharma</li> <li>- Director of Coalesce</li> <li>- Director representing SVR Invest BV, of Labo Phytophar NV</li> </ul>	<ul style="list-style-type: none"> <li>- Director of Dance Hold NV until May 2019</li> <li>- Managing director of Phytoscience NV until 30 October 2019</li> <li>- Co-managing representative in the civil-law partnership Uteron Pharma Participationsl until 17 May 2019</li> <li>- Director, acting through SVR Invest BV, of Novalon NV until 12 February 2016</li> </ul>
<p>Mr. Thomas Jacobsen (executive director)</p>	<ul style="list-style-type: none"> <li>- Director of TGJ Holding ApS</li> <li>- Director of Jacobsen Management BV</li> <li>- Director of GRNR Invest BV</li> </ul>	<ul style="list-style-type: none"> <li>- VP Business Development and board member, acting through GRNR Invest BV, of Alter Pharma NV (and its subsidiaries)</li> </ul>

	<ul style="list-style-type: none"> <li>- VP Business Development and board member, acting through Jacobsen Management BV, of the Alter Pharma Group</li> </ul>	
Mr. Leon Van Rompay (non-executive director)	<ul style="list-style-type: none"> <li>- Director of Van Rompay Management BV</li> <li>- Vice-president of the Belgian Association of Parallel Importers and Exporters</li> <li>- Director of J.D.P. consult NV</li> <li>- Managing representative in the civil-law partnership Uteron Pharma Invest</li> <li>- Director of PE Group NV</li> </ul>	N/A
Mr. Marc Foidart (independent director)	<ul style="list-style-type: none"> <li>- COO of Noshaq SA</li> <li>- Executive Chairman of Eyed Pharma SA</li> <li>- Chairman of UniD Manufacturing SA</li> <li>- Managing director of Ousia SRL</li> <li>- Managing director of Ousia Operations SRL</li> <li>- Board member of Pierre et Nature S.à r.l.</li> <li>- Board member and CEO, acting through Noshaq SA, of Noshaq Spin-Off SA</li> </ul>	<ul style="list-style-type: none"> <li>- Board member, acting through Noshaq SA, of Imcyse SA (until March 2020)</li> <li>- Board member, acting through Noshaq SA, of Biotech Coaching SA (until 21 May 2020)</li> <li>- Board member, acting through Meusinvest SA (now Noshaq SA), of Asit Biotech SA (until 17 September 2018)</li> <li>- Board member, acting through Meusinvest SA (now Noshaq SA), of Gesval SA (until 25 June 2019)</li> <li>- Board member, acting through Meusinvest SA (now Noshaq</li> </ul>

	<ul style="list-style-type: none"> <li>- Board member and CEO, acting through Noshaq SA, of Bridge To Health (B2H) SA</li> <li>- Board member, acting through Noshaq SA, of Accessia Pharma SA</li> <li>- Board member, acting through Noshaq SA, of Wishbone SA</li> <li>- Board member, acting through Noshaq SA, of Eklo ASBL</li> <li>- Board member of Science Park Services SA</li> <li>- Board member, acting through Noshaq SA, of Diagenode SA</li> <li>- Board member, acting through Noshaq SA, of Noshaq Venture SA</li> <li>- Board member, acting through Ousia Operations SRL, of Noshaq Immo SA</li> <li>- Board member, acting through Ousia Operations SRL, of Hi Tech Invest SA</li> <li>- Board member, acting through Ousia Operations SRL, of SGFIL SA</li> <li>- Board member, acting through Ousia Operations SRL, of Smart Industry Booster SA</li> </ul>	<ul style="list-style-type: none"> <li>SA), of Biosourcing SA (until 1 March 2020)</li> <li>- Board member, acting through Meusinvest SA (now Noshaq SA), of Amos SA (until 1 May 2019)</li> <li>- Board member, acting through Meusinvest SA (now Noshaq SA), of Spacebel SA (until 21 September 2019)</li> <li>- Board member, acting through Noshaq SA, of Magnisense S.à r.l. (until 1 March 2020)</li> <li>- Board member, acting through Noshaq SA, of Samtech SA (until 28 February 2019)</li> </ul>
<p>Ms. Carolyn Myers (independent director)</p>	<ul style="list-style-type: none"> <li>- President of BioEnsemble Ltd.</li> <li>- Executive Director of Urigen Pharmaceuticals Inc.</li> </ul>	<ul style="list-style-type: none"> <li>- Vice President, Global Alliance Management &amp; Business Development of</li> </ul>

	<ul style="list-style-type: none"> <li>- Director of the Interstitial Cystitis Association</li> </ul>	Allergan PLC (until 31 March 2017)
Mr. James Gale (independent director)	<ul style="list-style-type: none"> <li>- Managing Director of Signet Healthcare Partners</li> <li>- Chairman of Teligent Inc.</li> <li>- Chairman of Alpex Pharma</li> <li>- Chairman of Bionpharma Inc.</li> <li>- Chairman of Knight Therapeutics</li> <li>- Director of Pharmaceutics International</li> <li>- Director of RK Pharma</li> <li>- Director of Leon Nanodrugs GmbH</li> <li>- Director of Chr Olesen Synthesis A/S</li> <li>- Director of CoreRx</li> <li>- Director of Advantice Health</li> <li>- Director of Spepharm BV</li> </ul>	<ul style="list-style-type: none"> <li>- Director of Sancilio Pharmaceuticals (until 4 June 2018)</li> <li>-</li> </ul>
Ms. Astrid Heiremans (Acting CFO)	<ul style="list-style-type: none"> <li>- Director of FinFactory BV</li> <li>- Non-executive independent director and chairman of the audit committee of House of HR NV</li> <li>- Non-executive director of Novotan NV</li> <li>- Non-executive director of Cratus Invest NV</li> </ul>	<ul style="list-style-type: none"> <li>- CFO/COO of Soficotex NV, initially as employee and thereafter acting through FinFactory BV (until 15 December 2017)</li> <li>- Non-executive director of Perfect Print Invest NV (until 17 December 2015)</li> </ul>

		- Non-executive director of Cross Invest NV (until 16 February 2017)
Mr. Koenraad Van der Elst (CLO)	- Director of Herault BV - Director of HILKKA BV	- General Counsel and member of the Executive Committee of Nikon Metrology NV (until December 2019)  - Director (as representative of PMV – TINA Fund) of High Wind NV (until December 2019)  - Liquidator of Garda srl (Italian subsidiary of Nikon Metrology NV) (until 31 May 2020)
Mr. Edward Maloney (CBDO)	- Director of Humara Kinetics LLC	- President Oversee U.S. Operations at Milla Pharmaceuticals Inc. (subsidiary of the Alter Pharma Group <sup>195</sup> ) (until 31 May 2020)
Mr. Maurizio Passanisi (CCLO until 3 July 2020) <sup>196</sup>	N/A	N/A

<sup>195</sup> The Alter Pharma group is a related party (see also Section 12 (Related Party Transactions)).

<sup>196</sup> As Mr. Passanisi (CCLO of the Issuer) will leave the Company shortly after the Offering, he is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

## 11 SIGNIFICANT SHAREHOLDERS

The following table presents the ownership of the Shares immediately (i) prior to the closing of the Offering; (ii) after the closing of the Offering and listing of the Shares, assuming the placement of all of the 5,000,000 initially offered New Shares (*i.e.*, excluding the exercise, in part or in full, of the Increase Option); (iii) after the closing of the Offering and listing of the Shares, assuming the placement of the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option); (iv) after the closing of the Offering and listing of the Shares, assuming the placement of the maximum number of New Shares and exercise in full by the Stabilization Manager of the Over-allotment Option; and (v) immediately after the closing of the Offering and listing of the Shares, assuming the placement of the maximum number of New Shares and exercise in full by the Stabilization Manager of the Over-allotment Option, on a fully diluted basis. See the notes to the table below for more information. Furthermore, an assumption has been made that all Pre-commitments are allocated to the Participating Investors in full.

Except for the Pre-commitments of the Participating Investors (see Section 14.3 (Pre-commitments)), the Issuer has not received any indication from existing shareholders, members of the Board of Directors or Executive Management that such persons have the intention to subscribe for the Offering (see Section 14.4 (Intentions of the Shareholders, members of the Board of Directors and of the Executive Management of the Issuer)). Hence, an assumption has been made that the existing Shareholders will not participate in the Offering in addition to the Pre-commitments.

The persons holding less than 3%<sup>197</sup> of the outstanding Shares prior to the closing of the Offering and listing of the Shares and who will not hold 3% or more of the Shares following closing of the Offering and listing of the Shares pursuant to Pre-commitments and/or conversion of Convertible Bonds have been presented together under “other”.

Significant shareholder		Before the closing of the Offering <sup>(1)</sup>		On an undiluted basis, assuming placement of all of the 5,000,000 initially offered New Shares <sup>(2)</sup>		On an undiluted basis, assuming full placement of the New Shares <sup>(3)</sup>		On an undiluted basis, assuming full placement of the New Shares and an exercise in full of the Over-allotment Option <sup>(4)</sup>		On a fully diluted basis <sup>(5)</sup>	
				Number	%	Number	%	Number	%	Number	%
Mr. Stijn Van Rompay <sup>(6)</sup>	Existing Shares	6,438,064	36.17%	6,438,064	25.92%	6,438,064	25.16%	6,438,064	24.34%	6,438,064	23.00%
	Pre-commitment <sup>(8)</sup>	-	-	139,534	0.56%	139,534	0.55%	139,534	0.53%	139,534	0.50%

<sup>197</sup> The Issuer has introduced additional disclosure thresholds of 3% and 7.5% in its Articles of Association.

	Conversion of Convertible Bonds	-	-	134,240	0.54%	134,240	0.52%	134,240	0.51%	134,240	0.48%
	Exercise of Transaction Warrants	-	-	-	-	-	-	-	-	852,096	3.04%
	Exercise of ESOP Warrants	-	-	-	-	-	-	-	-	68,000	0.24%
	<b>Subtotal</b>	<b>6,438,064</b>	<b>36.17%</b>	<b>6,711,838</b>	<b>27.02%</b>	<b>6,711,838</b>	<b>26.23%</b>	<b>6,711,838</b>	<b>25.37%</b>	<b>7,631,934</b>	<b>27.27%</b>
Mr. Thomas Jacobsen <sup>(7)</sup>	Existing Shares	3,437,760	19.31%	3,437,760	13.84%	3,437,760	13.43%	3,437,760	12.99%	3,437,760	12.28%
	Exercise of Transaction Warrants	-	-	-	-	-	-	-	-	163,512	0.58%
	<b>Subtotal</b>	<b>3,437,760</b>	<b>19.31%</b>	<b>3,437,760</b>	<b>13.84%</b>	<b>3,437,760</b>	<b>13.43%</b>	<b>3,437,760</b>	<b>12.99%</b>	<b>3,601,272</b>	<b>12.87%</b>
Mr. Nick Reunbrouck	Existing Shares	1,610,184	9.05%	1,610,184	6.48%	1,610,184	6.29%	1,610,184	6.09%	1,610,184	5.75%
	<b>Subtotal</b>	<b>1,610,184</b>	<b>9.05%</b>	<b>1,610,184</b>	<b>6.48%</b>	<b>1,610,184</b>	<b>6.29%</b>	<b>1,610,184</b>	<b>6.09%</b>	<b>1,610,184</b>	<b>5.75%</b>
Mr. Pieter Van Rompay	Existing Shares	915,000	5.14%	915,000	3.68%	915,000	3.58%	915,000	3.46%	915,000	3.27%
	Exercise of Transaction Warrants	-	-	-	-	-	-	-	-	60,244	0.22%
	<b>Subtotal</b>	<b>915,000</b>	<b>5.14%</b>	<b>915,000</b>	<b>3.68%</b>	<b>915,000</b>	<b>3.58%</b>	<b>915,000</b>	<b>3.46%</b>	<b>975,244</b>	<b>3.48%</b>
Scorpiaux SRL	Pre-commitment <sup>(8)</sup>	-	-	558,139	2.25%	558,139	2.18%	558,139	2.11%	558,139	1.99%
	Conversion of Convertible Bonds	-	-	539,600	2.17%	539,600	2.11%	539,600	2.04%	539,600	1.93%
	<b>Subtotal</b>	<b>0</b>	<b>0.00%</b>	<b>1,097,739</b>	<b>4.42%</b>	<b>1,097,739</b>	<b>4.29%</b>	<b>1,097,739</b>	<b>4.15%</b>	<b>1,097,739</b>	<b>3.92%</b>
Saffelberg Investments SA	Existing Shares	361,764	2.03%	361,764	1.46%	361,764	1.41%	361,764	1.37%	361,764	1.29%
	Pre-commitment <sup>(8)</sup>	-	-	223,255	0.90%	223,255	0.87%	223,255	0.84%	223,255	0.80%
	Conversion of Convertible Bonds	-	-	215,840	0.87%	215,840	0.84%	215,840	0.82%	215,840	0.77%
	<b>Subtotal</b>	<b>361,764</b>	<b>2.03%</b>	<b>800,859</b>	<b>3.22%</b>	<b>800,859</b>	<b>3.13%</b>	<b>800,859</b>	<b>3.03%</b>	<b>800,859</b>	<b>2.86%</b>
Other	Existing Shares	5,038,996	28.31%	5,038,996	20.28%	5,038,996	19.69%	5,038,996	19.05%	5,038,996	18.00%
	New Shares (including Pre-commitments <sup>(8)</sup> )	-	-	4,079,072	16.42%	4,829,072	18.87%	5,691,572	21.51%	5,691,572	20.34%
	Conversion of Convertible Bonds	-	-	1,151,184	4.63%	1,151,184	4.50%	1,151,184	4.35%	1,151,184	4.11%
	Exercise of Transaction Warrants	-	-	-	-	-	-	-	-	124,148	0.44%
	Exercise of ESOP Warrants	-	-	-	-	-	-	-	-	265,000	0.95%
	<b>Subtotal</b>	<b>5,038,996</b>	<b>28.31%</b>	<b>10,269,252</b>	<b>41.34%</b>	<b>11,019,252</b>	<b>43.06%</b>	<b>11,881,752</b>	<b>44.91%</b>	<b>12,270,900</b>	<b>43.84%</b>
Total		17,801,768	100.0%	24,842,632	100.0%	25,592,632	100.0%	26,455,132	100.0%	27,988,132	100.0%

**Notes:**

- (1) It is assumed that (a) none of the outstanding Convertible Bonds have been converted into new Shares, and (b) none of the Adjustment Warrants, Anti-dilution Warrants, Transaction Warrants and ESOP Warrants have been exercised.
- (2) It is assumed that (a) all 5,000,000 initially offered New Shares are placed in the Offering (excluding the exercise in full or in part of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal

amount as per the expected Closing Date, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), and (c) none of the Transaction Warrants and ESOP Warrants have been exercised.

- (3) It is assumed that (a) the maximum number of New Shares is placed in the Offering (including as a result of the exercise in full of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal amount, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), and (c) none of the Transaction Warrants and ESOP Warrants have been exercised.
- (4) It is assumed that (a) the maximum number of New Shares is placed in the Offering (including as a result of the exercise in full of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal amount, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), (c) the Stabilization Manager exercises its Over-allotment Option in full, and (d) none of the Transaction Warrants and ESOP Warrants have been exercised.
- (5) It is assumed that (a) the maximum number of New Shares is placed in the Offering (including as a result of the exercise in full of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal amount, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), (c) the Stabilization Manager exercises its Over-allotment Option in full, and (d) all of the Transaction Warrants and all of the ESOP Warrants have been exercised.
- (6) Abstraction is made of the Call Option, pursuant to which Mr. Stijn Van Rompay may become entitled to acquire from other shareholders (who are included in the "other" group) 132,619 Shares, i.e., 0.5% of the Shares outstanding immediately after the closing of the Offering and listing of the Shares assuming a full placement of the maximum number of New Shares (i.e., including the exercise in full of the Increase Option) and exercise in full by the Stabilization Manager of the Over-allotment Option on a fully diluted basis. For more information regarding the Call Option, see section 13.5.1 (Call Option on existing Shares).
- (7) Abstraction is made of the Call Option, pursuant to which Mr. Thomas Jacobsen may become entitled to acquire from other shareholders (who are included in the "other" group) 66,329 Shares, i.e., 0.25% of the Shares outstanding immediately after the closing of the Offering and listing of the Shares assuming a full placement of the maximum number of New Shares (i.e., including the exercise in full of the Increase Option) and exercise in full by the Stabilization Manager of the Over-allotment Option on a fully diluted basis. For more information regarding the Call Option, see section 13.5.1 (Call Option on existing Shares).
- (8) Assuming the total amount of the Pre-commitment is not reduced but allocated entirely,

Each Share entitles its holder to one vote, except in the cases of suspension of the voting right provided for by law. For further details of the Issuer's share capital as well as outstanding Share options and the Convertible Bonds, reference is made to Section 13 (Share capital and Articles of Association). As of the date of this Prospectus, all of the shareholders, and most of the existing security holders of the Issuer and the Issuer itself have entered into the Shareholders' Agreement, containing, amongst other things, terms regarding the Issuer's governance, as well as transfer restrictions regarding the Issuer's securities. The Shareholders' Agreement was entered into by certain existing security holders of the Issuer on 10 March 2020 and replaces a previous shareholders' agreement that had been entered into on 31 May 2018. The Shareholders' Agreement was entered into for an initial term of ten years, but will be terminated as of the closing of the Offering, save for a post-IPO lock-up arrangement between the current Shareholders as described in Section 15.3.2 (Conventional post-IPO lock-up) of this Prospectus. The Issuer is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described in Section 15.3 (Lock-up)).

As of the date of this Prospectus, the Issuer is not being controlled in the sense of Article 1:14 CCA.

## **12 RELATED PARTY TRANSACTIONS**

As part of its business, the Issuer has entered into several transactions with related parties, including its significant shareholders. The Company reasonably believes that all related party transactions have been concluded and executed at arm's length. The following is a summary of the Issuer's most significant transactions with related parties for the period covered by the historical financial information and as of the date hereof. For further detail on related party transactions, see Note 27 to the Annual Financial Statements and Note 18 of the Interim Financial Statements.

### **12.1 SHAREHOLDERS' AGREEMENT**

As of the date of this Prospectus, most of the existing security holders of the Issuer and the Issuer itself have entered into the Shareholders' Agreement, containing, amongst other things, terms regarding the Issuer's governance, as well as transfer restrictions regarding the Issuer's securities. The Shareholders' Agreement was entered into on 10 March 2020 and replaces a previous shareholders' agreement that had been entered into on 31 May 2018. The Shareholders' Agreement was entered into for an initial term of ten years, but will be terminated as of the closing of the Offering, save for a post-IPO lock-up arrangement between the current Shareholders as described in Section 15.3.2 (Conventional post-IPO lock-up) of this Prospectus. The Issuer is not aware of shareholders entering into a new shareholders' agreement or agreeing to act in concert following the closing of the Offering (other than certain lock up arrangements as described in Section 15.3 (Lock-up)).

### **12.2 RELATED PARTY LOANS**

- On 28 June 2019, the Issuer and Mr. Stijn Van Rompay (CEO of the Issuer) entered into a loan agreement pursuant to which Mr. Stijn Van Rompay lent the Issuer USD 2,100,000 and EUR 8,500,000. As of the date of this Prospectus, USD 2,100,000 and EUR 2,719,494.31 in principal are still outstanding under this loan agreement. The loan is unsecured and bears an interest of 4% per annum, payable when the principal is due. On 3 June 2020 it was specified and agreed that the Issuer will repay the outstanding amounts under this loan agreement on the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.
- On 28 June 2019, the Issuer and Mr. Pieter Van Rompay (sibling of Mr. Stijn Van Rompay) entered into a loan agreement pursuant to which Mr. Pieter Van Rompay lent the Issuer USD 1,100,000 and EUR 500,000. As of the date of this Prospectus, USD 1,100,000 in principal is still outstanding under this loan agreement. The loan is unsecured and bears an interest of 4% per annum, payable when the principal is due. On 3 June 2020 it was specified and agreed that the Issuer will repay the outstanding amounts under this loan agreement on the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.
- On 28 June 2019, the Issuer and GRNR Invest BV (an entity controlled by Mr. Thomas Jacobsen, executive director of the Issuer) entered into a loan agreement pursuant to which GRNR Invest BV lent the Issuer EUR 1,400,000, which was increased later up to a maximum amount in principal of EUR 1,875,000. As of the date of this Prospectus, EUR 1,125,000 in

principal is still outstanding under this loan agreement. The loan is unsecured and bears an interest of 4% per annum, payable at the same time as the principal is due. On 3 June 2020 it was specified and agreed that the Issuer will repay the outstanding amounts under this loan agreement on the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.

- On 31 December 2019, various amounts were lent by Mr. Stijn Van Rompay and his spouse, for an aggregate principal amount of 200,000. As of the date of this Prospectus, EUR 200,000 in principal is still outstanding under this loan agreement. On 3 June 2020 it was specified and agreed that the Issuer will repay the outstanding amounts under this loan agreement on the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.
- On 31 March 2020, an amount was lent by Ms. Van Rompay-Delimon to the Issuer for an aggregate principal amount of EUR 750,000. As of the date of this Prospectus, EUR 250,000 in principal is still outstanding under this loan agreement. The loan is unsecured and bears an interest of 4% per annum, payable at the same time as the principal is due. On 3 June 2020 it was specified and agreed that the Issuer will repay the outstanding amounts under this loan agreement on the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.

### **12.3 RTU PHARMA ACQUISITION**

On 17 September 2018, the Issuer and Mr. Stijn Van Rompay (holding 66% of the shares in RTU Pharma), Mr. Thomas Jacobsen (holding 33% of the shares in RTU Pharma) and Mr. Ivo Peeters (CFO of Hyloris at that time, holding 1% of the shares in RTU Pharma) entered into a share sale and purchase agreement relating to the acquisition by the Issuer of all shares in RTU Pharma SA. In consideration of the shares in RTU Pharma SA, the Issuer paid a purchase price of EUR 200,000 in the aggregate.

### **12.4 DERMAX ACQUISITION**

In December 2019, the Issuer and Mr. Nick Reunbrouck (Mr. Stijn Van Rompay's brother-in-law), Mr. Stijn Van Rompay, Mr. Thomas Jacobsen, Mr. Maurizio Passanisi (CCLO of the Issuer until 3 July 2020<sup>198</sup>), Mr. Edward Maloney (CBDO of the Issuer) and Ms. Joann Maloney (Mr. Edward Maloney's spouse), and other shareholders of Dermax (which weren't related parties at that time), entered into a subscription agreement (in the presence of Dermax) relating to (i) the contribution in kind by the aforementioned persons (being the shareholders of Dermax at that time) of all the shares in Dermax into the capital of the Issuer and (ii), in consideration thereof, the issue of a total of 855,409 new Shares to such persons. For purposes of the capital increase of the Issuer through contribution in kind of the shares issued by Dermax, the contributed shares were attributed an aggregate value of EUR 18,259,783, resulting in a price per Share of EUR 21.35. The price for the shares in Dermax was determined on the basis of a valuation of Dermax based on a discounted cashflow analysis, adjusted by a probability factor specific for

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<sup>198</sup> As Mr. Passanisi will leave the Company shortly after the Offering, he is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

each product, and reduced with the forecasted net debt of Dermax. In the valuation, expected synergies between Dermax and the other entities of the Hyloris group were also taken into account. The valuation of the Issuer that was used to determine the number of new Shares that were issued to the former Dermax shareholders was based on a weighted average of a discounted cashflow valuation and an EBITDA multiple (reduced with net debt), as agreed between the Issuer and the former shareholders of Dermax. The transaction was completed and new Shares of the Issuer were issued on 31 December 2019. Immediately following the completion of the Dermax acquisition the Company was valued at EUR 95 million.

In addition to the Lock-up set out under Section 15.3 (Lock up), these shareholders will, pursuant to Article 11 of the Royal Decree of 17 May 2007 regarding primary market practices (*“Arrêté royal du 17 mai 2007 relatif aux pratiques de marché primaire”*), be under a legal lock-up obligation in respect of the new Shares so acquired. Depending on the difference between the issue price of these new Shares (EUR 21.35) and the final Offer Price, this legal lock-up obligation will be more or less stringent. In principle, this legal lock-up obligation will apply to all of these new Shares, for a duration of one year. In the event the price difference would be less than 30%, the duration of the legal lock-up obligation will, at the option of the shareholder, be: (i) six months for all of these new Shares; (ii) nine months for two thirds of these new Shares or (iii) 12 months for one third of these new Shares). All concerned shareholders have indicated to the Issuer that, if applicable, they will opt for the six months lock up for all of these new Shares.

## **12.5 EMPLOYMENT SERVICES AGREEMENTS**

- The Issuer and SVR Management BV have entered into a services agreement effective as from 1 September 2019, pursuant to which the latter must provide services to the Issuer on a self-employed basis as CEO of the Issuer, for an indefinite term. In performing the services, SVR Management BV must be permanently represented by Mr. Stijn Van Rompay. In consideration of the services, the Issuer must pay to SVR Management BV a monthly service fee of EUR 12,000 (excl. VAT) which will be increased to EUR 15,000 (excl. VAT) following the completion of the Offering. The service provider is also entitled to a yearly target variable bonus of up to EUR 30,000 (excl. VAT) based on an agreed set of performance targets as evaluated by the Issuer. The Issuer must pay a fixed one-time bonus of EUR 25,000 (excl. VAT) to the service provider if the Issuer *“is successfully introduced on the Euronext Stock Exchange during 2020”*. The total remuneration is subject to a yearly review and may be adjusted by the Issuer. The service agreement further provides that the service provider may from time to time be eligible for and participate in incentive plans. See also Section 10.5.3.3 (Payments upon Termination) for more information on the payments and other obligations upon termination of the services agreement with SVR Management BV.
- The Issuer and Jacobsen Management BV have entered into a services agreement effective as from 1 November 2019, pursuant to which the latter must provide services to the Issuer on a self-employed basis as executive director of the Issuer, for an indefinite term. In performing the services, Jacobsen Management BV must be permanently represented by Mr. Thomas Jacobsen. In consideration of the services, the Issuer must pay to Jacobsen Management BV a monthly service fee of EUR 6,000 (excl. VAT) which will be increased to EUR 7,500 (excl.

VAT) following the completion of the Offering. The service provider is also entitled to a yearly target variable bonus of up to EUR 15,000 (excl. VAT) based on an agreed set of performance targets as evaluated by the Issuer. The Issuer must pay a fixed one-time bonus of EUR 12,500 (excl. VAT) to the service provider if the Issuer “*is successfully introduced on the Euronext Stock Exchange during 2020*”. The total remuneration is subject to a yearly review and may be adjusted by the Issuer. The service agreement further provides that the service provider may from time to time be eligible for and participate in incentive plans. See also Section 10.5.3.3 (Payments upon Termination) for more information on the payments and other obligations upon termination of the services agreement with Jacobsen Management BV.

- The Issuer and Herauld BV entered into a services agreement effective as from 1 January 2020, pursuant to which the latter must provide services to the Issuer on a self-employed basis as Chief Legal Officer of the Issuer, for an indefinite term. In performing the services, Herauld BV must be permanently represented by Mr. Koenraad Van der Elst. In consideration of the services, the Issuer must pay to Herauld BV a monthly service fee of EUR 15,000 (excl. VAT). The service provider is also entitled to a yearly target variable bonus of up to EUR 15,000 (excl. VAT) based on an agreed set of performance targets as evaluated by the Issuer. The total remuneration is subject to a yearly review and may be adjusted by the Issuer. The service agreement further provides that the service provider may from time to time be eligible for and participate in incentive plans. See also Section 10.5.3.3 (Payments upon Termination) for more information on the payments upon termination of the services agreement with Herauld BV.
- The Issuer and PaJe SRL have entered into a services agreement effective as from 23 April 2020, pursuant to which the latter must provide services to the Issuer on a self-employed basis as Chief Financial Officer of the Issuer, for an indefinite term. In performing the services, PaJe SRL must be permanently represented by Mr. Patrick Jeanmart. In consideration of the services, the Issuer must pay to PaJe SRL a monthly service fee of EUR 15,500 (excl. VAT). The service provider is also entitled to a yearly target variable bonus, no amount being specified, based on an agreed set of performance targets as evaluated by the Issuer. See also Section 10.5.3.3 (Payments upon Termination) for more information on the payments upon termination of the services agreement with PaJe SRL. On 15 June 2020, Mr. Patrick Jeanmart (acting through PaJe SRL), CFO of the Issuer at that time, in common agreement resigned as CFO due to personal circumstances. This services agreement has thus been terminated as of 15 June 2020.
- On 29 January 2015, Hyloris Developments and Mr. Maurizio Passanisi CCLO of the Issuer until 3 July 2020<sup>199</sup>) entered into a full-time employment agreement for an indefinite term. Mr. Maurizio Passanisi serves as CCLO of Hyloris and is responsible for R&D and pharmacovigilance. He is entitled to a monthly salary of EUR 5,400 and certain fringe benefits. The employment agreement with Mr. Maurizio Passanisi has been entered into between Mr. Maurizio Passanisi and the Issuer on 26 June 2015, for an indefinite period. The agreement is governed by standard termination provisions under Belgian employment law (e.g., 38 hours per week, 20 days of annual leave, confidentiality clause, etc). In the event of termination of the

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<sup>199</sup> As Mr. Passanisi will leave the Company shortly after the Offering, he is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

employment agreement, the agreement provides for a non-compete period of 12 months after termination, against a payment of nine months gross salary. No non-compete indemnity will be payable in the event of termination by the Issuer for a serious breach of contract by Mr. Maurizio Passanisi and in the event of termination by him for other reasons than a serious breach of contract by the Issuer.

- Since 2012, Humara Kinetics LLC provides services to the Issuer on the basis of a services agreement, on a self-employed basis as Chief Business Development Officer of the Issuer, mainly concerning business development opportunities. In performing the services, Humara Kinetics LLC is primarily represented by Mr. Edward Maloney. The services agreement has since been amended with an effective date as of 1 January 2020. In consideration of the services, the Issuer must pay a monthly service fee of USD 10,000 (excl. VAT) to Humara Kinetics LCC. See also Section 10.5.3.3 (Payments upon Termination) for more information on the payments and other obligations upon termination of the services agreement with Humara Kinetics LLC.
- The Issuer and FinFactory BV entered into a services agreement effective as from 15 June 2020, pursuant to which the latter must provide services to the Issuer on a self-employed basis as interim Chief Financial Officer of the Issuer, for a fixed term of three months and after that automatically renewed for an indefinite term. In performing the services, FinFactory BV must be permanently represented by Ms. Astrid Heiremans. In consideration of the services, the Issuer must pay to FinFactory BV a daily service fee of EUR 850 (excl. VAT). See also Section 10.5.3.3 (Payments upon Termination) for more information on the payments upon termination of the services agreement with FinFactory BV.
- For more information on the remuneration of the directors of the Company, reference is made to Section 10.5.2 (Directors).

## 12.6 BUSINESS AGREEMENTS

As stated in Risk Factor 2.1.4.1, Hyloris' CEO, Mr. Stijn Van Rompay, and board member and executive director, Mr. Thomas Jacobsen, have material ownership interests in the Alter Pharma group (owning 21.8% and 5%, respectively as well as < 0.01% each, indirectly, through civil-law partnership Burgerlijke Maatschap Eden<sup>200</sup>), from the subsidiaries of which Hyloris has licensed or acquired product development and marketing rights, *i.e.*, Generic Specialty Pharma (GSP), Nordic Specialty Pharma (NSP), Stasisport Pharma and Neogen Developments (Neogen). Mr Thomas Jacobsen also holds an executive position in the Alter Pharma group (see Section 10.7.3 (Other Mandates)). Most of the agreements described in this Section 12.6 (Business Agreements) therefore relate to agreements entered into with subsidiaries of the Alter Pharma group.

- On 22 May 2012, Hyloris Pharmaceuticals and Neogen Developments (Neogen) (a subsidiary of the Alter Pharma group) signed a "Patent and know-how license agreement", pursuant to

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<sup>200</sup> Mr. Stijn Van Rompay is also the managing partner of civil-law partnership Burgerlijke Maatschap Eden, with the power and duty to, amongst other things, administer the partnership and exercise the rights attached to the shares in the Alter Pharma group held by the partnership, in accordance with the terms and conditions of the partnership agreement. If Mr. Stijn Van Rompay no longer fulfil this mandate, Mr. Thomas Jacobsen will succeed him as managing partner of the partnership.

which Neogen granted to Hyloris Pharmaceuticals a worldwide, exclusive, irrevocable and sub-licensable license to manufacture, have manufactured, use, import, supply, sell or otherwise commercialize any pharmaceutical product containing paracetamol and ibuprofen in approximately a 3.3:1 ratio in all appropriate dosages and in a formulation appropriate and intended for intravenous delivery and related patents. For more information regarding this agreement, reference is made to Section 8.12.6.1 (Neogen Developments – Patent know-how and license agreement).

- Hyloris Pharmaceuticals has subcontracted certain parts of the development work (such as hereunder formulation, submission batches, stability and process validation) under the development and collaboration agreement with AFT Pharmaceuticals relating to Maxigesic® IV (as described in Section 8.12.6.2 (AFT Pharmaceuticals – Development collaboration agreement)) to Neogen Developments. This subcontract started on 2012 and is still in force. As of the date of this Prospectus a total amount of EUR 580,000 has been paid by Hyloris Pharmaceuticals to Neogen Developments under this subcontract. For more information regarding this agreement, reference is made to Section 8.12.6.2 (Neogen Developments – Development subcontract).
- On 25 August 2017, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group) entered into an Asset purchase and development agreement with Hyloris Developments, pursuant to which GSP assigned and transferred to Hyloris Developments all (intellectual property) rights, title and interests in the product HY-REF-028, the development of which has since been put on hold because Hyloris ultimately decided to focus on its other product candidates as these showed higher potential, it being understood that Hyloris may restart the project at a later stage. The purchase price that had to be paid by Hyloris consisted of a fixed price of EUR 2,800,000 and a variable price (due on a yearly basis) between 15% and 35% of the net margin derived from the product (*i.e.* of the total turnover derived from the (worldwide) sales of the product as invoiced by Hyloris, minus a fixed percentage of 40% for marketing and distribution costs), depending on the volume of the total net margin that year. Further, in the event the total net margin would have reached or exceeded EUR 20,000,000, a (first) additional “milestone payment” of EUR 500,000 would have been due. In the event the net margin would have reached or exceed EUR 30,000,000, a second additional “milestone payment” of EUR 500,000 would subsequently have been due. However, in the event the product would not have been granted “orphan drug designation” and adequate patent protection, the variable price would only have amounted to 12.5% to the extent the net margin did not exceed EUR 2,500,000 and the “milestone payments” would have been reduced by 50%. Before any variable payment would have been made, Hyloris would have been able to deduct the cost for its key-investments made for the product development, increased with EUR 1 million.
- On 28 February 2018, Hyloris Developments and Dermax (*i.e.*, before Dermax was acquired on 31 December 2019 by Hyloris Pharmaceuticals<sup>201</sup>) signed an “Asset Purchase Agreement” whereby Hyloris Developments transferred and assigned to Dermax all of its (intellectual property) rights and interests relating to HY-EMP-016. For more information regarding this

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<sup>201</sup> In December 2019, the Issuer has acquired all shares in Dermax (see Section 12.4 (Dermax Acquisition)).

agreement, reference is made to Section 8.12.13.1 (Hyloris Developments - Asset Purchase Agreement). Due to the acquisition of Dermax by Hyloris Pharmaceuticals, Hyloris reobtained the rights relating to HY-EMP-016.

- On 21 December 2018, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group) entered into an Asset purchase and development agreement with Hyloris Developments, pursuant to which GSP assigned and transferred to Hyloris Developments all (intellectual property) rights, title and interests in a product that has since been discontinued. The parties agreed that GSP would further develop the (patentable) product, would be responsible for the patent application (which would however be filed in the name of Hyloris) and for the submission of the NDA with the FDA (in relation to which any due fees are to be paid by Hyloris). The intellectual property rights developed during the cited development services are also assigned to Hyloris. In consideration of all assigned assets, Hyloris had to pay a fixed price of EUR 500,000 (of which EUR 350,000 has already been paid) and a variable price (due on a yearly basis) amounting to (i) 25% of the net margin (*i.e.*, of the total turnover derived from the (worldwide) sales of the product as invoiced by Hyloris, minus a fixed percentage of 40% for marketing and distribution costs), in the event the product is granted an “orphan drug designation”; or to (ii) 12.5% of the net margin if the product has not been granted such status. In the event the supply of the product would have been managed by GSP, GSP would have been entitled to take a 13% margin on the cost of goods, prior to the profit split. Hyloris would have been entitled to take over at any time supply of the product. Before any variable payment would have been made, Hyloris would have been able to deduct the cost for its key-investments as made for the product development, increased with EUR 1 million. In addition, in a “special agreement” with GSP, it had been agreed that (i) if the total development costs would have exceeded EUR 500,000, GSP would have been entitled to invoice these additional costs to Hyloris Developments; and that (ii) if Hyloris Developments would have no further interest in the development of the product, the parties would have to discuss in good faith the replacement thereof by another product and the fee already paid and the costs already incurred will be reallocated to such replacement product. Given the discontinuation of the product, negotiations are ongoing in order to have the agreement relate to a different product. The final product selection still has to be made. If a replacement product is found, the fee already paid and the costs already incurred will be reallocated to such replacement product. If no replacement product is found, the amounts can be set off against any other existing project between Hyloris Developments and GSP (or any of its affiliates).
- On 21 December 2018, Hyloris Developments and Nordic Specialty Pharma (NSP) (a subsidiary of the Alter Pharma group) entered into an “Asset Purchase and Development Agreement”, whereby NSP assigned to Hyloris Developments its rights and interests relating to the medicine HY-REF-075 for the United States market. For more information regarding this agreement, reference is made to Section 8.12.12 (HY-REF-075).
- On 13 February 2019, Mr. Thomas Jacobsen, amongst others, assigned his rights, title and interests to the invention HY-REF-028 (including the relevant patent application and all other related patent (applications)), the development of which has since been put on hold (see above),

to Hyloris Developments. The agreement stipulates that the transfer was made “for good and valuable consideration, the receipt and sufficiency of which is acknowledged”, without however specifying any amount. No amounts are due or no obligations/services are to be performed anymore by Hyloris under this agreement. Because Hyloris ultimately decided to focus on its other product candidates as these showed higher potential, this product candidate has since been put on hold, it being understood that Hyloris may restart the project at a later stage. Hyloris had also obtained a government grant in relation to the development of this product.

- On 6 March 2019, Mr. Thomas Jacobsen, among others, assigned his rights, title and interests to the invention HY-REF-004 (including the relevant patent application and all other related patent (applications)) to Hyloris Developments. The agreement stipulates that the transfer was made “for good and valuable consideration, the receipt and sufficiency of which is acknowledged”, without however specifying any amount. No amounts are due or no obligations/services are to be performed anymore by Hyloris under this agreement.
- On 29 April 2019, Mr. Thomas Jacobsen, among others, assigned their rights, title and interests to the invention Tranexamic Acid RTU (including patent application US2019216823A1 and all other related patent (applications)) to Hyloris Developments. The agreement stipulates that the transfer was made “for good and valuable consideration, the receipt and sufficiency of which is acknowledged”, without however specifying any amount. No amounts are due or no obligations/services are to be performed anymore by Hyloris under this agreement.
- On 8 June 2019, Stasisport Pharma (a subsidiary of the Alter Pharma group) entered into a License agreement with Dermax, pursuant to which it granted Dermax a personal, sub-licensable and exclusive right to use all available development data and registration documents concerning Fusidic Acid Cream, in order to obtain (one or multiple) marketing authorizations for Fusidic Acid Cream in Canada, and to subsequently market, sell and distribute Fusidic Acid Cream in that territory. For more information regarding this agreement, reference is made to Section 8.12.14 (Fusidic Acid Cream).
- On 28 June 2019, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group) entered into a “development agreement” with Dermax, pursuant to which GSP agreed to carry out all development activities required for (the acquisition/ registration of ANDA/NDA approval for) the product HY-REF-038. For more information regarding this agreement, reference is made to Section 8.12.9.1 (Generic Specialty Pharma - Development Agreement).
- On 2 February 2020, Dermax and Alter Pharma (a subsidiary of the Alter Pharma group) entered into an “Asset Purchase Agreement” whereby Dermax assigned to Alter Pharma all (intellectual property) rights, title and interest in the product HY-REF-038 in vial form. Dermax has retained the ownership of HY-REF-038 in the form of prefilled syringes and the Development Agreement with GSP (described in the preceding bullet point) was amended as to clarify that its scope is limited to the development of HY-REF-038 in the form of prefilled syringes. In consideration of the transferred intellectual property rights and of the reduction of the scope of the development work described in the development agreement, Dermax has received EUR 1,400,000. For more

information regarding this agreement, reference is made to Section 8.12.9.2 (Alter Pharma – Asset Purchase Agreement).

As on the date of this Prospectus, the following amounts are still due with respect to the business agreements with related parties as listed hereabove:

- HY-REF-075:
  - A last milestone payment for an amount of 100,000 EUR becomes due upon completion of the formulation;
  - Royalty payments will become due once commercialization will start (see section 8.12.12 (HY-REF-075)).
- Maxigesic® IV:
  - Royalty payments will become due once commercialization will start (see section 8.12.6(Maxigesic® IV)).

## **12.7 WARRANTS AND CONVERTIBLE BONDS**

- On 12 May 2017, the Issuer issued 300,000 Transaction Warrants. The Transaction Warrants have been granted free of charge. Initially all Transaction Warrants have been subscribed for by Mr. Stijn Van Rompay. Thereafter they have been transferred at multiple occasions to other persons such as members of Hyloris' personnel and investors in the Issuer. Reference is made to Section 13.4.1 (Transaction Warrants) for more information on the Transaction Warrants and to Section 10.2.5 (Shares, warrants, Convertible Bonds and options on Shares held by directors) and Section 10.4.1 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management of the Issuer) for an overview of the Transaction Warrants offered to, and subscribed for by, members of the Board of Directors, respectively, the Executive Management.
- On 31 December 2019, the Issuer approved, in principle, the issue of 90,825 ESOP Warrants, subject to the ESOP Warrants being offered to, and accepted by, the beneficiaries thereof, who must be employees, directors or consultants of the Issuer and/or its subsidiaries. As of the date of this Prospectus, following the Share Split, 333,000 ESOP Warrants are outstanding and will lapse at closing of the Offering<sup>202</sup>. The ESOP Warrants have been granted free of charge. Reference is made to Section 13.4.4 (ESOP Warrants) for more information on the ESOP Warrants, and to Section 10.2.5 (Shares, warrants, Convertible Bonds and options on Shares held by directors) and Section 10.4.1 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management of the Issuer) for an overview of the ESOP Warrants offered to, and subscribed for by, members of the Board of Directors, respectively the Executive Management.
- On 31 March 2020, the Issuer approved, in principle, the issue of up to 500 Convertible Bonds with a principal amount of EUR 50,000 each. 303 Convertible Bonds have been subscribed for,

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<sup>202</sup> The Board of Directors has decided that 5,000 of a total of 10,000 ESOP Warrants that are held by Mr. Antoine Carlhian (CFO of the Issuer until 30 April 2020) and all 10,000 ESOP Warrants that are held by Mr. Patrick Jeanmart (CFO of the Issuer until 15 June 2020), are vested under the terms of the ESOP warrant scheme. The remaining 5,000 ESOP Warrants held by Mr. Antoine Carlhian have lapsed.

while the remaining 197 Convertible Bonds have not been subscribed for and have lapsed. Reference is made to Section 13.6 (Convertible Bonds) for more information on the Convertible Bonds and to Section 10.2.5 (Shares, warrants, Convertible Bonds and options on Shares held by directors) and Section 10.4.5 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management of the Issuer) for an overview of the Convertible Bonds subscribed for by members of the Board of Directors, respectively the Executive Management.

## **13 SHARE CAPITAL AND ARTICLES OF ASSOCIATION**

### **13.1 GENERAL**

The Issuer has the legal form of a public limited liability company (“*société anonyme*” / “*naamloze vennootschap*”) organized under the laws of Belgium. The Issuer was established as a limited liability company (“*société à responsabilité limitée*”) organized under the laws of the Grand Duchy of Luxembourg with the name “Everbright s.à r.l.” in June 2012. Following the Belgian Seat Transfer, the Issuer was ultimately transformed into a public limited liability company (“*société anonyme*” / “*naamloze vennootschap*”) organized under the laws of Belgium.

Pursuant to the provisions of the Belgian Code of Companies and Associations, the liability of the shareholders of the Issuer is in principle limited to the amount of their respective committed contribution to the capital of the Issuer. The Issuer is registered with the Belgian legal entities register (Liège, division Liège) under enterprise number 0674.494.151, and has 875500LZIWS7QEQE0173 as Legal Entity Identifier (LEI).

This Section summarizes information relating to the Issuer's share capital, the Articles of Association, certain material rights of its shareholders under Belgian law and the Issuer's Articles of Association. The contents of this section are derived primarily from the Issuer's Articles of Association, which were adopted by the General Shareholders' Meeting of 8 June 2020, and which will enter into force subject to the completion of the Offering and, except as otherwise indicated, with effect as from the Listing Date.

The description provided hereafter is only a summary and does not purport to provide a complete overview of the Articles of Association or the relevant provisions of Belgian law. Neither should it be considered as legal advice regarding these matters.

### **13.2 CORPORATE PURPOSE**

The Issuer's purpose, both in Belgium and abroad, is to carry out all industrial or commercial operations relating to chemical, pharmaceutical, diet food and cosmetic products as well as products useful in the medical sector.

Its purpose is also to represent third parties in the sale of all kinds of materials, equipment and services, representation, purchase and sale, import and export, rental and installation of medical equipment, pacemakers, medical and paramedical equipment and all peripheral equipment and accessories, as well as their maintenance.

The operation, concession, purchase, exchange, sale and rental of all real estate in which the above-mentioned activities can be carried out, as well as all ancillary activities.

The management of interests in relation to prices and reimbursements with respect to the various administrations and interest groups in the pharmaceutical sector.

Finally, its purpose is to carry out all operations relating directly or indirectly to the acquisition of participations, in any form whatsoever, in any company, as well as the administration, management, control, financing and development of its participations.

In particular, it may use its funds for the creation, management, development, enhancement and liquidation of a portfolio consisting of all securities and patents of any origin, participate in the creation, development and control of any business, acquire by way of contribution, subscription, underwriting or call option and in any other manner, all securities and patents, realize them by way of sale, transfer, exchange or otherwise, and enhance the value of such business and patents.

More generally, it may acquire and obtain all patents for inventions and improvements, licenses, processes and trademarks, exploit them, transfer them and grant all licenses.

It may grant any company of the group to which it may be a part or any shareholder any assistance, loans, advances or guarantees.

The company may take an interest by any legal means in any business, undertaking or company that would be likely to promote its development. This enumeration is enunciative and non-limitative and must be interpreted in its broadest sense.

It may enter into any agreement for rationalization, collaboration, association or other agreements with other enterprises, associations or companies.

It may lend or borrow, with or without guarantee, participate in the creation and development of any company and give them any assistance.

The company may carry out any operations of any kind whatsoever, whether commercial, industrial, financial, movable or immovable, relating directly or indirectly to its corporate purpose. In general, the company may take any action and take any measure to facilitate the achievement of its corporate purpose.

### **13.3 SHARE CAPITAL AND SHARES**

#### **13.3.1 CURRENT AMOUNT AND COMPOSITION**

As of the date of this Prospectus, the share capital of the Issuer amounts to EUR 89,008.84, represented by 17,801,768 Shares, without nominal value, each representing 1/17,801,768<sup>th</sup> of the share capital of the Issuer. The share capital of the Issuer is fully and unconditionally subscribed for and is fully paid up.

Approximately 19.22% of the current outstanding Shares (and current share capital) of the Issuer have been issued (and fully subscribed for) pursuant to the contribution in kind of all the shares in Dermax (see also Sections 13.3.3 (Development of the share capital) and 12.4 (Dermax Acquisition)).

### 13.3.2 AMOUNT AND COMPOSITION UPON CLOSING OF THE OFFERING

Assuming the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75, and taking into account the assumptions made in the notes referred to below, the below table shows the amount and composition of the share capital of the Issuer upon closing of the Offering:

Origin of Shares	On an undiluted basis, assuming placement of all of the 5,000,000 initially offered New Shares <sup>(1)</sup>			On an undiluted basis, assuming full placement of the New Shares <sup>(2)</sup>			On an undiluted basis, assuming full placement of the New Shares and an exercise in full of the Over-allotment Option <sup>(3)</sup>			On a fully diluted basis <sup>(4)</sup>		
	# Shares	Share capital		# Shares	Share capital		# Shares	Share capital		# Shares	Share capital	
		(excl. issue premium) (€)	(incl. issue premium) (€)		(excl. issue premium) (€)	(incl. issue premium) (€)		(excl. issue premium) (€)	(incl. issue premium) (€)		(excl. issue premium) (€)	(incl. issue premium) (€)
Existing Shares	17,801,768	89,008.84	24,071,282.84	17,801,768	89,008.84	24,071,282.84	17,801,768	89,008.84	24,071,282.84	17,801,768	89,008.84	24,071,282.84
New Shares	5,000,000	25,000.00	53,750,000.00	5,750,000	28,750.00	61,812,500.00	5,750,000	28,750.00	61,812,500.00	5,750,000	28,750.00	61,812,500.00
Conversion of Convertible Bonds	2,040,864	10,204.32	15,358,025.00	2,040,864	10,204.32	15,358,025.00	2,040,864	10,204.32	15,358,025.00	2,040,864	10,204.32	15,358,025.00
Exercise of Over-allotment Option	-	-	-	-	-	-	862,500	4,312.50	9,271,875.00	862,500	4,312.50	9,271,875.00

Exercise of Transaction Warrants	-	-	-	-	-	-	-	-	-	-	1,200,000	6,000.00	2,831,640.00
Exercise of ESOP Warrants	-	-	-	-	-	-	-	-	-	-	333,000	1.665.00	1,777,387.50
<b>Total</b>	<u>24,842,632</u>	<u>124,213.16</u>	<u>93,179,307.84</u>	25,592,63	127,963.1	101,241,8	26,455,13	132,275.6	110,513,6	<u>27,988,132</u>	<u>139,940.66</u>	115,122,71	<u>0.34</u>

**Notes:**

- (1) It is assumed that (a) all 5,000,000 initially offered New Shares are placed in the Offering (excluding the exercise in full or in part of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal amount as per the expected Closing Date, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), and (c) none of the Transaction Warrants and ESOP Warrants have been exercised.
- (2) It is assumed that (a) the maximum number of New Shares is placed in the Offering (including as a result of the exercise in full of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal amount, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), and (c) none of the Transaction Warrants and ESOP Warrants have been exercised.
- (3) It is assumed that (a) the maximum number of New Shares is placed in the Offering (including as a result of the exercise in full of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal amount, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), (c) the Stabilization Manager exercises its Over-allotment Option in full, and (d) none of the Transaction Warrants and ESOP Warrants have been exercised.
- (4) It is assumed that (a) the maximum number of New Shares is placed in the Offering (including as a result of the exercise in full of the Increase Option), (b) all of the outstanding Convertible Bonds have been converted into new Shares immediately after closing of the Offering (assuming that the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75 and that the principal amount, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted), (c) the Stabilization Manager exercises its Over-allotment Option in full, and (d) all of the Transaction Warrants and all of the ESOP Warrants have been exercised.

### **13.3.3 DEVELOPMENT OF THE SHARE CAPITAL**

The changes to the Issuer's actual share capital since its incorporation on 7 June 2012, can be summarized as follows (a more detailed description of each event is set forth further below):

<b>Date</b>	<b>Transaction</b>	<b>Increase of share capital (€)</b>	<b>Number of securities issued</b>	<b>Issue price / share (€, rounded, excl. issue premium)</b>	<b>Share capital after the transaction</b>	<b>Number of Shares after the transaction</b>
7 June 2012	Incorporation	50,000	10,000 Shares	5.00	50,000.00	10,000.00
31 March 2017	Capital increase	11,500	2,300 Shares	5.00	61,500.00	12,300.00
12 May 2017	Share split	-	-	-	61,500.00	3,075,000
12 May 2017	Warrants issue	-	300,000 Transaction Warrants	-	61,500.00	3,075,000
31 May 2018	Capital increase	4,974.22	248,711 Shares	0.02	66,474.22	3,323,711
31 May 2018	Warrants issue	-	5 Adjustment Warrants	-	66,474.22	3,323,711
31 May 2018	Warrants issue	-	5 Anti-dilution Warrants	-	66,474.22	3,323,711
31 May 2018	Capital increase	5,426.44	271,322 Shares	0.02	71,900.66	3,595,033
31 December 2019	Capital increase	17,108.18	855,409 Shares	0.02	89,008.84	4,450.442
31 December 2019	Warrants issue	-	90,825 ESOP Warrants o/w as of the date of this Prospectus, following the Share Split 333,000 are outstanding <sup>203</sup>	-	89,008.84	4,450.442
31 March 2020	Convertible Bonds issue	-	500 Convertible Bonds, o/w as of the date of this Prospectus 303 are outstanding	-	89,008.84	4,450.442
8 June 2020 (principle) 16 June 2020 (final share split)	Share split	-	Share split with ratio of 1:4	-	89,008.84	17,801,768

At the time of incorporation of the Issuer in June 2012 in the Grand Duchy of Luxembourg (cf. Section 7.1.3 (Incorporation) of this Prospectus), the share capital was set at EUR 50,000 represented by 10,000

Shares with a nominal value of EUR 5 each, which were fully and unconditionally subscribed and fully paid up.

At the time of the Belgian Seat Transfer on 31 March 2017, the share capital of the Issuer, as a private limited liability company ("*société privée à responsabilité limitée*" / "*besloten vennootschap met beperkte aansprakelijkheid*") under Belgian law, was determined to amount to EUR 50,000, represented by 10,000 Shares. On the same day, the share capital of the Issuer was increased with EUR 11,500 through the creation of 2,300 new Shares, which were fully and unconditionally subscribed and fully paid up. No issue premium was paid, resulting in an aggregate price per share of EUR 5. As a result of this capital increase, the share capital of the Issuer on 31 March 2017 amounted to EUR 61,500, represented by 12,300 (fully and unconditionally subscribed and fully paid up) Shares without nominal value, each representing 1/12,300<sup>th</sup> of the share capital of the Issuer.

Following this capital increase, the Issuer was transformed into a public limited liability company ("*société anonyme*" / "*naamloze vennootschap*") under Belgian law (see Section 7.1.3 (Incorporation) of this Prospectus).

On 12 May 2017, a share split was carried out pursuant to which each then outstanding Share was "divided" into 250. As a result, the outstanding share capital of the Issuer of EUR 61,500 was then represented by 3,075,000 (fully and unconditionally subscribed and fully paid up) Shares without nominal value, each representing 1/3,075,000<sup>th</sup> of the share capital of the Issuer.

Immediately after the share split, the Issuer issued 300,000 Transaction Warrants, each Transaction Warrant (if and when exercised) entitling its holder to subscribe for one new Share. Pursuant to the issue of the Transaction Warrants, the share capital of the Issuer was increased, subject to the condition precedent and to the extent that the Transaction Warrants are exercised, for a maximum amount resulting from the multiplication of the number of Transaction Warrants exercised (if any) with the par value of the then outstanding Shares (the positive difference between the exercise price of the Transaction Warrants (EUR 9.4388 per new Share) and the par value of the then outstanding Shares (if any) being allocated to a separate issue premium account). Reference is made to Section 13.4.1 (Transaction Warrants) of this Prospectus for more details in relation to the Transaction Warrants.

On 31 May 2018, the share capital of the Issuer was increased multiple times.

First the Issuer's share capital was increased with an amount of EUR 4,974.22 through the creation of 248,711 new Shares, each fully and unconditionally subscribed for and fully paid up. The aggregate issue premium paid amounted to EUR 2,745,025.78 (*i.e.*, a total investment of EUR 2,750,000), resulting in a price per Share of approximately EUR 11.06.

Immediately thereafter, the Issuer issued (i) five Adjustment Warrants, each Adjustment Warrant (if and when exercised) entitling its holder right to subscribe for a number of new Shares if on, or before 30 June 2020 neither an "exit" nor a "qualified IPO" has occurred and (ii) five Anti-dilution Warrants, each

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<sup>203</sup> The Board of Directors has decided that 5,000 of a total of 10,000 ESOP Warrants that are held by Mr. Antoine Carlhian (CFO of the Issuer until 30 April 2020) and all 10,000 ESOP Warrants that are held by Mr. Patrick Jeanmart (CFO of the Issuer until 15 June 2020), are vested under the terms of the ESOP warrant scheme. The remaining 5,000 ESOP Warrants held by Mr. Antoine Carlhian have lapsed.

Anti-dilution Warrant (if and when exercised) entitling its holder to subscribe for a number of new Shares in certain limited circumstances. Pursuant to the issue of the Adjustment Warrants and Anti-dilution Warrants, the share capital of the Issuer was increased, subject to the condition precedent and to the extent that the Adjustment Warrants, respectively the Anti-dilution Warrants are exercised, for a maximum amount resulting from the multiplication of the number of exercised Adjustment Warrants, respectively Anti-dilution Warrants, with the exercise price of the Adjustment Warrants (EUR 1 per Adjustment Warrant), respectively the Anti-dilution Warrants (EUR 1 per new Anti-dilution Warrant), whereby the positive difference with the amount resulting from the multiplication of the number of new Shares issued pursuant to the exercise of the Adjustment Warrants, respectively the Anti-dilution Warrants, with the then applicable par value of the Shares (if any) will be allocated to a separate issue premium account). Reference is made to Section 13.4.2 (Adjustment Warrants) and Section 13.4.3 (Anti-dilution Warrants) of this Prospectus for more details in relation to the Adjustment Warrants, respectively the Anti-dilution Warrants.

Following the first capital increase and the issue of the Adjustment Warrants, respectively the Anti-dilution Warrants, the share capital of the Issuer was increased again on the same date with EUR 5,426.44 through the creation of 271,322 new Shares, each fully and unconditionally subscribed for and fully paid up. The aggregate issue premium paid amounted to EUR 2,994,573.56 (*i.e.*, a total investment of EUR 3,000,000), resulting in a price per Share of approximately EUR 11.06.

As a result of the aforementioned first and second capital increases, the share capital of the Issuer on 31 May 2018 amounted to EUR 71,900.66, represented by 3,595,033 (fully and unconditionally subscribed and fully paid up) Shares without nominal value, each representing 1/3,595,033<sup>th</sup> of the share capital of the Issuer.

On 31 December 2019, all shares in Dermax were contributed in kind into the Issuer. Pursuant to this contribution in kind, the Issuer's share capital was increased with an amount of EUR 17,108.18 through the creation of 855,409 new Shares, each fully and unconditionally subscribed and fully paid up. The aggregate issue premium paid amounted to EUR 18,242,674.82 (*i.e.*, a total investment of EUR 18,259,783), resulting in a price per Share of EUR 21.35. As a result of this capital increase, the share capital of the Issuer on 31 December 2019 amounted to EUR 89,008.84, represented by 4,450,442 (fully and unconditionally subscribed and fully paid up) Shares without nominal value, each representing 1/4,450,442<sup>th</sup> of the share capital of the Issuer (see also Section 12.4 (Dermax Acquisition)).

On the same date, the Issuer approved, in principle, the issue of maximum 90,825 ESOP Warrants, each ESOP Warrant (if and when offered, accepted and exercised) entitling its holder to subscribe for one new Share. Pursuant to the issue of the ESOP Warrants, the share capital of the Issuer was increased, subject to the condition precedent and to the extent that the ESOP Warrants are offered, accepted and exercised, for a maximum amount resulting from the multiplication of the amount of new Shares issued pursuant to the exercise of the ESOP Warrants, with the then applicable par value of the Shares (the positive difference between the exercise price of the ESOP Warrants and the then applicable par value of the Shares (if any) being allocated to a separate issue premium account). Reference is made to Section 13.4.4 (ESOP Warrants) of this Prospectus for more details in relation to the ESOP Warrants.

On 31 March 2020, the Issuer decided (in principle) to issue 500 Convertible Bonds, each Convertible Bond automatically converting into new Shares in certain circumstances. Pursuant to the issue of the Convertible Bonds, the share capital of the Issuer was increased, subject to the condition precedent and to the extent that the Convertible Bonds are converted, for a maximum amount resulting from the multiplication of the number of new Shares issued pursuant to the conversion of the Convertible Bonds, with the par value of the then outstanding Shares (the positive difference between the converted amount of the Convertible Bonds and the amount of the capital increase) (if any) being allocated to a separate issue premium account). A total of 303 Convertible Bonds has been effectively subscribed for, in two tranches, on 31 March 2020 and on 30 April 2020 respectively, and the remaining 197 Convertible Bonds have lapsed. Reference is made to Section 13.6 (Convertible Bonds) of this Prospectus for more details in relation to the Convertible Bonds.

On 8 June 2020, a share split (the **Share Split**) was decided in principle, and on 16 June 2020, the final ratio of the share split was determined, pursuant to which each then outstanding Share was “divided” into 4. As a result, the outstanding share capital of the Issuer of EUR 89,008.84 as of the date of this Prospectus is represented by 17,801,768 (fully and unconditionally subscribed and fully paid up) Shares without nominal value, each representing 1/17,801,768<sup>th</sup> of the share capital of the Issuer. Immediately after the Share Split, the decision was taken to acknowledge the automatic consequences of the Share Split on the ESOP Warrants, the Convertible Bonds and the Transaction Warrants pursuant to their respective terms and conditions. Each ESOP Warrant was “divided” into 4, such that on the date of this Prospectus, 333,000 ESOP Warrants are outstanding (each ESOP Warrant entitling its holder to subscribe for one new Share), and the original exercise price per ESOP Warrant was divided by 4 (for details of their current terms, reference is made to Section 13.4.4 (ESOP Warrants)). Following the Share Split, each of the 300,000 Transaction Warrants entitles its holder to subscribe for 4 new Shares instead of one new Share, and the original subscription price per share was divided by 4 (for details of their current terms, reference is made to Section 13.4.1 (Transaction Warrants)). The Share Split does not impact the terms of the conversion of the Convertible Bonds upon closing of the Offering. The terms and conditions of the Adjustment Warrants and the Anti-Dilution Warrants were amended to neutralize the impact of the Share Split in accordance with their respective terms and conditions (for details of their current terms, reference is made to Section 13.4.2 (Adjustment Warrants) and Section 13.4.3 (Anti-dilution Warrants)).

#### **13.3.4 LEGISLATION UNDER WHICH THE SHARES ARE CREATED**

The Shares are subject to Belgian law.

#### **13.4 WARRANTS**

The Issuer created two stock option plans under which warrants were granted to employees, directors and consultants of the Issuer and its subsidiaries: the Transaction Warrants (as defined below) in May 2017 and the ESOP Warrants (as defined below) in December 2019. In addition, the Issuer issued the Adjustment Warrants and the Anti-dilution Warrants (as both terms are defined below) at the occasion of the capital increases of the Issuer on 31 May 2018 (see Section 13.3.3 (Development of the share capital) of this Prospectus for more information on these capital increases).

This Section provides an overview of the outstanding warrants as of the date of this Prospectus.

#### **13.4.1 TRANSACTION WARRANTS**

On 12 May 2017, the Issuer issued 300,000 warrants (the **Transaction Warrants**). All Transaction Warrants have been subscribed for. The Transaction Warrants have been granted free of charge. Initially all Transaction Warrants have been subscribed by Stijn Van Rompay. Thereafter they have been transferred at multiple occasions to other persons such as members of the Issuer's personnel and investors in the Issuer.

Each Transaction Warrant entitles its holder to subscribe for 4 new Shares at a subscription price per share of EUR 2.3597 per Share. The Transaction Warrants have a term of five years and are freely transferable. They are not subject to a vesting mechanism (*i.e.*, the Transaction Warrants are immediately acquired in a final manner). The new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants will be ordinary shares representing the capital, of the same class as the existing Shares, fully paid up, with voting rights and without nominal value. They will have the same rights as the existing Shares and will entitle their holder to the dividend distributed in the financial year during which the relevant Transaction Warrants are exercised, even if the dividend was declared or has been paid prior to the issuance of such new Shares, including, in particular in respect of any new Shares that would be issued upon exercise of Transaction Warrants in 2020 (if any), any distributions in relation to the financial year that started on 1 January 2020, as the case may be.

Upon completion of the Offering, the Transaction Warrants will become immediately exercisable. In the Shareholders' Agreement, all holders of Transaction Warrants have committed not to exercise their Transaction Warrants (i) during the 60 calendar days' period prior to the Annual General Shareholders' Meeting to be held in 2020 regarding the financial year 2019 and (ii) from the first day of trading of the Shares on Euronext Brussels until closing of the Offering, without prejudice to the right of each holder of Transaction Warrants to exercise its Transaction Warrant(s) as from the closing of the Offering in accordance with the terms and conditions of the Transaction Warrants. Hence, no Transactions Warrants will be exercised (and no Shares can be issued pursuant to any such exercise) prior to completion of the Offering.

For an overview of the Transaction Warrants offered to, and subscribed for by, members of the Board of Directors and the Executive Management, reference is made to the overview under Section 10.2.5 (Shares, warrants, Convertible Bonds and options on Shares held by directors), respectively Section 10.4.1 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management of the Issuer) of this Prospectus.

#### **13.4.2 ADJUSTMENT WARRANTS**

On 31 May 2018, the Issuer issued five adjustment warrants to certain shareholders of the Issuer (not being members of the Board of Directors and/or the Executive Management) (the **Adjustment Warrants**). All Adjustment Warrants have been subscribed for. The Adjustment Warrants have been granted free of charge.

The Adjustment Warrants entitle their holders (together) to subscribe for 142,104 new Shares in the aggregate, at a exercise price of EUR 1 per Adjustment Warrant except if on, or before 30 June 2020 neither an “exit” nor a “qualified IPO” has occurred.

However, the holders of the Adjustment Warrants have waived their right to exercise, and to transfer, all their Adjustment Warrants until 10 July 2020 and have waived, and have approved the cancellation (by the Issuer) of, all their Adjustment Warrants on the condition that (a) the Offer Price is not lower than EUR 6.769525, (b) subscription orders for an amount of at least EUR 40 million have been received no later than 30 June 2020 and (c) the Shares of the Company are admitted to trading on the regulated market of Euronext Brussels on an “if-and-when-issued-and/or-delivered” basis within 3 business days following the closing of the Offering Period. Furthermore, the Extraordinary General Shareholders' Meeting referred to in Section 14.18 (Authorizations) decided to cancel the Adjustment Warrants on the same condition. As a result of this waiver and cancellation, provided this condition is fulfilled, all Adjustment Warrants will lapse upon the closing of the Offering. Hyloris expects the Offering to meet all of the aforementioned conditions to which the waiver of the Adjustment Warrants was made subject.

#### **13.4.3 ANTI-DILUTION WARRANTS**

On 31 May 2018, the Issuer issued five anti-dilution warrants to certain shareholders of the Issuer (not being members of the Board of Directors and/or the Executive Management) (the **Anti-dilution Warrants**). All Anti-dilution Warrants have been subscribed for. The Anti-dilution Warrants have been granted free of charge.

The Anti-dilution Warrants entitle their holders to subscribe for new Shares, at an exercise price of EUR 1 per Anti-dilution Warrant, in certain limited circumstances. The number of new Shares to be issued pursuant to the exercise of the Anti-dilution Warrants is dependent on the transaction triggering their exercisability. The Anti-dilution Warrants will automatically lapse on 31 November 2020.

However, the holders of the Anti-dilution Warrants have waived their right to exercise, and to transfer, all their Anti-dilution Warrants until 10 July 2020 and have waived, and have approved the cancellation (by the Issuer) of, all their Anti-dilution Warrants on the condition that (a) the Offer Price is not lower than EUR 6.769525, (b) subscription orders for an amount of at least EUR 40 million have been received no later than 30 June 2020 and (c) the Shares of the Company are admitted to trading on the regulated market of Euronext Brussels on an “if-and-when-issued-and/or-delivered” basis within 3 business days following the closing of the Offering Period. Furthermore, the Extraordinary General Shareholders' Meeting referred to in Section 14.18 (Authorizations) decided to cancel the Anti-dilution Warrants on the same condition. As a result of this waiver and cancellation, provided this condition is fulfilled, all Anti-dilution Warrants will lapse upon the closing of the Offering. Hyloris expects the Offering to meet all of the aforementioned conditions to which the waiver of the Anti-dilution Warrants was made subject.

#### **13.4.4 ESOP WARRANTS**

On 31 December 2019, the Issuer approved, in principle, the issue of 90,825 warrants in the context of an employee stock ownership plan (the **ESOP Warrants**) subject to the ESOP Warrants being offered to, and accepted by, the beneficiaries thereof, who must be employees, directors or consultants of the

Issuer and/or its subsidiaries. As a result of the Share Split, each ESOP Warrant was automatically “divided” into 4.

As of the date of this Prospectus, following the Share Split, 333,000 ESOP Warrants are outstanding and will lapse at closing of the Offering. The ESOP Warrants have been granted free of charge.

Each ESOP Warrant entitles its holder to subscribe for one new Share at a exercise price determined by the Board of Directors in line with a report on the real value of the underlying Share at the date of the offering of the ESOP Warrants in accordance with article 43, §4, 2° of the Belgian Stock Option Act of 26 March 1999. The exercise price so determined for all ESOP Warrants, taking into account the Share Split, is equal to EUR 5.3375 per ESOP Warrant. The new Shares (if any) that will be issued pursuant to the exercise of the ESOP Warrants, will be ordinary shares representing the capital, of the same class as the then existing Shares, fully paid up, with voting rights and without nominal value. They will have the same rights as the then existing Shares and will be profit sharing as from any distribution in respect of which the relevant ex-dividend date falls after the date of their issuance.

The ESOP Warrants shall only be acquired in a final manner (“vested”) in cumulative tranches over a period of four years as of the starting date (determined for each beneficiary separately): *i.e.*, a first tranche of 25% vests on the first anniversary of the starting date and subsequently 1/48<sup>th</sup> vests each month. ESOP Warrants can only be exercised by the relevant holder of such ESOP Warrants, provided that they have effectively vested, as of the beginning of the fourth calendar year following the year in which the Issuer granted the ESOP Warrants to the holders thereof. As of that time, the ESOP Warrants can be exercised during the first fifteen days of each quarter. However, the terms and conditions of the ESOP Warrants provide that the ESOP Warrants can or must also be exercised, regardless of whether they have vested or not, in a number of specified cases of accelerated vesting set out in the issue and exercise conditions.

The terms and conditions of the ESOP Warrants contain customary good leaver and bad leaver provisions in the event of termination of the professional relationship between the beneficiary and Hyloris. The terms and conditions of the ESOP Warrants also provide that all ESOP Warrants (whether or not vested) will become exercisable during a special exercise period to be organized by the Board in the event of certain liquidity events. These liquidity events include (i) a transfer of all or substantially all Shares of the Issuer; (ii) a merger, demerger or other corporate restructuring resulting in the shareholders holding the majority of the voting rights in the Issuer prior to the transaction not holding the majority of the voting rights in the surviving entity after the transaction; (iii) the launch of a public takeover bid on the Shares; and (iv) any action or transaction with substantially the same economic effect as determined by the Board of Directors. The Offering is not such a liquidity event. ESOP Warrants that are not exercised in such special exercise period will automatically become null and void unless otherwise decided by the Board of Directors.

For an overview of the ESOP Warrants offered to, and subscribed for by, members of the Board of Directors and the Executive Management, reference is made to the overview under Section 10.2.5 (Shares, warrants and options on Shares held by directors), respectively Section 10.4.1 (Shares, warrants, Convertible Bonds and options on Shares held by Executive Management of the Issuer) of this Prospectus.

## 13.5 OPTIONS ON THE SHARES

### 13.5.1 CALL OPTION ON EXISTING SHARES

A number of shareholders, namely the holders of the Adjustment Warrants and Anti-dilution Warrants have granted a call option on a number of existing Shares to Mr. Stijn Van Rompay and Mr. Thomas Jacobsen pursuant to a call option agreement dated 31 May 2018 (the **Call Option**).

If (a) the Offer Price is not lower than EUR 6.769525, (b) subscription orders for an amount of at least EUR 40 million have been received no later than 30 June 2020 and (c) the Shares of the Company are admitted to trading on the regulated market of Euronext Brussels on an “if-and-when-issued-and/or-delivered” basis within 3 business days following the closing of the Offering Period, Mr. Stijn Van Rompay and Mr. Thomas Jacobsen will, pursuant to the Call Option, be entitled to purchase from all aforementioned shareholders together 198,948 Shares (proportionate to their investment in the Issuer on 31 May 2018) in exchange for a payment to the holders of the Adjustment Warrants and Anti-dilution Warrants of EUR 5 in the aggregate (*i.e.*, EUR 1 per holder of Adjustment Warrants and Anti-dilution Warrants). If the Call Option is exercised within twenty business days following the listing of the Shares, Mr. Stijn Van Rompay is entitled to 66.66% of the 198,948 called Shares (*i.e.*, 132,619 Shares) and Mr. Thomas Jacobsen is entitled to 33.34% of the 198,948 called Shares (*i.e.*, 66,329 Shares). Hyloris expects the Offering to meet all of the aforementioned conditions of the Call Option.

### 13.5.2 OVER-ALLOTMENT OPTION

See Section 15.4 (Over-allotment Option and price stabilization).

## 13.6 CONVERTIBLE BONDS

In the first half of 2020, a number of investors (including members of the Board of Directors and the Executive Management) (the **Participating Investors**), have (in the aggregate):

- (i) subscribed for 303 automatically convertible bonds, with a principal amount per unit of EUR 50,000, for a total aggregate amount of EUR 15,150,000, at a yearly interest rate of 6.00% (the **Convertible Bonds**); and
- (ii) committed themselves vis-à-vis the Issuer to irrevocably and conditional only on completion of the Offering, subscribe for New Shares in the Offering for a total aggregate amount of EUR 22,725,000 (*i.e.*, at a ratio of 1:1.5 (amount subscribed for under the Convertible Bonds : amount subscribed for in the Offering pursuant to the Pre-commitments)).

For more information on the Pre-commitments, reference is made to Section 14.3 (Pre-commitments).

On 31 March 2020, the Issuer decided (in principle) to issue the Convertible Bonds. 303 Convertible Bonds were effectively subscribed for, in two tranches, on 31 March 2020 and on 30 April 2020 respectively.

The Convertible Bonds are convertible bonds in accordance with Articles 7:65 et seq. of the CCA and are in registered form in accordance with Articles 7:27 et seq. of the CCA. The Convertible Bonds constitute direct, unconditional and unsecured obligations of the Issuer ranking equally (*pari passu*) among themselves, and are subordinated to the Issuer's senior debt.

The completion of the Offering will result in the automatic conversion of all outstanding Convertible Bonds (for their full outstanding principal amount, increased, if requested by the Issuer (which it intends to do), by all or part of any unpaid interests due) in new Shares, at the Offer Price less a discount of 30%. The Issuer believes this discount is justified in the light of the risk assumed by the Participating Investors by making the Pre-commitments. The Convertible Bonds have only been subscribed by the Participating Investors. The new Shares that will be issued upon conversion of the Convertible Bonds will be ordinary shares representing the capital, of the same class as the existing Shares, fully paid up, with voting rights and without nominal value. They will have the same rights as the existing Shares and will be profit sharing as from any distribution in respect of which the relevant ex-dividend date falls after the date of their issuance, including, in particular, any distributions in relation to the financial year that started on 1 January 2020, as the case may be.

The new Shares issued pursuant to the automatic conversion of the Convertible Bonds will be subject to the lock-up arrangement described in Section 15.3.1 (Lock-up pursuant to the IPO).

The Convertible Bonds were subscribed for by, and subsequently issued to, the Participating Investors in the following proportions:

Name Participating Investor	# Convertible Bonds	Total Principal Amount of Convertible Bonds (€)	New Shares following conversion <sup>(1)</sup>
Scorpiaux SRL	80 <sup>(2)</sup>	4,000,000	539,600
NOSHAQ SA	32 <sup>(3)</sup>	1,600,000	214,784
Saffelberg Investments SA	32 <sup>(2)</sup>	1,600,000	215,840
Jean-Claude Marian	20 <sup>(2)</sup>	1,000,000	134,900
NomalInvest SA	20 <sup>(3)</sup>	1,000,000	134,240
Dirk Van Praag	20 <sup>(2)</sup>	1,000,000	134,900
Stijn Van Rompay	20 <sup>(3)</sup>	1,000,000	134,240
TrustCapital SA	15 <sup>(3)</sup>	750,000	100,680
GIPAR SA	8 <sup>(2)</sup>	400,000	53,960
Atlantis Invest SRL	6 <sup>(2)</sup>	300,000	40,470
Thojo BM	6 <sup>(2)</sup>	300,000	40,470
Arno Verhoeven	6 <sup>(2)</sup>	300,000	40,470
Marc Corluy	4 <sup>(2)</sup>	200,000	26,980
Koen Matthijs	4 <sup>(2)</sup>	200,000	26,980
Dirk Vandeputte	4 <sup>(2)</sup>	200,000	26,980
Peter Hellings	3 <sup>(2)</sup>	150,000	20,235
Ludo and Ria Schellens-Brullemans	3 <sup>(2)</sup>	150,000	20,235
Pierre-Yves André	2 <sup>(2)</sup>	100,000	13,490
Johan De Meester	2 <sup>(2)</sup>	100,000	13,490
Joris De Meester	2 <sup>(2)</sup>	100,000	13,490
Fiduciam	2 <sup>(2)</sup>	100,000	13,490
Bart Roscam	2 <sup>(2)</sup>	100,000	13,490
Sediaal SA	2 <sup>(2)</sup>	100,000	13,490
Koenraad Van der Elst	2 <sup>(2)</sup>	100,000	13,490
Stefan Vandeputte	2 <sup>(2)</sup>	100,000	13,490
Serge Vermeersch	2 <sup>(2)</sup>	100,000	13,490
Inge Weyns-Verlinden	2 <sup>(2)</sup>	100,000	13,490
<b>Total</b>	<b>303</b>	<b>15,150,000</b>	<b>2,040,864</b>

**Notes:**

- (1) Assuming the Offer Price is the midpoint of the Price Range, i.e., EUR 10.75, the conversion takes place immediately after closing of the Offering and that the principal amount, increased with the unpaid interests accrued

- during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted.
- (2) Convertible Bonds issued in principle on 31 March 2020 and subscribed for on 31 March 2020, bearing interest as of 31 March 2020 (included).
  - (3) Convertible Bonds issued in principle on 31 March 2020 and subscribed for on 30 April 2020, bearing interest as of 30 April 2020 (included).

## **13.7 RIGHTS ATTACHED TO THE SHARES**

### **13.7.1 RIGHTS IN RELATION TO THE GENERAL SHAREHOLDERS' MEETINGS**

#### **13.7.1.1 GENERAL SHAREHOLDERS' MEETING**

##### **A General**

Generally, the General Shareholders' Meeting has sole authority with respect to:

- the approval of the annual financial statements of the Issuer;
- the distribution of profits (except interim dividends (see Section 13.7.2 (Dividend Rights) below);
- the appointment (at the proposal of the Board of Directors and upon recommendation by the Remuneration and Nomination Committee) and dismissal of directors of the Issuer;
- the appointment (at the proposal of the Board of Directors and upon recommendation by the Audit Committee) and dismissal of the Statutory Auditor of the Issuer;
- the granting of release from liability to the members of the Board of Directors and the Statutory Auditor of the Issuer;
- the determination of the remuneration of the members of the Board of Directors and of the Statutory Auditor for the exercise of their mandate;
- the approval of the remuneration policy;
- the advisory vote on the remuneration report included in the annual report of the Board of Directors and the determination of the certain features of the remuneration or compensation of directors, members of the Executive Management and certain other executives (if any) (as the case may be) (see Section 10.5 (Remuneration and Benefits)
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, merger and certain other reorganizations of the Issuer; and
- the approval of amendments to the Articles of Association.

## **B Annual General Shareholders' Meeting**

The Annual General Shareholders' Meeting is held in Liège or at the place determined in the notice convening the General Shareholders' Meeting. As of the date of this Prospectus, the meeting is held every year on the second Tuesday of June at 2.00 p.m. (Belgian time). If this day is a public holiday, the meeting will be held on the next business day. At the Annual General Shareholders' Meeting, the Board of Directors submits to the shareholders the audited non-consolidated and consolidated annual financial statements and the reports of the Board of Directors and of the Statutory Auditor with respect thereto.

The General Shareholders' Meeting then decides on the approval of the statutory annual financial statements, the proposed allocation of the Issuer's profit or loss, the release from liability of the members of the Board of Directors and the Statutory Auditor, the advisory vote on the remuneration report included in the annual report of the Board of Directors and, when applicable, the (re-)appointment or dismissal of the Statutory Auditor and/or of all or certain directors. In addition, as relevant, the General Shareholders' meeting must also decide on the approval of the remuneration policy, the approval of the remuneration of the directors and statutory auditor for the exercise of their mandate, and on the approval of provisions of service agreements to be entered into with executive directors, members of the Executive Management and certain other executives (if any) providing (as the case may be) for severance payments exceeding 12 months' remuneration (or, subject to a reasoned positive opinion by the Remuneration and Nomination Committee, 18 months' remuneration).

## **C Special and Extraordinary General Shareholders' Meetings**

The Board of Directors or the Statutory Auditor (or the liquidators, if appropriate) may, whenever the interest of the Issuer so requires, convene a Special or Extraordinary General Shareholders' Meeting. The Board of Directors and the Statutory Auditor are required to convene such a General Shareholders' Meeting within three weeks if shareholders representing 10% of the share capital so request, including at least the agenda items proposed by the shareholders concerned.

## **D Convening Notices**

The notice convening the General Shareholders' Meeting must state the place, date and hour of the meeting and must include an agenda indicating the items to be discussed and the proposed resolutions (or updates of the agenda if shareholders have put additional items or draft resolutions on the agenda). The notice needs to contain a clear description of the formalities that shareholders must fulfil in order to be admitted to the General Shareholders' Meeting and exercise their voting right, the proposal of the Audit Committee on the appointment of a Statutory Auditor (as the case may be), information on the manner in which shareholders can put additional items on the agenda and table draft resolutions, information on the manner in which shareholders can ask questions prior and during the General Shareholders' Meeting, information on the procedure to participate to the General Shareholders' Meeting by means of a proxy or, if specifically allowed in the notice convening the meeting, to vote by means of a remote vote, and, as applicable, the registration date for the General Shareholders' Meeting. The notice must also mention where shareholders can obtain a copy of the documentation that will be submitted to the General Shareholders' Meeting, the forms to vote by proxy, if specifically allowed in the notice convening the meeting, or by means of a remote vote, and the address of the webpage on which

the documentation and information relating to the General Shareholders' Meeting will be made available. This documentation and information, together with the notice and the total number of outstanding voting rights, must also be made available on the Issuer's website at the same time as the publication of the notice convening the meeting, for a period of five years after the relevant general shareholders' meeting.

The notice convening the General Shareholders' Meeting has to be published at least 30 calendar days prior to the General Shareholders' Meeting in the Belgian Official Gazette ("*Moniteur Belge*" / "*Belgisch Staatsblad*"), in a newspaper that is published nation-wide in Belgium on paper or digitally, in media that can be reasonably relied upon for the dissemination of information within the EEA in a manner ensuring fast access to such information on a non-discriminatory basis and on the Issuer's website. A publication in a nation-wide newspaper is not needed for Annual General Shareholders' Meetings taking place on the date, hour and place indicated in the Articles of Association of the Issuer if the agenda is limited to the treatment and approval of the financial statements, the annual report of the Board of Directors and the report of the Statutory Auditor, the remuneration report and the severance pay for executive directors, members of the Executive Management, and certain other executives (if any) (as the case may be) and the discharge from liability of the members of the Board of Directors and Statutory Auditor. The term of 30 calendar days prior to the General Shareholders' Meeting for the publication and distribution of the convening notice can be reduced to 17 calendar days for a second meeting if, as the case may be, the applicable quorum for the meeting is not reached at the first meeting, the date of the second meeting was mentioned in the notice for the first meeting and no new item is put on the agenda of the second meeting. See also Section 13.7.1.1.E (Quorum and Majorities).

At the same time as its publication, the convening notice must also be sent to the holders of registered Shares, holders of registered convertible bonds, holders of registered warrants, holders of registered certificates issued with the co-operation of the Issuer (if any), and, as the case may be, to the directors and statutory auditor of the Issuer. In accordance with Article 7:128 *jo*. Article 2:32 CCA, this communication needs to be made by letter or e-mail (in the event the Issuer possess the relevant e-mail addresses).

### **E Quorum and Majorities**

In general, there is no attendance quorum requirement for a General Shareholders' Meeting and decisions are generally passed with a simple majority of the votes of the Shares present or represented.

However, capital increases (other than those decided by the Board of Directors pursuant to the authorized capital (see Section 13.7.4.2 (Capital increase decided by the Board of Directors)), decisions with respect to the Issuer's dissolution, mergers, de-mergers and certain other reorganizations of the Issuer, amendments to the Articles of Association (other than an amendment of the corporate purpose), and certain other matters referred to in the Belgian Code of Companies and Associations do not only require the presence or representation of at least 50% of the share capital of the Issuer but also a majority of at least 75% of the votes cast. An amendment of the Issuer's corporate purpose requires the approval of at least 80% of the votes cast at a General Shareholders' Meeting, which can only validly pass such resolution if at least 50% of the share capital of the Issuer and at least 50% of the profit certificates (if any) are present or represented. In the event where the required quorum is not present or represented at the first meeting, a second meeting needs to be convened through a new notice. The

second General Shareholders' Meeting may validly deliberate and decide regardless of the number of Shares present or represented. The special majority requirements, however, remain applicable.

### **13.7.1.2**      **THE RIGHT TO ATTEND AND VOTE**

Shareholders may participate in the General Shareholders' Meeting of the Issuer and exercise their voting rights during such meetings, provided the following requirements are met (article 25 of the Articles of Association of the Issuer):

- (i) the registration for accounting purposes of the Shares in the shareholder's name at midnight (Belgian time) on the 14<sup>th</sup> day prior to the relevant General Shareholders' Meeting (the "record date"), by their entry in the Issuer's share register, their entry in the accounts of a recognized account holder or settlement institution, regardless of the number of Shares that the shareholder holds on the day of the relevant General Shareholders' Meeting.
- (ii) Owners of registered Shares who wish to participate in the General Shareholders' Meeting must communicate their intention to the Issuer, or the person appointed for that purpose by the Issuer, via the Issuer's e-mail address or the specific e-mail address mentioned in the notice convening the General Shareholders' Meeting, to be sent no later than the sixth day prior to the date of the relevant General Shareholders' Meeting.
- (iii) Owners of dematerialized Shares who wish to participate in the meeting must submit a certificate issued by a recognized account holder or settlement institution which indicates with how many dematerialized Shares, as entered in the name of the shareholder in his accounts on the record date, the shareholder has indicated that he wishes to participate in the relevant General Shareholders' Meeting. This certificate must be sent to the Issuer's e-mail address or to the specific e-mail address mentioned in the notice convening the General Shareholders' Meeting, no later than the sixth day prior to the date of the General Shareholders' Meeting.

The formalities for the registration of securities holders, and the notification of the Issuer must be further described in the notice convening the General Shareholders' Meeting.

Holders of non-voting Shares, non-voting profit-sharing certificates, convertible bonds, warrants or certificates issued with the cooperation of the Issuer (if any) may attend the General Shareholders' Meeting, but only in an advisory capacity. The Articles of Association lay down the formalities that they must fulfil in order to be admitted to the General Shareholders' Meeting.

Each Share entitles its holder to one vote, except in the cases of suspension of the voting right provided for by law. Voting rights in relation to Shares may be suspended, inter alia, in the following cases:

- If several persons have rights in rem in respect of the same Share, until a single person has been designated as the holder of the voting right vis-à-vis the Issuer (see also below);

- when a shareholder hold Shares which entitle it to voting rights above the threshold of 5%, 10%, 15%, 20% and any further multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Issuer on the date of the relevant General Shareholders' Meeting, in the event that the relevant shareholder has not notified the Issuer and the FSMA at least 20 calendar days prior to the date of the General Shareholders' Meeting in accordance with the applicable rules on disclosure of major shareholdings; and
- when the voting right was suspended by a competent court or the FSMA.

Pursuant to the Belgian Code of Companies and Associations, the voting rights attached to Shares owned by the Issuer, as the case may be, are suspended.

Vis-à-vis the Issuer, the Shares are indivisible. If several persons have rights in rem in respect of the same Share, the Board of Directors may, in accordance with article 9 of the Articles of Association of the Issuer, suspend the exercise of the rights attached to such Shares until a single person has been designated vis-à-vis the Issuer as the holder of the voting rights. If a Share is encumbered with a usufruct or a pledge, the exercise of the voting right attached to that Share will be exercised by the usufructuary and by the owner constituting the pledge, unless otherwise jointly notified to the Issuer by the parties involved.

Each shareholder has, subject to compliance with the requirements set forth above, the right to attend a General Shareholders' Meeting and to vote at the General Shareholders' Meeting in person or through a proxy holder, who need not be a shareholder. A shareholder may designate, for a given meeting, only one person as proxy holder, except in circumstances where Belgian law allows the designation of multiple proxy holders (see Article 7:143 CCA). The appointment of a proxy holder may take place in paper form or electronically (in which case the form shall be signed by means of an electronic signature in accordance with applicable Belgian law). The originally signed paper or electronic form must be received by the Issuer at the latest on the sixth calendar day preceding the meeting. It will be sent to the Issuer via the Issuer's e-mail address or the specific e-mail address mentioned in the notice convening the Shareholders' Meeting. The appointment of a proxy holder must be made in accordance with the applicable rules of Belgian law, including in relation to conflicts of interest and the keeping of a register.

The notice convening the meeting may allow shareholders to vote remotely in relation to the General Shareholders' Meeting, by sending a paper form and/or via the Issuer's website. The form shall be made available by the Issuer. The signed paper form must be received by the Issuer at the latest on the sixth calendar day preceding the date of the meeting. Voting via the website may occur until the last calendar day before the meeting.

The notice convening the meeting may also allow shareholders to participate in the General Shareholders' Meeting remotely.

### **13.7.1.3**      **THE RIGHT TO PUT ITEMS ON THE AGENDA OF THE GENERAL SHAREHOLDERS' MEETING AND TO TABLE DRAFT RESOLUTIONS**

Shareholders who hold alone or together with other shareholders at least 3% of the Issuer's share capital have the right to put additional items on the agenda of a General Shareholders' Meeting that has been convened and to table draft resolutions in relation to items that have been or are to be included in the agenda. This right does not apply to General Shareholders' Meetings that are being convened on the grounds that a legal quorum was not met at the first duly convened meeting (see Section 13.7.1.1E (Quorum and Majorities)). Shareholders wishing to exercise this right must prove on the date of their request that they own at least 3% of the outstanding share capital. The ownership must be based, for dematerialized Shares, on a certificate issued by a certified account holder or by a settlement institution, confirming the number of Shares that have been registered in the name of the relevant Shareholders and, for registered Shares, on a certificate of registration of the relevant Shares in the share register of the Issuer. In addition, the Shareholder concerned must register for the meeting concerned with at least 3% of the outstanding share capital (see also Section 13.7.1.1 ("The right to attend and vote")). A request to put additional items on the agenda and/or to table draft resolutions must be submitted in writing, and must contain, in the event of an additional agenda item, the text of the agenda item concerned and, in the event of a new draft resolution, the text of the draft resolution. The request must reach the Issuer at the latest on the twenty second calendar day preceding the date of the General Shareholders' Meeting concerned, and the Issuer acknowledges receipt of these requests to the postal or e-mail address provided by the relevant shareholders within a period of forty-eight hours as from such receipt. If the Issuer receives a request, it will have to publish an update of the agenda of the meeting with the additional agenda items and draft resolutions at the latest on the fifteenth calendar day preceding the General Shareholders' Meeting.

### **13.7.1.4**      **THE RIGHT TO ASK QUESTIONS**

Within the limits of Article 7:139 CCA, shareholders have a right to ask questions to the members of the Board of Directors in connection with the items on the agenda of such General Shareholders' Meeting. Shareholders can also ask questions to the statutory auditor in connection with the items on the agenda on which it reports. Such questions can be submitted in writing prior to the meeting or can be asked at the meeting. Written questions must be received by the Issuer no later than the sixth calendar day prior to the meeting. Written and oral questions will be answered during the meeting concerned in accordance with applicable law. In addition, in order for written questions to be considered, the shareholders who submitted the written questions concerned must comply with the formalities to attend the meeting, as explained above in Section 13.7.1.2 (The right to attend and vote).

### **13.7.2**      ***DIVIDEND RIGHTS***

All of the Shares will participate equally in the Issuer's profits (if any). Pursuant to the CCA, the Shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the Annual General Shareholders' Meeting, based on the most recent statutory audited financial statements, prepared in accordance with the generally accepted accounting principles in Belgium and based on a (non-binding) proposal of the Issuer's Board of Directors. The Issuer's Articles of Association also authorize the Board of Directors to declare interim dividends without Shareholder.

Under Belgian law (Article 2277 of the Belgian Civil Code), the right to receive dividends payable on shares lapses five years after their distribution date. From that date onwards, the Issuer is no longer required to pay-out such dividends.

In accordance with Article 7:212 CCA, the Issuer's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law on the basis of the Issuer's statutory unconsolidated financial statements rather than its consolidated financial statements. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Issuer's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (*i.e.*, summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased with the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves. In addition, prior to distributing dividends, 5% of the net profits must be allotted to a legal reserve, until the legal reserve amounts to 10% of the Issuer's share capital. The Issuer's legal reserve currently does not meet this requirement nor will it do so at the completion of the Offering. Accordingly, 5% of its Belgian GAAP annual net profit during the next years will have to be allocated to the legal reserve, limiting the Issuer's ability to pay out dividends to its shareholders.

Furthermore, additional financial restrictions and other limitations may be contained in future credit agreements. While no restrictions of this nature currently exist, certain covenants may be included in future credit agreements that, for example, may require debt service payments to be satisfied before dividends are paid.

For further information in relation to the Issuer's dividend policy, see Section 6.6 "Dividends and dividend policy".

### **13.7.3 RIGHTS IN THE EVENT OF LIQUIDATION**

All Shares represent an equal part of the Issuer's share capital and have the same rank in the event of insolvency of the Issuer.

The Issuer can only be voluntarily dissolved by way of a shareholders' resolution passed with a majority of at least 75% of the votes cast at an Extraordinary General shareholders' Meeting where at least 50% of the share capital is present or represented.

Pursuant to Article 7:228 CCA, if, as a result of losses incurred, the ratio of the Issuer's net assets (determined in accordance with Belgian legal and accounting rules for non-consolidated financial statements) to share capital is less than 50%, the Board of Directors must convene a General Shareholders' Meeting within two months as of the date upon which the Board of Directors discovered or, by virtue of the provisions of the Articles of Associations or legal provision, should have discovered this undercapitalization. At this General Shareholders' Meeting the Board of Directors needs to propose either the dissolution of the Issuer or the continuation of the Issuer, in which case the Board of Directors

must propose measures to redress the Issuer's financial situation. The Board of Directors must justify its proposals in a special report to the shareholders. Shareholders representing at least 75% of the votes validly cast at this meeting have the right to dissolve the Issuer, provided that at least 50% of the Issuer's share capital is present or represented at the meeting.

If, as a result of losses incurred, the ratio of the Issuer's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in that event shareholders representing 25% of the votes validly cast at the meeting can decide to dissolve the Issuer.

Pursuant to Article 7:229 CCA, if the amount of the Issuer's net assets has dropped below EUR 61,500 (the minimum amount of share capital of a public limited liability company organized under the laws of Belgium ("*société anonyme*" / "*naamloze vennootschap*")), any interested party is entitled to request the competent court to dissolve the Issuer. The court can order the dissolution of the Issuer or grant a grace period within which the Issuer is to remedy the situation.

These same rules apply to the Issuer's subsidiaries, who are also public limited liability companies organized under the laws of Belgium ("*société anonyme*" / "*naamloze vennootschap*"). In view of the negative net equity of the Issuer's subsidiaries, which was established inter alia on the basis of their (non-consolidated) financial statements for the financial year ended on 31 December 2019 prepared in accordance with Belgian GAAP, the Issuer (as sole shareholder of its subsidiaries) resolved on 15 June 2020, in accordance with Article 7:228 CCA, to continue the activities of the subsidiaries, and not to dissolve them.

If the Issuer is dissolved for any reason, the liquidation must be carried out by one or more liquidators, unless the Articles of Association state otherwise, appointed by the General Shareholders' Meeting with a simple majority. In some cases, the appointment of the liquidator(s) must be ratified by the president of the enterprise court (see Article 2:84 CCA). Any balance remaining after discharging all debts, liabilities, liquidation costs and taxes must first be applied to reimburse, in cash or in kind, the paid-up capital of the Shares not yet reimbursed. Any remaining balance shall be equally distributed amongst all the shareholders (see also Risk Factor 2.2.1 (Hyloris has a limited operating history, has incurred operating losses, negative operating cash flows and an accumulated deficit since inception and may not be able to achieve or subsequently maintain profitability)).

#### **13.7.4 CHANGES TO THE SHARE CAPITAL**

##### **13.7.4.1 CHANGES TO THE SHARE CAPITAL DECIDED BY THE SHAREHOLDERS**

In principle, changes to the share capital are decided by the shareholders. The General Shareholders' Meeting may at any time decide to increase or reduce the share capital of the Issuer. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the Articles of Association, as described in Section 13.7.1.1E (Quorum and Majorities)).

##### **13.7.4.2 CAPITAL INCREASES DECIDED BY THE BOARD OF DIRECTORS**

Subject to the same quorum and majority requirements, the General Shareholders' Meeting may authorize the Board of Directors, within certain limits, to increase the Issuer's share capital once or

several times without any further approval of the shareholders. This is the so-called authorized capital. This authorization needs to be limited in time (*i.e.*, it can only be granted for a renewable period of maximum five years) and scope (*i.e.* the authorized capital may not exceed the amount of the registered capital at the time of the authorization).

On 8 June 2020, the Issuer's General Shareholders' Meeting authorized, subject to and with effect as from the completion of the Offering, the Board of Directors to increase the registered share capital of the Issuer within the framework of the authorized capital with a maximum of 100% of its amount as at the completion of the Offering (without taking into account, however, the capital increase resulting from the conversion of the Convertible Bonds).

In this context, the Issuer's General Shareholders' Meeting also decided, in application of Article 7:200 CCA, that the Board of Directors, when exercising its powers under the authorized capital, will be authorized to restrict or cancel the statutory preferential subscription rights of the existing shareholders (within the meaning of Article 7:188 and following CCA, see also Section 13.7.4.3 (statutory preferential subscription right)). This authorization includes the restriction or cancellation of preferential subscription rights of existing shareholders for the benefit of one or more specific persons (whether or not employees of the Issuer or its subsidiaries). The authorization is valid for a term of five years as from the date of the publication of the authorization in the Annexes to the Belgian State Gazette.

See also Section 13.9 (Applicable regulation regarding mandatory public takeover bids and public squeeze-out bids).

### **13.7.4.3**      **STATUTORY PREFERENTIAL SUBSCRIPTION RIGHT**

#### **A**      ***General***

In the event of a capital increase for cash with the issue of new Shares, or in the event of an issue of convertible bonds or warrants, the existing shareholders have a statutory preferential right to subscribe, *pro rata*, for such new Shares, convertible bonds or warrants. These statutory preferential subscription rights are transferable during the subscription period.

The General Shareholders' Meeting may decide to limit or cancel this statutory preferential subscription right, subject to special reporting requirements. Such decision by the General Shareholders' Meeting needs to satisfy the same quorum and majority requirements as are required for a decision to amend the Issuer's Articles of Association.

The shareholders may also decide to authorize the Board of Directors to limit or cancel the statutory preferential subscription right within the framework of the authorized capital, subject to the terms and conditions set forth in the CCA.

Generally, unless expressly authorized in advance by the General Shareholders' Meeting, the authorization of the Board of Directors to increase the share capital of the Issuer through contributions in cash with cancellation or limitation of the statutory preferential subscription right of the existing shareholders is suspended as of the notification to the Issuer by the FSMA of a public takeover bid on the financial instruments of the Issuer.

On 8 June 2020, the Extraordinary General Shareholders' Meeting of the Issuer decided to authorize the Board of Directors to increase the Issuer's share capital, including with limitation or cancellation of the existing shareholders' statutory preferential subscription rights, in one or more times and including the authorization to make use of such authorized capital in the framework of a public tender offer.

See also Section 13.7.4.2 (Capital increases decided by the Board of Directors).

## **B Foreign Shareholders**

Certain shareholders of the Issuer who do not reside in Belgium, such as those in the United States, Australia, Switzerland, Canada or Japan, may be restricted in their ability to exercise such rights. See Risk Factor 2.4.6 (Investors resident in countries other than Belgium may not be able to exercise their statutory preferential subscription rights, resulting in a dilution of their stake in the Issuer.) for further information.

### **13.7.4.4 ACQUISITION, ACCEPTANCE IN PLEDGE AND TRANSFER OF OWN SHARES**

The Issuer may acquire and accept in pledge its own Shares in accordance with the Belgian Code of Companies and Associations and article 10 of its Articles of Association. The Issuer must inform the FSMA of any such contemplated transactions.

Pursuant to the resolution of the General Shareholders' Meeting of 8 June 2020, and subject to and with effect as from the completion of the Offering, the Board of Directors of the Issuer is authorized to acquire and accept in pledge its own Shares without the total number of own Shares, held or accepted in pledge by the Issuer exceeds 20% of the total number of Shares, for a consideration of at least EUR 1 and at most thirty% above the arithmetic average of the closing price of the Issuer's Share during the last thirty days of stock exchange listing prior to the decision of the Board of Directors to acquire or accept in pledge. This authorization has been granted for a renewable period of five years as from the date of publication of the minutes of the Extraordinary General Shareholders' Meeting of 8 June 2020 in the Annexes to the Belgian Official Gazette.

The Board of Directors is furthermore authorized, subject to and with effect as from the completion of the Offering, to acquire or accept in pledge own Shares where such acquisition or acceptance in pledge is necessary to prevent imminent serious harm to the Issuer. This authorization has been granted for a renewable period of three years as from the date of publication of the minutes of the Extraordinary General Shareholders' Meeting of 8 June 2020 in the Annexes to the Belgian Official Gazette.

The Issuer may transfer of its own Shares in accordance with the Belgian Code of Companies and Associations and article 11 of its Articles of Association.

Pursuant to the resolution of the General Shareholders' Meeting of 8 June 2020, and subject to and with effect as from the completion of the Offering, the Board of Directors of the Issuer is authorized to transfer its own Shares to one or more specific persons other than personnel.

The Board of Directors is furthermore authorized, subject to and with effect as from the completion of the Offering, to transfer own Shares where such transfer is necessary to prevent serious imminent harm

to the Issuer. This authorization has been granted for a renewable period of three years as from the date of publication of the minutes of the Extraordinary General Shareholders' Meeting of 8 June 2020 in the Annexes to the Belgian Official Gazette.

The authorizations referred to above also apply to the Issuer, the direct subsidiaries of the Issuer, insofar as necessary, the indirect subsidiaries of the Issuers, and, insofar as necessary, every third party acting in its own name but on behalf of those companies.

### **13.8 RESTRICTIONS ON THE FREE TRANSFERABILITY OF THE SHARES**

The Shares are freely transferable. This is without prejudice to certain restrictions that may apply pursuant to applicable securities laws requirements which are further described in Section 16 (Transfer restrictions). In addition, certain existing shareholders entered into contractual restrictions. See Section 15.3 (Lock-up).

### **13.9 APPLICABLE REGULATION REGARDING MANDATORY PUBLIC TAKEOVER BIDS AND PUBLIC SQUEEZE-OUT BIDS**

#### **13.9.1 GENERAL PROVISIONS**

The Issuer is subject to the Belgian regulations on public takeover bids and public squeeze-out bids. This concerns Article 7:82, §1 CCA, the Law of 1 April 2007 on takeover bids and the two Royal Decrees of 27 April 2007, namely the Royal Decree on takeover bids on the one hand and the Royal Decree on public squeeze-out bids on the other hand, the main principles of which are summarized and completed below.

#### **13.9.2 MANDATORY PUBLIC BID**

Any public takeover bid is subject to the supervision of the FSMA and requires the preparation of a prospectus that must be submitted to the FSMA for prior approval.

The Law of 1 April 2007 obliges anyone who, directly or indirectly, as a result of an acquisition by himself or by other persons with whom he acts in concert or by persons acting on his behalf or on behalf of such other persons, holds more than 30% of the securities with voting rights in a company whose registered office is located in Belgium and of which at least part of the securities with voting rights is admitted to trading on a regulated market, to make a public takeover bid on all securities with voting rights, or granting access to voting rights, issued by the company.

Generally, and subject to the application of certain exceptions, the simple exceedance of the 30% threshold after an acquisition of securities leads to the obligation to make a bid, regardless of whether or not the consideration paid for the acquisition exceeds the market price.

The regulations provide for a number of derogations from the obligation to make a public takeover bid, such as (i) a capital increase with the statutory preferential subscription rights of the existing shareholders decided by the General Shareholders' Meeting, (ii) where it is shown that a third party

controls the company or holds a holding larger than the person who, alone or acting in concert, holds 30% of the voting rights of the company and (iii) in certain cases in the event of a merger.

The price of the mandatory bid shall be at least equal to the higher of the following amounts: (i) the highest price paid for the securities by the bidder or a person acting in concert with him during the 12 months preceding the announcement of the bid and (ii) the weighted average of the market prices on the most liquid market for the relevant securities over the period of 30 calendar days preceding the date on which the obligation to make the bid arose.

In principle, the bid can be made in cash, in securities or in a combination of both. If the offered consideration consists of securities, then the bidder must propose a cash price as an alternative in two cases: (i) in the event the bidder or a person acting in concert with him has acquired or committed to acquire securities for cash during the period of 12 months preceding the announcement of the bid or during the period covered by the bid, or (ii) in the event the price does not consist of liquid securities admitted to trading on a regulated market.

The mandatory takeover bid must relate to all securities with voting rights or granting access to voting rights, such as convertible bonds or warrants, and must be unconditional in nature.

The CCA, other regulations (such as the regulations on the disclosure of major shareholdings (see Section 13.10 (Disclosure of major shareholdings)) and the regulations on the control of concentrations, include other provisions that may apply to the Issuer and that may have an impact on, or make it more difficult to implement, a hostile takeover bid or a change of control.

In accordance with the CCA and the provisions of its Articles of Association, the Issuer is permitted to acquire its own Shares and to increase its capital through the authorized capital (see in this respect Sections 13.7.4.4 (Purchase and sale of own Shares) and 13.7.4.2 (Capital increases decided by the Board of Directors)), which could deter or frustrate public takeover bids through dilutive issuances of equity securities.

The Issuer is a party to the following significant agreements or instruments which, upon a fundamental change in shareholders or change of control of the Issuer or following a takeover bid can be terminated by the other parties thereto:

- All credit agreements of the Issuer, as they contain so-called change of control clauses, which allows the relevant financial institution to request the full repayment of the credits prematurely in the event of a change of control of the Issuer; and
- The manufacturing agreement between RTU Pharma and S.M. Farmaceutici SRL dated 2 October 2019, relating to Tranexamic Acid, may be terminated by either party if the organization or capital control of the other party changes in such a way that renders it unacceptable for the terminating party to continue the agreement.

In addition, the ESOP Warrants include a change of control clause, see Section 13.4.4 (ESOP Warrants).

### **13.9.3 PUBLIC SQUEEZE-OUT BID**

In accordance with Article 7:82, §1 CCA and the Royal Decree of 27 April 2007 on public squeeze-out bids, a natural person or a legal entity, or several natural persons or legal entities acting in concert, who, together with the listed company own(s) 95% of the securities with voting rights in a listed company, can, by way of a public squeeze-out bid, acquire all securities with voting rights, or granting access to voting rights (the “ordinary squeeze-out”).

The securities not offered voluntarily in the context of such bid will be deemed to have been automatically transferred to the bidder, with consignment of the price, and the company will then no longer be considered as a listed company. The price must be an amount in cash representing the fair value of the securities (verified by an independent expert) in a manner that safeguards the interests of the holders of the securities.

Moreover, if, as a result of a voluntary or mandatory takeover bid, the bidder (or any person acting in concert with it) holds 95% of the capital to which voting rights are attached and 95% of the securities with voting rights, he may require all other holders of securities with voting rights or granting access to voting rights to sell him their securities at the price of the takeover bid (the “simplified squeeze-out”). In the event of a voluntary takeover bid, a simplified squeeze-out is only possible provided that the bidder, as a result of the voluntary bid, has acquired securities representing at least 90% of the voting capital covered by the voluntary bid. The bidder shall then reopen the bid within three months as of the end of the acceptance period of the bid. Such reopening of the bid shall take place under the same conditions as the original bid, and is regarded as an squeeze-out within the meaning of Article 7:82, §1 CCA, to which the Royal Decree of 27 April 2007 on public squeeze-outs does not apply. The securities that have not been offered after the expiry of the acceptance period of the thus reopened bid are deemed to have been automatically transferred to the bidder. After the closing of the bid, the market operator of a Belgian regulated market or the operator of a Belgian multilateral trading facility will ex-officio proceed to the delisting of the securities admitted to trading on such market.

### **13.9.4 MANDATORY REPURCHASE OFFER (SELL-OUT)**

Within three months after the end of an acceptance period related to a public takeover bid, holders of securities with voting rights or granting access to voting rights may require a bidder, who, acting alone or in concert with others, after a voluntary or mandatory public takeover bid, or re-opening thereof, holds 95% of the capital to which voting rights are attached and 95% of the securities with voting rights in a listed company, to take over their securities with voting rights, or granting access to voting rights, at the price of the bid (the “sell-out”). In the event of a voluntary takeover bid, a sell-out is only possible provided that the bidder, as a result of the voluntary bid, has acquired securities representing at least 90% of the voting capital covered by the voluntary bid.

### **13.10 STATUTORY DISCLOSURE OF MAJOR SHAREHOLDINGS**

Belgian legislation (the Law of 2 May 2007 on the disclosure of major shareholdings in issuers whose shares are admitted to trading on a regulated market, and the Royal Decree of 14 February 2008 on the disclosure of major shareholdings) imposes disclosure requirements on each natural person or legal

entity (including registered business associations without legal personality and trusts) that acquires or transfers, directly or indirectly, (i) securities with voting rights or (the right to exercise) voting rights, (ii) securities granting the right to acquire existing securities with voting rights, or (iii) securities that are referenced to existing securities with voting rights and with economic effect similar to that of the securities referred to in (ii), whether or not they confer a right to a physical settlement, if, as a result of such acquisition or transfer, the total number of voting rights ((deemed to be) linked to securities referred to in (i) through (iii)) directly or indirectly held by such natural person or legal entity, acting alone or in concert with others, reaches, rises above or falls below a threshold of 5%, or a multiple of 5%, of the total number of voting rights attached to the securities of the Issuer. A notification duty applies also if (a) the voting rights (linked to securities) referred to in (i) or (b) the voting rights deemed to be linked to securities referred to in (ii) and (iii), taken separately, reaches, rises above or falls below the threshold.

The Issuer has introduced additional disclosure thresholds of 3% and 7.5% in its Articles of Association.

The disclosure obligations mentioned above arise each time the above-mentioned thresholds are reached or crossed (downwards or upwards) as a result of, among other things:

- (iv) the acquisition or transfer of securities with voting rights or securities granting the right to acquire existing securities with voting rights, regardless of how the acquisition or transfer takes place, e.g., by purchase, sale, exchange, contribution, merger, division, or succession;
- (v) events that have changed the distribution of voting rights, even if no acquisition or transfer took place (i.e., passively crossing these thresholds);
- (vi) the conclusion, amendment or termination of an agreement for acting in concert;
- (vii) the holding of a participation when shares of an issuer are admitted to trading on the regulated market for the first time; or
- (viii) the acquisition or transfer of voting rights or the right to exercise voting rights.

The disclosure provisions apply to any natural person or legal entity that “directly” or “indirectly” acquires, transfers or holds securities mentioned in the first paragraph of this Section 13.10. In this respect, a natural person or legal entity is deemed to “indirectly” acquire, transfer or hold securities with voting rights of the company:

- (i) when voting rights ((deemed to be) linked to securities) mentioned in the first paragraph of this Section 13.10 are acquired, transferred or held by a third party that, whether acting in its own name or not, acts for the account of such natural person or legal entity;
- (ii) when voting rights ((deemed to be) linked to securities) mentioned in the first paragraph of this Section 13.10 are acquired, transferred or held by an enterprise controlled (within the meaning of Articles 1:14 and 1:16 CCA) by that natural person or legal entity; or

- (iii) when that natural person or legal entity acquires or transfers control over an enterprise holding voting rights ((deemed to be) linked to securities) mentioned in the first paragraph of this Section 13.10 in the company.

When the law requires a transparency notification, such notification must be communicated as soon as possible to the FSMA and to the Issuer, and at the latest within four trading days. This period commences on the trading day following the day on which the event that caused the notification obligation occurred.

Violation of the disclosure requirements may result in the suspension of voting rights, a court order to sell the securities to a third party and/or criminal liability. The FSMA can also impose administrative sanctions.

The Issuer must publish the information received by way of such notification within three trading days after receiving the notification. Furthermore, the Issuer must state its shareholder structure (as it appears from the notifications received) in the notes to its annual accounts. In addition, the Issuer must publish the total share capital, the total number of securities and voting rights and the total number of voting securities and voting rights for each class (if any) at the end of each calendar month in which one of these numbers has changed. In addition, the Issuer must, where appropriate, publish the total number of bonds convertible in voting securities (if any) as well as the total number of rights, whether or not included in securities, to subscribe for not yet issued voting securities (if any), the total number of voting securities that can be obtained upon the exercise of these conversion or subscription rights, and the total number of shares without voting rights (if any). All transparency notifications received by the Issuer can be consulted on the Issuer's website ([www.hyloris.com](http://www.hyloris.com)), where they are published in their entirety.

## **13.11 TAXATION**

### **13.11.1 *PRIOR WARNING***

The following paragraphs summarize certain Belgian and U.S. federal income tax consequences of the acquisition, ownership and transfer of Shares under Belgian and U.S. tax law.

This summary is based on the tax laws, regulations and administrative interpretations applicable in Belgium and the U.S. as in force at the date of the preparation of this Prospectus and is provided subject to changes in Belgian and U.S. law, including retroactive changes.

This summary does not purport to address all tax consequences of the investment in, ownership in and disposal of the Shares, and does not take into account the specific circumstances of particular investors, some of which may be subject to special rules, or the tax laws of any country other than Belgium and the U.S. This summary does not describe the tax treatment of investors that are subject to special rules, such as banks, insurance companies, collective investment undertakings, dealers in securities or currencies, persons that hold, or will hold, Shares as a position in a straddle, Share repurchase transaction, conversion transactions, synthetic security or other integrated financial transactions. This summary does not address the tax regime applicable to Shares held by Belgian tax residents through a fixed basis or a permanent establishment situated outside Belgium. This summary does in principle not

address the local taxes that may be due in connection with an investment in the Shares, other than Belgian local surcharges which generally vary from 0% to 9% of the investor's income tax liability.

For purposes of this summary, a Belgian resident is (i) a person subject to Belgian personal income tax (*i.e.*, an individual who has his domicile or seat of fortune in Belgium, or an equivalent person), (ii) a company subject to Belgian corporate income tax (*i.e.*, a company who has its main establishment or its seat of management or administration in Belgium), or (iii) a legal person subject to Belgian income tax on legal entities (*i.e.*, a legal person other than a company subject to Belgian corporate income tax, having its main establishment or seat of management or administration in Belgium). A non-resident is a person who is not a Belgian resident.

Potential investors who would like more information about the Issuer's tax regime and/or more information, both in Belgium, the U.S. and abroad, regarding the acquisition, holding and transfer of Shares and the collection of dividends or proceeds from Shares, are invited to consult their usual financial and tax advisers.

### **13.11.2 BELGIAN TAXATION**

#### **13.11.2.1 DIVIDENDS**

##### **A *Belgian Withholding Tax***

For Belgian income tax purposes, the gross amount of all benefits paid on or attributed to the Shares is generally treated as a dividend distribution. By way of exception, the repayment of capital carried out in accordance with the Belgian Code of Companies and Associations is not treated as a dividend distribution to the extent that such repayment is imputed to the fiscal paid-up capital and the amounts assimilated to the paid-up capital. This fiscal paid-up capital includes, in principle, the actual paid-up contributions in cash or in kind (other than contributions of labor) to the extent that no reimbursement or reduction has been made and, subject to certain conditions, the paid-up share premiums and the other amounts representing actual paid-up contributions in cash or in kind (other than contributions of labor), at the time of the issue of shares or profit sharing certificates, assimilated to paid-up capital. However, as of 1 January 2018 (for repayments of capital and the amounts assimilated to the paid-up capital, decided by the general meeting of shareholders as of 1 January 2018), a repayment of capital carried out in accordance with the Belgian Code of Companies and Associations is partly considered to be a dividend distribution, more specifically the portion that is deemed to be the distribution of the existing taxed reserves (irrespective of whether they are incorporated into capital) and/or of the tax-free reserves incorporated into the capital whereby such portion is determined on the basis of the ratio of certain taxed reserves and tax-free reserves incorporated into the capital over the aggregate of such reserves and the fiscal paid-up capital.

Belgian withholding tax of 30% is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

In the event of redemption of the Shares, the redemption gain (*i.e.*, the redemption proceeds after deduction of the portion of fiscal paid-up capital represented by the redeemed Shares) will be treated

as a dividend subject to a Belgian withholding tax of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if such redemption is carried out on Euronext or a similar stock exchange and meets certain conditions.

In the event of liquidation of the Issuer, the liquidation gain (*i.e.*, the amount distributed in excess of the fiscal paid-up capital) will in principle be subject to Belgian withholding tax at a rate of 30%, subject to such relief as may be available under applicable domestic or tax treaty provisions.

Non-Belgian dividend withholding tax, if any, will neither be creditable against any Belgian income tax due nor reimbursable to the extent that it exceeds Belgian income tax due.

### ***B Belgian Resident Individuals***

For Belgian resident individuals who acquire and hold the Shares as a private investment, the Belgian dividend withholding tax (at a tax rate of 30%) fully discharges their personal income tax liability. They may nevertheless elect to report the dividends in their personal income tax return. Where such individual opts to report them, dividends will normally be taxable at the lower of the generally applicable 30% withholding tax rate on dividends or at the progressive personal income tax rates applicable to the taxpayer's overall declared income (local surcharges will not apply). The first EUR 812 (amount applicable for income year 2020) of reported ordinary dividend income will be exempt from tax. For the avoidance of doubt, all reported dividends (hence, not only dividends distributed on the Shares) are taken into account to assess whether said maximum amount is reached. In addition, if the dividends are reported, the dividend withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, provided that the dividend distribution does not result in a reduction in value of or a capital loss on the Shares. This condition is not applicable if the individual can demonstrate that he has held the Shares in full legal ownership for an uninterrupted period of 12 months prior to the attribution of the dividends.

For Belgian resident individuals who acquire and hold the Shares for professional purposes, the Belgian withholding tax does not fully discharge their personal income tax liability. Dividends received must be reported by the investor and will, in such case, be taxable at the investor's personal income tax rate increased with local surcharges. Withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the personal income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if the investor can demonstrate that he has held the full legal ownership of the Shares for an uninterrupted period of 12 months prior to the attribution of the dividends.

### ***C Belgian Legal Entities***

For taxpayers subject to the Belgian income tax on legal entities, the Belgian dividend withholding tax (at a tax rate of 30%) in principle fully discharges their income tax liability.

## **D Belgian Resident Companies**

### **Corporate income tax**

For Belgian resident companies, the dividend withholding tax does not fully discharge the corporate income tax liability. For such companies, the gross dividend income (including the withholding tax) must be declared in the corporate income tax return and will be subject to a corporate income tax rate of 25% as of assessment year 2021 for financial years starting on or after 1 January 2020. Subject to certain conditions, a reduced corporate income tax rate of 20% as of 2020 (*i.e.*, for financial years starting on or after 1 January 2020) may apply for small companies (as defined by Article 1:24, §1 to §6 of the Belgian Code of Companies and Associations) on the first EUR 100,000 of taxable profits.

Any Belgian dividend withholding tax levied at source may be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the corporate income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified; and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable (a) if the company can demonstrate that it has held the Shares in full legal ownership for an uninterrupted period of 12 months prior to the attribution of the dividends; or (b) if, during said period, the Shares never belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Shares in a permanent establishment (**PE**) in Belgium.

As a general rule, Belgian resident companies can (subject to certain limitations) deduct, as of assessment year 2019, 100% of gross dividends received from their taxable income (dividend received deduction), provided that at the time of a dividend payment or attribution: (1) the Belgian resident company holds Shares representing at least 10% of the share capital of the Issuer or a participation in the Issuer with an acquisition value of at least EUR 2,500,000; (2) the Shares have been held or will be held in full ownership for an uninterrupted period of at least one year; and (3) the conditions relating to the taxation of the underlying distributed income, as described in article 203 of the Belgian Income Tax Code (the **Article 203 ITC Taxation Condition**) are met (together, the **Conditions for the application of the dividend received deduction regime**). Under certain circumstances the conditions referred to under (1) and (2) do not need to be fulfilled in order for the dividend received deduction to apply.

The Conditions for the application of the dividend received deduction regime depend on a factual analysis, upon each distribution, and for this reason the availability of this regime should be verified upon each distribution.

### **Withholding tax**

Dividends distributed to a Belgian resident company will be exempt from Belgian withholding tax provided that the Belgian resident company holds, upon payment or attribution of the dividends, at least 10% of the share capital of the Issuer and such minimum participation is held or will be held during an uninterrupted period of at least one year.

In order to benefit from this exemption, the Belgian resident company must provide the Issuer or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions. If the Belgian resident company holds the required minimum participation for less than one year, at the time the dividends are paid on or attributed to the Shares, the Issuer will levy the withholding tax but will not transfer it to the Belgian Treasury provided that the Belgian resident company certifies its qualifying status, the date from which it has held such minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The Belgian resident company must also inform the Issuer or its paying agent if the one-year period has expired or if its shareholding will drop below 10% of the share capital of the Issuer before the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the Belgian resident company.

Please note that the above described dividend received deduction and withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements (*“rechtshandeling of geheel van rechtshandelingen”/“acte juridique ou un ensemble d’actes juridiques”*) for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (*“kunstmatig”/“non authentique”*) and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the EU Parent-Subsidiary Directive of 30 November 2011 (2011/96/EU) (**Parent-Subsidiary Directive**) in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

## **E Non-residents**

### **Non-resident income tax**

For non-resident individuals and companies, the dividend withholding tax will be the only tax on dividends in Belgium, unless the non-resident holds the Shares in connection with a business conducted in Belgium through a fixed base in Belgium or a Belgian PE.

If the Shares are acquired by a non-resident in connection with a business in Belgium, the investor must report any dividends received, which will be taxable at the applicable non-resident personal or corporate income tax rate, as appropriate. Belgian withholding tax levied at source may be credited against non-resident personal or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (1) the taxpayer must own the Shares in full legal ownership on the day the beneficiary of the dividend is identified and (2) the dividend distribution may not result in a reduction in value of or a capital loss on the Shares. The latter condition is not applicable if (a) the non-resident individual or the non-resident company can demonstrate that the Shares were held in full legal ownership for an uninterrupted period of 12 months prior to the attribution of the dividends or (b) with regard to non-resident companies only, if, during said period, the Shares have not belonged to a taxpayer other than a resident company or a non-resident company which has, in an uninterrupted manner, invested the Shares in a Belgian PE.

Non-resident companies whose Shares are invested in a Belgian PE may deduct 100% of the gross dividends received from their taxable income if, at the date the dividends are paid or attributed, the Conditions for the application of the dividend received deduction regime are met (see Section 13.11.2.1D (Belgian Resident Companies)). Application of the dividend received deduction regime depends, however, on a factual analysis to be made upon each distribution and its availability should be verified upon each distribution.

### **Belgian dividend withholding tax relief for non-residents**

Dividends distributed to non-resident individuals who do not use the Shares in the exercise of a professional activity, may be eligible for the newly introduced tax exemption with respect to ordinary dividends in an amount of up to EUR 812 (amount applicable for income year 2020) per year. For the avoidance of doubt, all dividends paid or attributed to such non-resident individual (and hence not only dividends paid or attributed on the Shares) are taken into account to assess whether said maximum amount is reached. Consequently, if Belgian withholding tax has been levied on dividends paid or attributed to the Shares, such non-resident individual may request in its Belgian non-resident income tax return to credit and, as the case may be, reimburse the Belgian withholding tax levied on the exempted amount. However, if no Belgian non-resident income tax return has to be filed by the non-resident individual, any Belgian withholding tax levied could in principle be reclaimed (up to the exempted amount) by filing a request thereto addressed to the tax official to be appointed in a Royal Decree. Such a request has to be made at the latest on 31 December of the calendar year following the calendar year in which the relevant dividend(s) have been received, together with an affidavit confirming the non-resident individual status and certain other formalities which are still to be determined in a Royal Decree.

Dividends distributed to non-resident qualifying parent companies established in a Member State of the EU or in a country with which Belgium has concluded a double tax treaty that includes a qualifying exchange of information clause, will, under certain conditions, be exempt from Belgian withholding tax provided that the Shares held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of the share capital of the Issuer and such minimum participation is held or will be held during an uninterrupted period of at least one year. A non-resident company qualifies as a parent company provided that (i) for companies established in a Member State of the EU, it has a legal form as listed in the annex to the Parent-Subsidiary Directive, as amended from time to time, or, for companies established in a country with which Belgium has concluded a qualifying double tax treaty, it has a legal form similar to the ones listed in such annex; (ii) it is considered to be a tax resident according to the tax laws of the country where it is established and the double tax treaties concluded between such country and third countries; and (iii) it is subject to corporate income tax or a similar tax without benefiting from a tax regime that derogates from the ordinary tax regime. In order to benefit from this exemption, the non-resident company must provide the Issuer or its paying agent with a certificate confirming its qualifying status and the fact that it meets the required conditions.

If the non-resident company holds a minimum participation for less than one year at the time the dividends are attributed to the Shares, the Issuer must levy the withholding tax but does not need to transfer it to the Belgian Treasury provided that the non-resident company provides the Issuer or its paying agent with a certificate confirming, in addition to its qualifying status, the date as of which it has

held the minimum participation, and its commitment to hold the minimum participation for an uninterrupted period of at least one year. The non-resident company must also inform the Issuer or its paying agent when the one-year period has expired or if its shareholding drops below 10% of the Issuer's share capital before the end of the one-year holding period. Upon satisfying the one-year holding requirement, the dividend withholding tax which was temporarily withheld, will be refunded to the non-resident company.

Please note that the above withholding tax exemption will not be applicable to dividends which are connected to an arrangement or a series of arrangements (*"rechtshandeling of geheel van rechtshandelingen"*/*"acte juridique ou un ensemble d'actes juridiques"*) for which the Belgian tax administration, taking into account all relevant facts and circumstances, has proven, unless evidence to the contrary, that this arrangement or this series of arrangements is not genuine (*"kunstmatig"*/*"non authentique"*) and has been put in place for the main purpose or one of the main purposes of obtaining the dividend received deduction, the above dividend withholding tax exemption or one of the advantages of the Parent-Subsidiary Directive in another EU Member State. An arrangement or a series of arrangements is regarded as not genuine to the extent that they are not put into place for valid commercial reasons which reflect economic reality.

Dividends distributed by a Belgian company to non-resident companies on a share participation of less than 10% will under certain conditions be subject to an exemption from withholding tax, provided that the non-resident companies (i) are either established in another Member State of the EEA or in a country with which Belgium has concluded a double tax treaty, where that treaty, or any other treaty concluded between Belgium and that jurisdiction, includes a qualifying exchange of information clause; (ii) have a legal form as listed in Annex I, Part A to the Parent-Subsidiary Directive as amended from time to time, or a legal form similar to the legal forms listed in the aforementioned annex and which is governed by the laws of another Member State of the EEA or a similar legal form in a country with which Belgium has concluded a double tax treaty; (iii) hold a share participation in the Belgian dividend distributing company, upon payment or attribution of the dividends, of less than 10% of the Issuer's share capital but with an acquisition value of at least EUR 2,500,000; (iv) hold or will hold the Shares which give rise to the dividends in full legal ownership during an uninterrupted period of at least one year; and (v) are subject to the corporate income tax or a tax regime similar to the corporate income tax without benefiting from a tax regime which deviates from the ordinary regime. The exemption from withholding tax is only applied to the extent that the Belgian withholding tax, which would be applicable absent the exemption, could not be credited nor reimbursed at the level of the qualifying, dividend receiving, company. The non-resident company must provide the Issuer or its paying agent with a certificate confirming, in addition to its full name, legal form, address and fiscal identification number (if applicable), its qualifying status and the fact that it meets the required conditions mentioned under (i) to (v) above, and indicating to which extent the withholding tax, which would be applicable absent the exemption, is in principle creditable or reimbursable on the basis of the law as applicable on 31 December of the year preceding the year during which the dividend is paid or attributed.

Belgian dividend withholding tax is subject to such relief as may be available under applicable tax treaty provisions. Belgium has concluded tax treaties with a lot of countries, reducing the dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of those countries, depending on conditions, among

others, related to the size of the shareholding and certain identification formalities. Such reduction may be obtained either directly at source or through a refund of taxes withheld in excess of the applicable treaty rate.

Prospective holders of Shares should consult their own tax advisers to determine whether they qualify for a reduction in withholding tax upon payment or attribution of dividends, and, if so, to understand the procedural requirements for obtaining a reduced withholding tax upon the payment of dividends or for making claims for reimbursement.

### **13.11.2.2**      **CAPITAL GAINS AND LOSSES**

#### **A**      ***Belgian Resident Individuals***

In principle, Belgian resident individuals acquiring the Shares as a private investment should not be subject to Belgian capital gains tax on the disposal of the Shares and capital losses will not be tax deductible.

However, capital gains realized by a Belgian resident individual are taxable at 33% (plus local surcharges) if the capital gain on the Shares is deemed to be realized outside the scope of the normal management of the individual's private estate (e.g. in the event of speculation). Capital losses are, however, not tax deductible.

Moreover, capital gains realized by Belgian resident individuals on the disposal of the Shares, outside the exercise of a professional activity, to a non-resident company (or body constituted in a similar legal form), to a foreign State (or one of its political subdivisions or local authorities) or to a non-resident legal entity, each time established outside the EEA, are in principle taxable at a rate of 16.5% (plus local surcharges) if, at any time during the five years preceding the sale, the Belgian resident individual has owned, directly or indirectly, alone or with his or her spouse or with certain relatives, a substantial shareholding in the Issuer (*i.e.*, a shareholding of more than 25% in the Issuer). Capital losses are, however, not tax deductible in such event.

Capital gains realized by Belgian resident individuals upon redemption of the Shares or upon liquidation of the Issuer will generally be taxable as a dividend (see Section 13.11.2.1B (Belgian Resident Individuals)).

Belgian resident individuals who hold the Shares for professional purposes are taxable at the ordinary progressive personal income tax rates (plus local surcharges) on any capital gains realized upon the disposal of the Shares, except for the Shares held for more than five years, which are taxable at a separate rate of 10% (capital gains realized in the framework of the cessation of activities under certain circumstances) or 16.5% (other), both plus local surcharges. Capital losses on the Shares incurred by Belgian resident individuals who hold the Shares for professional purposes are in principle tax deductible.

## **B Belgian Legal Entities**

Capital gains realized upon disposal of the Shares by Belgian resident legal entities are in principle not subject to Belgian income tax and capital losses are not tax deductible.

Capital gains realized upon disposal of (part of) a substantial participation in a Belgian company (*i.e.*, a participation representing more than 25% of the share capital of the Issuer at any time during the last five years prior to the disposal) may, however, under certain circumstances be subject to income tax in Belgium at a rate of 16.5%.

Capital gains realized by Belgian resident legal entities upon redemption of the Shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

## **C Belgian Resident Companies**

Belgian resident companies are normally not subject to Belgian capital gains taxation on gains realized upon the disposal of the Shares provided that the Conditions for the application of the dividend received deduction regime are met.

If one or more of the Conditions for the application of the dividend received deduction regime are not met, as of assessment year 2021 (for financial years starting as of 1 January 2020), any capital gain realized would be taxable at the standard corporate income tax rate of 25%, unless the reduced corporate income tax rate of 20% applies.

Capital losses on the Shares incurred by Belgian resident companies are as a general rule not tax deductible.

Shares held in the trading portfolios of Belgian qualifying credit institutions, investment enterprises and management companies of collective investment undertakings are subject to a different regime. As of assessment year 2021 for financial years starting as of 1 January 2020, the capital gains on such Shares are taxable at the ordinary corporate income tax rate of 25%, unless the reduced corporate income tax rate of 20% applies, and the capital losses on such Shares are tax deductible. Internal transfers to and from the trading portfolio are assimilated to a realization.

Capital gains realized by Belgian resident companies upon redemption of the Shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

## **D Non-residents**

Non-resident individuals, companies or entities are, in principle, not subject to Belgian income tax on capital gains realized upon disposal of the Shares, unless the Shares are held as part of a business conducted in Belgium through a fixed base in Belgium or a Belgian PE. In such a case, the same principles apply as described with regard to Belgian individuals (holding the Shares for professional purposes), Belgian companies or Belgian resident legal entities subject to Belgian legal entities tax.

Non-resident individuals who do not use the Shares for professional purposes and who have their fiscal residence in a country with which Belgium has not concluded a tax treaty or with which Belgium has concluded a tax treaty that confers the authority to tax capital gains on the Shares to Belgium, might be subject to tax in Belgium if the capital gains are obtained or received in Belgium and arise from transactions which are to be considered speculative or beyond the normal management of one's private estate or in the event of disposal of a substantial participation in a Belgian company as mentioned in the tax treatment of the disposal of the Shares by Belgian individuals. See Section 13.11.2.2A (Belgian Resident Individuals) above. Such non-resident individuals might therefore be obliged to file a tax return and should consult their own tax adviser.

Capital gains realized by non-resident individuals or non-resident companies upon redemption of the Shares or upon liquidation of the Issuer will, in principle, be subject to the same taxation regime as dividends.

### **13.11.2.3      SYSTEM OF TAXATION ON STOCK EXCHANGE TRANSACTIONS (TSET)**

The purchase and the sale and any other acquisition or transfer for consideration of existing Shares (secondary market transactions) is subject to the Belgian tax on stock exchange transactions ("*taks op de beursverrichtingen*" / "*taxe sur les opérations de bourse*") if (i) it is entered into or carried out in Belgium through a professional intermediary, or (ii) deemed to be entered into or carried out in Belgium, which is the case if the order is directly or indirectly made to a professional intermediary established outside of Belgium, either by private individuals with habitual residence in Belgium, or legal entities for the account of their seat or establishment in Belgium (both referred to as a "Belgian Investor"). The tax on stock exchange transactions is not due upon the issuance of the New Shares (primary market transactions).

The tax on stock exchange transactions is levied at a rate of 0.35% of the purchase price, capped at EUR 1,600 per transaction and per party.

Such tax is separately due by each party to the transaction, and each of those is collected by the professional intermediary. However, if the order is made directly or indirectly to a professional intermediary established outside of Belgium, the tax will in principle be due by the Belgian Investor, unless that Belgian Investor can demonstrate that the tax has already been paid. In the latter case, the foreign professional intermediary also has to provide each client (which gives such intermediary an order) with a qualifying order statement ("*bordereau*" / "*bordere*"), at the latest on the business day after the day the transaction concerned was realized. The qualifying order statements must be numbered in series and a duplicate must be retained by the financial intermediary. The duplicate can be replaced by a qualifying day-to-day listing, numbered in series. Alternatively, professional intermediaries established outside of Belgium can, subject to certain conditions and formalities, appoint a Belgian stock exchange tax representative (**Stock Exchange Tax Representative**), which will be liable for the tax on stock exchange transactions in respect of the transactions executed through the professional intermediary and for complying with the reporting obligations and the obligations relating to the order statement in that respect. If such a Stock Exchange Tax Representative has paid the tax on stock exchange transactions due, the Belgian Investor will, as per the above, no longer be the debtor of the tax on stock exchange transaction.

No tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account: (i) professional intermediaries described in article 2, 9° and 10° of the Belgian Law of 2 August 2002 on the supervision of the financial sector and financial services; (ii) insurance companies described in article 2, §1 of the Belgian Law of 9 July 1975 on the supervision of insurance companies; (iii) pension institutions referred to in article 2, 1° of the Belgian Law of 27 October 2006 concerning the supervision of pension institutions; (iv) undertakings for collective investment; (v) regulated real estate companies; and (vi) Belgian non-residents provided they deliver a certificate to their financial intermediary in Belgium confirming their non-resident status.

The EU Commission adopted on 14 February 2013 the Draft Directive on a common Financial Transaction Tax. The Draft Directive currently stipulates that, once the FTT enters into force, the Participating Member States shall not maintain or introduce taxes on financial transactions other than the FTT (or VAT as provided in the Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax). For Belgium, the tax on stock exchange transactions should thus be abolished once the FTT enters into force. The Draft Directive regarding the FTT is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

### **13.11.3 CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS**

The following is a summary of certain U.S. federal income tax considerations relating to the acquisition, ownership and disposition of Offered Shares by a U.S. Holder (as defined below). This summary addresses only the U.S. federal income tax considerations for U.S. Holders that are initial purchasers of Offered Shares pursuant to the Offering and that will hold such Offered Shares as capital assets for U.S. federal income tax purposes (generally, assets held for investment) and that are not residents of, or ordinarily resident in, Belgium for tax purposes nor hold their Offered Shares as part of a permanent establishment in Belgium.

This summary does not address all U.S. federal income tax matters that may be relevant to a particular U.S. Holder. Additionally, this summary does not address tax considerations that could be relevant to particular holders in light of their personal circumstances or applicable to a holder of Offered Shares that may be subject to special tax rules including, without limitation, the following:

- banks, financial institutions or insurance companies;
- brokers, dealers or traders in securities, currencies, commodities, or notional principal contracts;
- tax-exempt entities or organizations;
- individual retirement accounts and other tax-deferred accounts;
- real estate investment trusts, regulated investment companies or grantor trusts;
- persons that hold Offered Shares as part of a “hedging,” “integrated” or “conversion” transaction or as a position in a “straddle” for U.S. federal income tax purposes;
- partnerships (including entities and arrangements classified as partnerships for U.S. federal income tax purposes) or other pass-through entities, or persons that will hold Offered Shares through such an entity;
- certain former citizens or long-term residents of the United States;

- persons subject to special tax accounting as a result of any item of gross income with respect to the Offered Shares being taken into account in an applicable financial statement;
- a person that purchases or sells Shares as part of a wash sale for tax purposes;
- holders that own (directly, indirectly, or through attribution) 10% or more of our Shares by vote or value; and
- holders that have a “functional currency” for U.S. federal income tax purposes other than the U.S. dollar.

Further, this summary does not address the U.S. federal estate, gift, or alternative minimum tax considerations, or any U.S. state, local, or non-U.S. tax considerations of the acquisition, ownership and disposition of Offered Shares.

This description is based on the U.S. Internal Revenue Code of 1986, as amended (the **Code**); existing, proposed and temporary U.S. Treasury Regulations promulgated thereunder, administrative and judicial interpretations thereof; and the Treaty (as defined below) between Belgium and the United States in each case as of and available as of the date hereof. All the foregoing is subject to change, which change could apply retroactively, and to differing interpretations, all of which could affect the tax considerations described below. There can be no assurances that the IRS will not take a contrary or different position concerning the tax consequences of the acquisition, ownership and disposition of Offered Shares or that such a position would not be sustained. Holders should consult their own tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning, and disposing of Offered Shares in their particular circumstances.

For the purposes of this summary, a **U.S. Holder** is a beneficial owner of Offered Shares that is (or is treated as), for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, (1) if a court within the United States is able to exercise primary supervision over its administration and one or more U.S. persons have the authority to control all of the substantial decisions of such trust or (2) if the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a United States person.

If a partnership (or any other entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds Offered Shares, the U.S. federal income tax consequences relating to an investment in the Offered Shares will depend in part upon the status of the partner and the activities of the partnership. Such a partner or partnership should consult its tax advisor regarding the U.S. federal income tax considerations of owning and disposing of Offered Shares in its particular circumstances.

As indicated below, this discussion is subject to U.S. federal income tax rules applicable to a “passive foreign investment company,” or a **PFIC**.

***This discussion is for general information only and is not intended to be, nor should it be construed to be, legal or tax advice to any holder or prospective holder of Offered Shares and no opinion or representation with respect to the U.S. federal income tax consequences to any such holder or prospective holder is made. Persons considering an investment in Offered Shares should consult their own tax advisors as to the particular tax consequences applicable to them relating to the acquisition, ownership and disposition of Offered Shares, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.***

### **13.11.3.1 DISTRIBUTIONS**

Although the Issuer does not currently plan to pay dividends, and subject to the discussion under “—Passive Foreign Investment Company Considerations” below, the gross amount of any distribution (before reduction for any amounts withheld in respect of Belgian withholding tax) actually or constructively received by a U.S. Holder with respect to Offered Shares will be taxable to the U.S. Holder as a dividend to the extent of the U.S. Holder’s pro rata share of the Issuer’s current and accumulated earnings and profits as determined under U.S. federal income tax principles. Distributions in excess of earnings and profits will be non-taxable to the U.S. Holder to the extent of, and will be applied against and reduce, the U.S. Holder’s adjusted tax basis in Offered Shares. Distributions in excess of earnings and profits and such adjusted tax basis will generally be taxable to the U.S. Holder as either long-term or short-term capital gain depending upon whether the U.S. Holder has held the Offered Shares for more than one year as of the time such distribution is received. However, since the Issuer does not calculate its earnings and profits under U.S. federal income tax principles, it is expected that any distribution will be reported as a dividend, even if that distribution would otherwise be treated as a non-taxable return of capital or as capital gain under the rules described above. Dividends received by a corporate U.S. Holder will not be eligible for the dividends-received deduction generally allowed to corporate U.S. Holders.

Non-corporate U.S. Holders may qualify for the preferential rates of taxation with respect to dividends on Offered Shares applicable to long-term capital gains (i.e., gains from the sale of capital assets held for more than one year) applicable to qualified dividend income (as discussed below) if the Issuer is a “qualified foreign corporation” and certain other requirements (discussed below) are met. A non-U.S. corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation if it is eligible for the benefits of a comprehensive tax treaty with the United States which the Secretary of Treasury of the United States determines is satisfactory for purposes of this provision and which includes an exchange of information provision. The Issuer is incorporated under the laws of Belgium, and the Issuer believes that it currently qualifies as a resident of Belgium for purposes of, and is eligible for the benefits of, The Convention between the Government of the United States and the Government of the Kingdom of Belgium for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income, signed on November 27, 2006 (the **Treaty**), although there can be no assurance in this regard. Further, the IRS has determined that the Treaty is satisfactory for purposes of the qualified dividend rules and that it includes an exchange-of-information program. Therefore, subject to the discussion under “—Passive Foreign Investment Company Considerations” below, such dividends will generally be “qualified dividend income” in the hands of individual U.S. Holders, provided that in the year a U.S. Holder receives the dividend the Issuer is eligible for the

benefits of the Treaty, and a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. The Issuer makes no assurance, however, that its dividends will be qualified dividend income.

In general, the amount of a distribution paid to a U.S. Holder in a foreign currency will be the dollar value of the foreign currency calculated by reference to the spot exchange rate on the day the U.S. Holder actually or constructively receives the distribution, regardless of whether the foreign currency is converted into U.S. dollars at that time. The U.S. Holder will take a tax basis in the foreign currency equal to their U.S. dollar equivalent on such date. The conversion of the foreign currency into U.S. dollars at a later date will give rise to foreign currency exchange gain or loss equal to the difference between their U.S. dollar equivalent at such later time and their tax basis. Any foreign currency gain or loss a U.S. Holder recognizes on a subsequent conversion of foreign currency into U.S. dollars will be U.S. source ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. If a distribution received in a foreign currency is converted into U.S. dollars on the day of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the distribution.

A U.S. Holder generally may claim the amount of any Belgian withholding tax as either a deduction from gross income or a credit against U.S. federal income tax liability. However, Belgian income taxes that are withheld in excess of the rate applicable under the Treaty or that are refundable under Belgian law will not be eligible for credit against a U.S. Holder's federal income tax liability. For foreign credit limitation purposes, distributions paid on Offered Shares that are treated as dividends will generally be foreign source income and will generally constitute passive category income. The foreign tax credit is subject to numerous complex limitations that must be determined and applied on an individual basis. Each U.S. Holder should consult its own tax advisors regarding the foreign tax credit rules.

### **13.11.3.2 SALE, EXCHANGE OR OTHER TAXABLE DISPOSITION OF OFFERED SHARES**

A U.S. Holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale, exchange or other taxable disposition of Offered Shares in an amount equal to the difference between the amount realized from such sale or exchange and the U.S. Holder's tax basis for those Offered Shares, in each case as determined in U.S. dollars. Subject to the discussion under "—Passive Foreign Investment Company Considerations" below, this gain or loss will generally be a capital gain or loss. The adjusted tax basis in Offered Shares generally will be equal to the cost of such Offered Shares. Capital gain from the sale, exchange or other taxable disposition of Offered Shares of a non-corporate U.S. Holder is generally eligible for a preferential rate of taxation applicable to capital gains, if the non-corporate U.S. Holder's holding period determined at the time of such sale, exchange or other taxable disposition for such Offered Shares exceeds one year (i.e., such gain is long-term taxable gain). The deductibility of capital losses for U.S. federal income tax purposes is subject to limitations. Any such gain or loss that a U.S. Holder recognizes generally will be treated as U.S. source income or loss for foreign tax credit limitation purposes.

If a U.S. Holder sells or otherwise disposes of the Offered Shares in exchange for currency other than U.S. dollars, the amount realized generally will be the U.S. dollar value of the currency received. If the Offered Shares are traded on an established securities market when the U.S. Holder sells or otherwise

disposes of the Offered Shares, the amount realized will be, in the case of cash basis and electing accrual basis U.S. Holders, determined using the spot rate on the settlement date. An accrual basis U.S. Holder that does not elect to determine the amount realized using the spot exchange rate on the settlement date will recognize foreign currency gain or loss equal to the difference between the U.S. dollar value of the amount received based on the spot exchange rates in effect on the date of the sale or other disposition and the settlement date. A U.S. Holder will have a tax basis in the currency received equal to the U.S. dollar value of the currency received at the spot rate on the settlement date. Any currency gain or loss realized on the settlement date or the subsequent sale, conversion, or other disposition of the non-U.S. currency received for a different U.S. dollar amount generally will be U.S.-source ordinary income or loss and will not be eligible for the reduced tax rate applicable to long-term capital gains. If an accrual basis U.S. Holder makes the election described in the second sentence of this paragraph, it must be applied consistently from year to year and cannot be revoked without the consent of the IRS. A U.S. Holder should consult its own tax advisors regarding the treatment of any foreign currency gain or loss realized with respect to any currency received in a sale or other disposition of the Offered Shares.

#### **13.11.3.3 MEDICARE TAX**

Certain U.S. Holders that are individuals, estates or trusts are subject to a 3.8% tax on all or a portion of their “net investment income,” which may include all or a portion of their dividend income and net gains from the disposition of Offered Shares. Each U.S. Holder that is an individual, estate or trust is urged to consult its tax advisors regarding the applicability of the Medicare tax to its income and gains in respect of its investment in the Offered Shares.

#### **13.11.3.4 PASSIVE FOREIGN INVESTMENT COMPANY CONSIDERATIONS**

If Hyloris is a PFIC for any taxable year when a U.S. Holder owns Offered Shares, the U.S. Holder would be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

A corporation organized outside the United States generally will be classified as a PFIC for U.S. federal income tax purposes in any taxable year in which, after applying certain look-through rules with respect to the income and assets of its subsidiaries, either: (i) at least 75% of its gross income is “passive income” or (ii) at least 50% of the average quarterly value of its total gross assets (which is measured by the fair market value of our assets, and for which purpose the total value of our assets may be determined in part by reference to the market value of the Shares, which is subject to change) is attributable to assets that produce “passive income” or are held for the production of “passive income.”

Passive income for this purpose generally includes dividends, interest, royalties, rents, gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income, and includes amounts derived by reason of the temporary investment of cash, including the funds raised in the Offering. If a non-U.S. corporation owns directly or indirectly at least 25% by value of the stock of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation and as receiving directly its proportionate share of the other corporation’s income. If Hyloris is a PFIC for any year with

respect to which a U.S. Holder owns Offered Shares, it will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the Offered Shares, regardless of whether Hyloris continues to meet the tests described above.

Whether the Issuer is a PFIC for any taxable year will depend on the composition of its income and the composition and fair market values of its assets in each year, and because this is a factual determination made annually after the end of each taxable year, there can be no assurance that the Issuer will not be considered a PFIC for any taxable year. An important aspect of the determination of whether Hyloris is or will be a PFIC is whether Hyloris' royalty income should be treated as passive income (and whether its related assets are treated as held for the production of passive income). Although royalties are generally treated as passive, royalties that are derived in the "active conduct of a trade or business" as provided under applicable U.S. Treasury regulations are not treated as passive income. There is little guidance available to determine whether royalty income received by Hyloris is treated as derived in the active conduct of a trade or business. In general, royalties received on property that Hyloris, through its own officers, staff or employees, has developed, created or produced, or property that Hyloris acquired and through its own officers, staff and employees has added substantial value will be treated as royalties derived in the active conduct of a trade or business, provided that Hyloris is regularly engaged in the development, creation or production of, or in the acquisition and addition of substantial value to, property of such kind. Although Hyloris intends to increase its staff over time after the Offering, it currently has a relatively small number of officers, staff and employees, which includes several scientists that are involved in certain aspects of the creation and development of intellectual property and in the addition of substantial value to such property. Hyloris believes that its royalty income currently may be treated as derived in the active conduct of a trade or business, and therefore does not believe it should be treated as a PFIC for its most recent taxable year. However, Hyloris has not sought, and Hyloris does not expect to seek, an IRS ruling on this matter. No assurance can be given that the IRS or a court of law will accept Hyloris' position.

With respect to the current taxable year and future taxable years, as noted above Hyloris must make a separate determination after the close of each taxable year as to whether it was a PFIC for such year. As a result, Hyloris' PFIC status may change from year to year. For example, the total value of Hyloris' assets for purposes of the asset test generally may be determined in part by reference to the market price of the Shares, which may fluctuate considerably. Fluctuations in the market price of the Shares, among other uncertainties, may result in Hyloris being a PFIC for any taxable year. Further, the application of the PFIC rules is subject to uncertainty in several respects, including with respect to whether royalty income for the current year or any subsequent year will be treated as derived in the active conduct of a trade or business. Moreover, the composition of Hyloris' income and assets will vary over time. As the application of the relevant rules to Hyloris' business is not entirely clear and certain aspects of the relevant tests will be outside Hyloris' control, Hyloris cannot provide any assurances regarding its PFIC status for the current, prior or future taxable years. Hyloris does not undertake to monitor its PFIC status on an ongoing basis.

If Hyloris is a PFIC for any taxable year, then, unless a U.S. Holder makes one of the elections described below, a special tax regime will apply to both (a) any "excess distribution" by Hyloris to a U.S. Holder (generally, the U.S. Holder's ratable portion of distributions in any year which are greater than 125% of the average annual distribution received by the U.S. Holder in the shorter of the three preceding years or the U.S. Holder's holding period for the Offered Shares) and (b) any gain realized on the sale or other

disposition of the Offered Shares. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over the U.S. Holder's holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before Hyloris became a PFIC, which would be subject to tax at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. A U.S. Holder that is not a corporation will be required to treat any such interest paid as nondeductible personal interest. The tax liability for amounts allocated to years prior to the year of the excess distribution or disposition cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the Offered Shares cannot be treated as capital gains, even if a U.S. Holder holds the Offered Shares as capital assets. Further, for these purposes, a U.S. Holder who uses Offered Shares as collateral for a loan would be treated as having disposed of such Offered Shares. In addition, dividend distributions made to a U.S. Holder will not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under "—Distributions."

If the Issuer is treated as a PFIC with respect to a U.S. Holder for any taxable year, the U.S. Holder will be deemed to own shares in any of the Issuer's subsidiaries that are also PFICs (each, a **lower-tier PFIC**), and the U.S. Holder may be subject to the tax consequences described above with respect to the shares of such lower-tier PFICs.

Certain elections exist that would result in an alternative treatment (such as mark-to-market treatment) of the Offered Shares. If a U.S. Holder makes the mark-to-market election, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the Offered Shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the Offered Shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the Offered Shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of Offered Shares in a year when Hyloris is a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

The mark-to-market election is available only if Hyloris is a PFIC and the Offered Shares are "regularly traded" on a "qualified exchange." The Offered Shares will be treated as "regularly traded" in any calendar year in which more than a de minimis quantity of the Offered Shares are traded on a qualified exchange on at least 15 days during each calendar quarter, except in the case of the year in which the Offering takes place, any calendar quarters prior to the quarter in which the Offering takes place are ignored, and the requirement for the quarter in which the Offering takes place is that the Offered Shares trade for one-sixth of the days remaining in such quarter (and subject to the rule that trades that have as one of their principal purposes the meeting of the trading requirement are disregarded). The Offered Shares will be traded on Euronext Brussels which may qualify as a "qualified exchange" for this purpose, but no assurances can be given in this regard.

However, because a mark-to-market election cannot be made for any lower-tier PFICs that the Issuer may own, a U.S. Holder generally will continue to be subject to the PFIC rules discussed above with respect to the Issuer's direct or indirect subsidiaries that are PFICs.

If a U.S. Holder makes an effective mark-to-market election, it will be effective for the taxable year for which the election is made and all subsequent taxable years unless the Shares are no longer regularly traded on a qualified exchange or the IRS consents to the revocation of the election. A U.S. Holder should consult its tax advisor about the availability of the mark-to-market election and whether making the election would be advisable in its particular circumstances.

In certain circumstances, a U.S. Holder in a PFIC may avoid the adverse tax and interest-charge regime described above by making a qualified electing fund (or **QEF**) election to include in income the holder's share of the PFIC's income on a current basis. However, a U.S. Holder may make a QEF election only if the PFIC provides the U.S. Holder with certain tax information. Hyloris does not intend to provide to U.S. Holders the information necessary to make QEF elections, if the Issuer or its subsidiaries are classified as PFICs. Each U.S. Holder therefore should assume that it will not receive such information from Hyloris and consequently will be unable to make potentially favorable QEF elections if Hyloris or any of its subsidiaries are or become PFICs.

If the Issuer is determined to be a PFIC, the general tax treatment for U.S. Holders described in this section would apply to indirect distributions and gains deemed to be recognized by U.S. Holders in respect of any subsidiaries that also may be determined to be PFICs.

If a U.S. Holder owns Offered Shares in any year in which the Issuer is treated as a PFIC, the U.S. Holder generally will be required to file an annual report on IRS Form 8621 with respect to the Issuer and each subsidiary that is a PFIC, generally with its federal income tax return for that year. Each U.S. Holder should consult its tax advisor concerning this annual filing requirement. A U.S. Holder's failure to file this annual report will cause the statute of limitations for its U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report. Further, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period.

The U.S. federal income tax rules relating to PFICs are complex. Prospective U.S. Holders are urged to consult their own tax advisors with respect to the acquisition, ownership and disposition of the Offered Shares, the consequences to them of an investment in a PFIC, any elections available with respect to the Offered Shares and the IRS information reporting obligations with respect to the acquisition, ownership and disposition of the Offered Shares.

#### **13.11.3.5**      **INFORMATION REPORTING AND BACKUP WITHHOLDING**

In general, information reporting will apply to dividends paid to U.S. Holders in respect of Offered Shares and the proceeds received by U.S. Holders from the sale or other taxable disposition of Offered Shares within the United States or through U.S.-related financial intermediaries, unless the U.S. Holder is an exempt recipient. Backup withholding tax may apply to these payments if the U.S. Holder fails to timely provide in the appropriate manner an accurate taxpayer identification number or otherwise fails to comply with, or establish an exemption from, such backup withholding tax requirements.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or credit against a U.S. Holder's U.S. federal income tax liability, provided that the required information is timely furnished to the IRS.

#### **13.11.3.6**      **FOREIGN ASSET REPORTING**

Certain U.S. Holders who are individuals and certain entities controlled by individuals may be required to report information relating to an interest in the Offered Shares, subject to certain exceptions (including an exception for shares held in accounts maintained by U.S. financial institutions) by filing IRS Form 8938 (Statement of Specified Foreign Financial Assets) with their federal income tax return.

A U.S. Holder that purchases Offered Shares for cash will be required to file an IRS Form 926 or similar form with the IRS if, among other things, the amount of cash transferred by such person (or any related person) to Issuer during the 12-month period ending on the date of such transfer exceeds \$100,000.

The U.S. Treasury and IRS continue to issue new guidance regarding information reporting requirements. Failure to comply with applicable disclosure requirements could result in the imposition of substantial penalties. U.S. Holders should consult their tax advisors regarding the information reporting obligations that may arise from their acquisition, ownership or disposition of Offered Shares.

THE DISCUSSION ABOVE IS A GENERAL SUMMARY. IT DOES NOT COVER ALL TAX MATTERS THAT MAY BE OF IMPORTANCE TO A PROSPECTIVE INVESTOR. EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OFFERED SHARES IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

## 14 INFORMATION ON THE OFFERING

### 14.1 EXPECTED TIMETABLE FOR THE OFFERING

Certain key dates in connection with the Offering are summarized in the following table. The Issuer can adjust the dates and times of the capital increase and the periods indicated in the below Timetable and in this Prospectus. In that case, the Issuer will inform Euronext Brussels and the investors thereof through a press release and on the website of the Issuer. Insofar as legally required, the Issuer will furthermore publish a supplement to this Prospectus.

17 June 2020, at 9:00 (CEST)	Expected start of the Offering Period
25 June 2020, at 16:00 (CEST)	Expected end of the Offering Period for Retail Investors
26 June 2020, at 13:00 (CEST)	Expected end of the Offering Period for Institutional Investors <sup>(1)</sup>
26 June 2020	Expected publication of the Offer Price and results of the Offering and communication of allocations
29 June 2020	Expected Listing Date (listing and start of “if-and-when-issued-and/or-delivered” trading)
30 June 2020	Expected Closing Date (payment, settlement and delivery of the Offered Shares)
29 July 2020	Expected last possible exercise date of the Over-allotment Option <sup>(2)</sup>

Notes:

- (1) In the event of an early closing or extension of the Offering Period, these dates will be amended and published in the same manner as the announcement of the start of the Offering Period. If the Offering Period is extended with more than five business days, this will also be published in a supplement to this Prospectus.
- (2) To enable the Stabilization Manager, acting on behalf of the Underwriters, to cover over-allotments or short positions, if any, resulting from the over-allotment, if any (for further information, see section 14.17 (Over-allotment Option)).

### 14.2 CONDITIONS AND NATURE OF THE OFFERING

The Offering consists of: (i) an offer to the public (as defined in Article 2(d) of the Prospectus Regulation) in Belgium; (ii) a private placement in the European Economic Area (the EEA) (other than in Belgium) pursuant to applicable exemptions under the Prospectus Regulation, including but not limited to

“qualified investors” within the meaning of Article 2(e) of the Prospectus Regulation; (iii) a private placement in the United States to persons who are reasonably believed to be “QIBs” (as defined in Rule 144A under the U.S. Securities Act), in reliance on Rule 144A; and (iv) private placements to certain qualified and/or institutional investors under applicable laws of the relevant jurisdiction in the rest of the world. All aforementioned “qualified investors” and QIBs are collectively being referred to as Institutional Investors. The Offering outside the United States will be made in compliance with Regulation S under the U.S. Securities Act.

The Offering is an offering of up to 5,000,000 new Shares, it being understood that:

- this aggregate number of 5,000,000 initially offered new Shares sold in the Offering may, pursuant to the Increase Option, be increased by up to 15% to 5,750,000 New Shares (see section 14.12 (Increase Option));
- in order to facilitate stabilization by the Stabilization Manager in connection with the Offering, if any, the Stabilization Manager will be able to over-allot Shares in the Offering (the Additional Shares – see 14.17 (Over-allotment Option) for more information); and
- to enable the Stabilization Manager to cover the placement of Additional Shares in the Offering, if any, or short positions created by such over-allotment, it is expected that the Stabilization Manager will be granted a warrant to subscribe for additional new Shares during the Stabilization Period in a number equal to up to 15% of the number of New Shares subscribed for in the Offering (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offer Price (the Over-allotment Option – see Section 14.17 (Over-allotment Option) for more information).

The 5,000,000 initially offered new Shares, together with the new Shares (if any) issued pursuant to the Increase Option, collectively being referred to as the New Shares, and the New Shares, together with the Additional Shares (if any) issued pursuant to the over-allotment in the Offering, collectively being referred to as the Offered Shares.

The Underwriters are KBC Securities NV/SA and Van Lanschot Kempen Wealth Management N.V. (see Section 15.1 (Underwriting Agreement)).

The actual number of Offered Shares subscribed for in the Offering will only be determined after the Offering Period and will be published in the financial press and by way of a press release of the Issuer, simultaneously with the publication of the Offer Price and the allocation of the Offered Shares to Retail Investors. Such publication is currently expected to be made on or about 26 June 2020 and in any event no later than the first business day after the end of the Offering Period. The results of the stabilization and the exercise of the Over-allotment Option (if any) by the Stabilization Manager during the Stabilization Period will be made public within one week of the end of the Stabilization Period (see also Section Over-allotment Option (Over-allotment Option)).

No minimum amount is set for the Offering. If not all of the 5,000,000 initially offered New Shares are subscribed for in the Offering, the net proceeds from the Offering could be limited to the net proceeds from the Pre-commitments of the Participating Investors. The Issuer reserves the right to withdraw the Offering or suspend the Offering Period (see Section 14.9 (Withdrawal of suspension of the Offering)).

or to reduce the number of the 5,000,000 initially offered New Shares at any time prior to the allocation of the 5,000,000 initially offered New Shares.

A reduction in the number of the 5,000,000 initially offered New Shares prior to expiry of the Offering Period will be published in the financial press, by means of a press release, through electronic information services such as Reuters or Bloomberg, and in a supplement to this Prospectus. In the event of a publication of a supplement to this Prospectus, investors will have the right to withdraw their orders provided that the significant new factor, a material mistake or material inaccuracy arose or was noted before closing of the Offering Period (see Section 14.10 (Right to withdraw subscription orders)). Investors withdrawing their order will not have any claim to the delivery of the 5,000,000 initially offered New Shares or any compensation.

### 14.3 PRE-COMMITMENTS

The Participating Investors, who are all lenders pursuant to the Convertible Bonds (see Section 13.6 (Convertible Bonds)), have, by way of the Pre-commitments, irrevocably and conditional only on completion of the Offering, committed themselves to subscribe for New Shares in the Offering for a total aggregate amount of EUR 22.725 million (*i.e.*, at a ratio of 1:1.5 (amount subscribed for under the Convertible Bonds: amount subscribed for in the Offering pursuant to the Pre-commitments)).

In the event the Offering is oversubscribed, a maximum of one third of the Pre-commitment of each individual Participating Investor (*i.e.*, EUR 7,575,000 in the aggregate) can be reduced in line with the allocation principles that apply in the context of the Offering, whereas a minimum of two thirds of the Pre-commitment of each individual Participating Investor (*i.e.*, EUR 15,150,000 in the aggregate) will not be reduced but will be allocated entirely to the relevant Participating Investor (see Section 14.13 (Allocation)).

The table below gives an overview of the individual amounts of the Pre-commitments of each Participating Investor:

Name Participating Investor	Amount Pre-commitment (€)	New Shares pursuant to the Pre-commitment assuming full allocation and assuming the Offer Price is the midpoint of the Price Range, <i>i.e.</i> , EUR 10.75
Scorpioux SRL	6,000,000	558,139
NOSHAQ SA	2,400,000	223,255
Saffelberg Investments SA	2,400,000	223,255
Jean-Claude Marian	1,500,000	139,534
NomalInvest SA	1,500,000	139,534
Dirk Van Praag	1,500,000	139,534
Stijn Van Rompay	1,500,000	139,534
TrustCapital SA	1,125,000	104,651
GIPAR SA	600,000	55,813
Atlantis Invest SRL	450,000	41,860
Thojo BM	450,000	41,860
Arno Verhoeven	450,000	41,860
Marc Corluy	300,000	27,906
Koen Matthijs	300,000	27,906
Dirk Vandeputte	300,000	27,906
Peter Hellings	225,000	20,930
Ludo and Ria Schellens-Brullemans	225,000	20,930
Pierre-Yves André	150,000	13,953
Johan De Meester	150,000	13,953
Joris De Meester	150,000	13,953

Fiduciam	150,000	13,953
Bart Roscam	150,000	13,953
Sediaal SA	150,000	13,953
Koenraad Van der Elst	150,000	13,953
Stefan Vandeputte	150,000	13,953
Serge Vermeersch	150,000	13,953
Inge Weyns-Verlinden	150,000	13,953
<b>Total</b>	<b>22,725,000</b>	<b>2,113,937</b>

#### **14.4 INTENTIONS OF THE SHAREHOLDERS, MEMBERS OF THE BOARD OF DIRECTORS AND OF THE EXECUTIVE MANAGEMENT OF THE ISSUER**

The existing shareholders of the Issuer have explicitly and irrevocably waived their statutory preferential subscription right in the context of the Offering.

Except for the Pre-commitments of the Participating Investors (see Section 14.3 (Pre-commitments)), the Issuer has not received any indication from existing shareholders, members of the Board of Directors or Executive Management that such persons have the intention to subscribe for the Offering.

The existing shareholders and the Issuer have entered into a lock-up agreement (see Section 15.3.2(Conventional post-IPO lock-up) for more information thereon).

#### **14.5 OFFER PRICE**

The Offer Price will be a single price in euro, exclusive of the Belgian tax on stock exchange transactions, if applicable (see Section 13.11.2.3 (System of taxation on stock exchange transactions (TSET))), and costs, if any, charged by financial intermediaries for the submission of applications, and will apply to all investors, whether Retail Investors or Institutional Investors.

The Offer Price will be determined within the Price Range on the basis of a book-building process in which only Institutional Investors can participate, taking into account various relevant qualitative and quantitative elements, including but not limited to the number of Offered Shares for which subscriptions are received, the size of subscription orders received, the quality of the investors submitting such subscription orders and the prices at which the subscription orders were made, as well as market conditions at that time.

The Price Range has been determined by the Issuer after consultation with the Underwriters, taking into account market conditions and factors including but not limited to:

- the condition of the financial markets;
- the Issuer's financial position;
- qualitative assessment of the demand for the Offered Shares; and
- all other factors deemed relevant.

The Issuer reserves the right to increase or decrease the lower limit of the Price Range or to decrease the upper limit of the Price Range. If the Price Range is narrowed through an increase of the lower limit

and/or a decrease of the upper limit, or if the Price Range is narrowed to a single price, the change will be published in the financial press and by means of a press release, through electronic information services such as Reuters or Bloomberg. However, Investors who have submitted subscription orders will not be individually notified of any such Price Range narrowing. A change to the Price Range by a decrease of the lower limit of the Price Range will also be published in the financial press and by means of a press release, through electronic information services, as well as in a supplement to this Prospectus. The relevant financial intermediary shall contact investors on the day when a supplement is published. The Offer Price for investors shall not, however, exceed the higher end of the Price Range. In the event of a publication of a supplement to this Prospectus, investors will have the right to withdraw their orders made prior to the publication of the supplement (see Section 14.10 (Right to withdraw subscription orders) below).

Retail Investors can only acquire the Offered Shares at the Offer Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void or (ii) in the event of the publication of a supplement to this Prospectus in accordance with the Prospectus Regulation, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement in accordance with the Prospectus Regulation, as further specified below (see Section 14.10 (Right to withdraw subscription orders) below).

#### **14.6 DILUTION RESULTING FROM THE OFFERING**

See Section 11 (Significant Shareholders) of this Prospectus.

#### **14.7 OFFERING PERIOD**

The Offering Period will begin at 9:00 (CEST) on 17 June 2020 and is expected to close no later than 13:00 (CEST) on 26 June 2020, subject to the possibility of an early closing (without placement of all of the 5,000,000 initially offered New Shares, thereby resulting in a reduction in the number of initially offered New Shares), or extension, provided that the Offering Period will in any event be open for at least six business days. This Prospectus will be made available as of the first calendar day of the Offering Period. The Offering Period can be closed, at the earliest, six business days after the start of the Offering Period and, hence, prospective investors can submit their orders at least during six business days after the start of the Offering Period. However, in accordance with the possibility provided for in art. 3, § 2 of the Royal Decree of May 17, 2007 on primary market practices, the Issuer expects the Offering Period for the Retail Investors to end on 25 June 2020 at 16:00 (CEST), the day before the end of the institutional bookbuilding period, due to the timing and logistical constraints associated with the centralization of the subscriptions placed by Retail Investors with the Underwriters and with other financial institutions. Any extension or early closing of the Offering Period will be announced by means of a press release by the Issuer, and the respective dates for pricing, allocation, publication of the Offer Price and the results of the Offering, “as-if-and-when-issued-and/or-delivered” trading and closing of the Offering will in such case be adjusted accordingly.

In the event the Offering Period is extended with more than five business days, this will be published in a supplement to this Prospectus. Investors who have already agreed to subscribe for the Offered Shares

before the supplement is published will have the right, exercisable within at least two business days after the publication of the supplement, to withdraw their subscription orders, provided that the significant new development, material mistake or inaccuracy referred to above arose before the closing of the Offering and the delivery of the Offered Shares. The Offering Period can only be closed earlier in the event of a coordinated action between the Underwriters. In the event the Offering Period is extended with five business days or less, this will only be announced by means of a press release by the Issuer. Prospective investors can submit their subscription orders during the Offering Period. Taking into account the fact that the Offering Period may be closed early, investors are invited to submit their applications as promptly as possible.

The timeline, validity and form of instructions to financial intermediaries in relation to the subscription for or purchase of Offered Shares will be determined by each financial intermediary in accordance with its usual procedures or as otherwise notified to the investors. The Issuer is not liable for any action or failure to act by a financial intermediary in connection with any subscription or purchase, or purported subscription or purchase, of Offered Shares.

#### **14.8 APPLICATION**

Subscription orders by Retail Investors may be submitted through Bolero, the online investment platform of KBC Bank NV/SA and CBC Banque SA/NV, at the counters of KBC Bank NV/SA, CBC Banque SA/NV in Belgium, and at the counters of Van Lanschot Kempen Wealth Management N.V., Belgian branch, at no cost to the investor or alternatively through other than the aforementioned intermediaries. Applications are not binding upon the Issuer or the Underwriters as long as they have not been accepted in accordance with the allocation rules described below under Section 14.13 (Allocation).

Investors wishing to place purchase orders for the Offered Shares through intermediaries other than Bolero, KBC Bank NV/SA in Belgium, CBC Banque SA/NV in Belgium, or Van Lanschot Kempen Wealth Management N.V., Belgian branch, should request details of the costs which these intermediaries may charge, and which they will have to pay themselves.

To be valid, the subscription orders must be submitted no later than 25 June 2020 at 16:00 (CEST), unless the Offering Period is closed earlier or extended, in which case the subscription orders must be submitted no later than 16:00 (CEST) at such earlier or extended closing date of the Offering Period.

##### **14.8.1 RETAIL INVESTORS**

A **Retail Investor** shall mean an individual person resident in Belgium or a legal entity located in Belgium that does not qualify as a “qualified investor” within the meaning of Article 2(e) of the Prospectus Regulation.

Retail Investors must indicate in their subscription orders the number of Offered Shares they are committing to subscribe for. Every order must be expressed in number of Offered Shares with no indication of price and shall be deemed placed at the Offer Price. Only one application per Retail Investor will be accepted. If the Underwriters determine, or have reason to believe, that a single Retail Investor has submitted several subscription orders, through one or more intermediaries, they may disregard such

subscription orders. There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in Section 14.13 (Allocation).

KBC Securities NV/SA will act as centralization agent for subscription orders by Retail Investors.

#### **14.8.2 INSTITUTIONAL INVESTORS**

Institutional Investors must indicate in their subscription orders the number of Offered Shares or an amount they are committing to subscribe for, and the prices at which they are making such subscription orders during the book-building period.

There is no minimum or maximum amount or number of Offered Shares that may be subscribed for in one subscription order. Subscription orders are subject to a possible reduction as described below in Section 14.13 (Allocation).

Only Institutional Investors can participate in the book-building process during the Offering Period.

#### **14.9 WITHDRAWAL OF THE OFFERING OR SUSPENSION OF THE OFFERING PERIOD**

The Issuer reserves the right to withdraw the Offering or suspend the Offering Period should the Underwriting Agreement not be signed. Furthermore, the Issuer reserves the right to withdraw or suspend the Offering if the Underwriting Agreement is dissolved in the foreseen circumstances as described in the Underwriting Agreement (see Section 15.1 (Underwriting Agreement)). Such withdrawal of the Offering or the suspension of the Offering Period can occur up to the closing of the Offering.

The Issuer also reserves the right to withdraw the Offering or suspend the Offering Period if the Board of Directors following recommendations from the Underwriters, acknowledges that the quality and quantity of the subscriptions received is such that the Offering cannot be closed in the interest of the Issuer.

Any withdrawal of the Offering or suspension of the Offering Period will be published in the financial press, by means of a press release, through electronic information services such as Reuters or Bloomberg. To the extent required, also a supplement will be published. In the event of a withdrawal of the Offering, all orders received will automatically be cancelled and withdrawn, and investors will not have any claim to the delivery of the Offered Shares or any compensation. The amounts already paid by the prospective investors will be reimbursed within three Business Days, without, however, being entitled to interest on this amount or to any form of compensation for any reason whatsoever.

In the event of withdrawal of the Offering or suspension of the Offering Period, the Issuer will also be able to withdraw the application for admission to trading of all Shares on the regulated market Euronext Brussels, and will immediately notify Euronext Brussels NV of this.

#### **14.10 RIGHT TO WITHDRAW SUBSCRIPTION ORDERS**

Retail Investors can only acquire the Offered Shares at the Offer Price and are legally bound to acquire the number of Offered Shares indicated in their subscription order at the Offer Price, unless (i) the Offering has been withdrawn in which case the subscription orders will become null and void, or (ii) in the event of the publication of a supplement to this Prospectus, in which case the Retail Investors will have the right to withdraw their orders made prior to the publication of the supplement.

In accordance with Article 23.1 Prospectus Regulation, every significant new factor, material mistake or material inaccuracy relating to the information included in this Prospectus which may affect the assessment of the Offered Shares and which arises or is noted between the date of approval of this Prospectus (*i.e.*, 16 June 2020) and the Listing Date, shall be mentioned in a supplement to this Prospectus without undue delay. Any supplement is subject to approval by the FSMA, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

In accordance with Article 23.3 of the Prospectus Regulation, where the securities are purchased or subscribed through a financial intermediary, that financial intermediary shall inform investors of the possibility of a supplement being published, where and when it would be published and that the financial intermediary would assist them in exercising their right to withdraw acceptances in such case. The financial intermediary shall contact investors on the day when the supplement is published.

Investors who have already agreed to purchase or subscribe for the Offered Shares before the supplement is published shall have the right, exercisable within two working days after the publication of the supplement, to withdraw their acceptances, provided that the significant new factor, material mistake or material inaccuracy referred to above arose or was noted before closing of the Offering Period. The final date of the right of withdrawal shall be stated in the supplement.

A supplement to this Prospectus will be published in accordance with Article 23 of the Prospectus Regulation, *inter alia* (i) in the event the Offer Price is set below the lower end of the Price Range, (ii) if the lower limit of the Price Range is decreased, (iii) if the Offering Period is extended with more than five business days, (iv) if the maximum number of Offered Shares is materially reduced, including due to an early closing of the Offering Period without placement of all of the 5,000,000 initially offered New Shares, (v) if the Underwriting Agreement is not executed or is executed but subsequently terminated or (vi) to the extent required, if the Offering is withdrawn. If such significant new factor, material mistake or material inaccuracy mentioned in a supplement arises or is noted before the closing of the Offering Period, investors shall have the right to withdraw their acceptances.

Retail Investors that wish to withdraw their subscription order should contact their financial intermediaries in order to check how their subscription order can be withdrawn.

#### **14.11 SHARE LENDING**

Stijn Van Rompay and/or Pieter Van Rompay is/are expected to agree to lend to the Stabilization Manager (acting on behalf of the Underwriters) a number of Shares equal to up to 15% of the number of New Shares subscribed for in the Offering (including the New Shares subscribed for pursuant to the

effective exercise of the Increase Option, if any) in order to enable the Stabilization Manager to settle over-allotments.

#### **14.12 INCREASE OPTION**

Depending on the volume of demand, the 5,000,000 initially offered new Shares sold in the Offering may be increased by up to 15% to a number of 5,750,000 New Shares. Any decision to exercise the Increase Option will be communicated at the latest on the date of announcement of the Offer Price, which is currently expected to be on or around 26 June 2020. To the extent that such Increase Option has been exercised and subject to entering into the Underwriting Agreement, the Underwriters will severally subscribe to such additional New Shares in the same proportion as set forth in the table in Section 15.1 (Underwriting Agreement).

#### **14.13 THE ALLOCATION OF THE OFFERED SHARES**

The exact number of Offered Shares allotted to investors will be determined at the end of the Offering Period by the Issuer after consultation with the Underwriters on the basis of the respective demand of both Retail Investors and Institutional Investors and on the quantitative, and, for Institutional Investors only, the qualitative analysis of the order book, in accordance with Belgian regulations relating to allocation to Retail Investors and Institutional Investors as set forth below.

In accordance with Belgian regulations, a minimum of 10% of the Offered Shares shall be allocated to Retail Investors, subject to sufficient retail demand. However, the proportion of Offered Shares allocated to Retail Investors may be increased or decreased if subscription orders received from them exceed, respectively, do not reach 10% of the Offered Shares effectively allocated.

In the event of over-subscription of the Offered Shares reserved for Retail Investors, the allocation to Retail Investors will be made on the basis of objective and quantitative allocation criteria, whereby all Retail Investors will be treated equally. The criteria to be used for allocation are the preferential treatment of applications submitted by Retail Investors at the counters of KBC Bank NV/SA and CBC Banque SA/NV and through Bolero (the online investment platform of KBC Bank NV/SA and CBC Banque SA/NV) in Belgium, and at the counters of Van Lanschot Kempen Wealth Management N.V., Belgian branch, and the number of Offered Shares for which applications are submitted by Retail Investors. Furthermore, in the event the Offering is oversubscribed, a maximum of one third of the Pre-commitment of each individual Participating Investor (*i.e.*, EUR 7,575,000 in the aggregate) can be reduced in line with the allocation principles that apply in the context of the Offering, whereas a minimum of two thirds of the Pre-commitment of each individual Participating Investor (*i.e.*, EUR 15,150,000 in the aggregate) will not be reduced but will be allocated entirely to the relevant Participating Investor (see Section 14.3 (Pre-commitments)).

The results of the Offering, the allocation to Retail Investors, the Offer Price, and the allocation criteria (in the event of over-subscription) will be announced by the Issuer on or about 26 June 2020 and in any event no later than the first business day after the end of the Offering Period. In the event of an over-allotment, the Underwriters will use reasonable efforts to deliver the New Shares to individual persons residing in Belgium and to investors subject to Belgian income tax on legal entities ("*impôt des*

*personnes morales*"/"rechtspersonenbelasting"), in this order of priority. No tax on stock exchange transactions is due on the subscription for newly issued Shares, but such tax could be due on the subscription for existing Shares (see Section 13.11.2.3 (System of taxation on stock exchange transactions (TSET))).

#### **14.14 PAYMENT, SETTLEMENT AND DELIVERY OF THE OFFERED SHARES**

The Offer Price must be paid by the investors in full, in euro, together with any applicable stock exchange taxes and costs. No tax on stock exchange transactions is due on the subscription for newly issued Shares. For further information about applicable taxes, see Section 13.11.2 (Belgian taxation).

The payment date for the Offered Shares, which is also the Closing Date, is expected to be 30 June 2020 unless the Offering Period is closed earlier or extended. The Offer Price must be paid by investors by authorizing their financial institutions to debit their bank accounts with such amount for value on the Closing Date.

It is expected that the Offered Shares will be delivered to the investors on or about 30 June 2020, which is also the Closing Date.

All Offered Shares will be delivered in dematerialized (book-entry) form only, and will be credited on or around the Closing Date to investors' securities accounts via Euroclear Belgium, and will be registered by one or more registrations in the share register of the Issuer in the name of Euroclear Belgium. By way of exception to the foregoing, the New Shares that will be issued to Participating Investors pursuant to the Pre-commitments (except if the Participating Investor that has an existing client relationship and securities account with KBC Bank NV/SA or CBC Banque SA/NV or Van Lanschot Kempen Wealth Management N.V. and has opted to have such New Shares delivered in dematerialized (book-entry) form and credited on such securities account), will be delivered in registered form on or about their issuance.

The new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, will also be delivered in registered form on or about their issuance.

#### **14.15 TYPE AND FORM OF THE SHARES**

##### **14.15.1 TYPE AND CLASS OF THE SHARES**

All New Shares, as well as the new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants, will be issued in accordance with Belgian law and will be ordinary shares representing the capital, of the same class as the existing Shares, fully paid up, with voting rights and without nominal value. They will have the same rights as the existing Shares.

All Offered Shares, as well as the new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the ESOP Warrants, will be profit sharing as from any distribution in respect of which the relevant ex-dividend date falls after the date of their issuance. The new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants will entitle their holder to the dividend distributed in the financial year during which the relevant Transaction Warrants are exercised, even if the dividend was declared or has been paid prior to the issuance of such new Shares.

#### **14.15.2 FORM**

As described in Section 14.14 (Payment, settlement and delivery of the Offered Shares), all Offered Shares (with the exception of the New Shares that will be issued to Participating Investors pursuant to the Pre-commitments) will be delivered in dematerialized (book-entry) form only, and will be credited on or around the Closing Date to investors' securities accounts via Euroclear Belgium, and will be registered by one or more registrations in the share register of the Issuer in the name of Euroclear Belgium.

By way of exception to the foregoing, the (i) New Shares that will be issued to Participating Investors pursuant to the Pre-commitments (except if the Participating Investor has an existing client relationship and securities account with KBC Bank NV/SA, CBC Banque SA/NV or Van Lanschot Kempen Wealth Management N.V. and has opted to have such New Shares delivered in dematerialized (book-entry) form and credited on such securities account), (ii) new Shares that will be issued upon conversion of the Convertible Bonds, (iii) new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and (iv) new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, will be delivered in registered form on or about their issuance.

Holders of Shares may elect, at any time, to have their registered Shares converted into dematerialized Shares, and vice versa, at their own expense. Shareholders should inquire with their bank on the costs associated with this conversion.

All Offered Shares, as well as the new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, will be fully paid-up upon their delivery and freely transferable, subject to what is set forth under Section 13.8 (Restrictions on the free transferability of the Shares).

#### **14.15.3 ISSUING CURRENCY**

All Offered Shares, the new Shares that will be issued upon conversion of the Convertible Bonds, the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and the new Shares (if any) that will be issued pursuant to the exercise of the

Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, will be issued in euro.

#### **14.16 ADMISSION TO TRADING ON THE REGULATED MARKET OF EURONEXT BRUSSELS**

Prior to the Offering, there has been no public market for the Shares.

An application has been made to admit (i) all of the Issuer's existing Shares, (ii) the newly issued Offered Shares, (iii) the new Shares that will be issued upon conversion of the Convertible Bonds, (iv) the new Shares (if any) that will be issued pursuant to the exercise by the Stabilization Manager of the Over-allotment Option, and (v) the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021, to trading on the regulated market of Euronext Brussels under the symbol "HYL", and will be allocated the ISIN code BE0974363955.

Trading on the regulated market of Euronext Brussels is expected to commence:

- (i) for the existing Shares and the newly issued Offered Shares: on an "if-and-when-issued-and/or-delivered" basis, on or about 29 June 2020 (the **Listing Date**), provided that this may be accelerated in the event of early closing or postponed in case of extension, and will start at the latest on the Closing Date, when the New Shares are delivered to investors;
- (ii) for the new Shares that will be issued upon conversion of the Convertible Bonds: on the Closing Date;
- (iii) for the new Shares (if any) that will be issued pursuant to the exercise of the Over-allotment Option: on or about the date of their issuance; and
- (iv) for the new Shares (if any) that will be issued pursuant to the exercise of the Transaction Warrants or the ESOP Warrants and that, pursuant to such exercise, would be admitted to trading prior to 15 June 2021: on or about the date of their issuance.

As of the Listing Date until the Closing Date and delivery of the Offered Shares, the Shares will be traded on the regulated market of Euronext Brussels on an "as-if-and-when issued and/or delivered" basis. Investors who wish to effect transactions in Shares prior to the Closing Date, whether such transactions are effected on the regulated market of Euronext Brussels or otherwise, should be aware that the issuance and delivery of the Offered Shares may not take place on the expected Closing Date, or at all, if certain conditions or events referred to in the Underwriting Agreement (see Section 15.1 (Underwriting Agreement)) are not satisfied or waived or do not occur on or prior to such date. Euronext Brussels may annul all transactions effected in the Shares if the Offered Shares are not delivered on the Closing Date. See Risk Factor 2.5.3 (The Shares will be listed and traded on the regulated market of Euronext Brussels on an "if-and-when-issued-and/or-delivered" basis from the Listing Date until the Closing Date. Euronext Brussels may annul all transactions effected in the Shares if they are not issued and delivered on the Closing Date.). Euronext Brussels cannot be held liable for any damage arising from the listing and trading on an "if-and-when-issued-and/or-delivered" basis as of the Listing Date until the expected Closing Date.

#### **14.17 OVER-ALLOTMENT OPTION**

To enable the Stabilization Manager to cover the placement of Additional Shares in the Offering, if any, or short positions created by such over-allotment, it is expected that the Stabilization Manager will be granted an Over-allotment Option in the form of a warrant to subscribe for additional new Shares in a number equal to up to 15% of the number of New Shares subscribed for in the Offering (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offer Price. The Over-allotment Option will be exercisable for a period of 30 calendar days following the Listing Date. The Stabilization Manager, acting on behalf of the Underwriters, may engage in transactions that stabilize, maintain or otherwise affect the price of the Shares during a period of 30 calendar days following the Listing Date. These activities may support the market price of the Shares at a level higher than that which might otherwise prevail. See also Section 15.4 (Over-allotment Option and price stabilization) for more information.

#### **14.18 AUTHORIZATIONS**

This Prospectus was approved by the Board of Directors of the Issuer on 8 June 2020. The issuance of the New Shares and required amendments to the Issuer's Articles of Association, both of which are subject to the condition precedent of the closing of the Offering, were approved by the Shareholders of the Issuer at their Extraordinary General Shareholders' Meeting held on 8 June 2020.

#### **14.19 FINANCIAL SERVICE**

As from the Listing Date, the financial service for the Shares of the Issuer will be provided by KBC Bank NV/SA.

Should the Issuer alter its policy in this respect, this will be announced in accordance with applicable law.

#### **14.20 JURISDICTION AND COMPETENT COURTS**

The courts of Brussels are exclusively competent for any dispute that may arise between the shareholders, investors and the Issuer arising out of or in connection with the Offering and/or the Offered Shares.

## 15 UNDERWRITING AGREEMENT

### 15.1 UNDERWRITING

The Underwriters are KBC Securities NV/SA, having its registered office at Havenlaan 2, 1080 Brussels, Belgium and Van Lanschot Kempen Wealth Management N.V., having its office at Beethovenstraat 300, 1077 WZ Amsterdam, the Netherlands.

The Underwriters and the Issuer have committed themselves in good faith to negotiate an agreement (the **Underwriting Agreement**) that will contain the contractual arrangements between them in relation to the Offering. In line with normal market practice, such an agreement is only entered into upon the determination of the Offer Price, which is expected to take place on or about 26 June 2020. Therefore, at present, the Underwriters and the Issuer have no obligation to enter into such an agreement, to subscribe for the Offered Shares or to issue the New Shares.

In the event such an agreement is entered into between the Underwriters and the Issuer, it is expected that it will, in addition to a number of other elements, contain the following principles:

- Subject to the terms and conditions to be set forth in the Underwriting Agreement, the Underwriters will severally but not jointly agree to subscribe and procure payment for the following percentage of the total number of New Shares (including the New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) less those New Shares subscribed for by the Participating Investors pursuant to the Pre-commitments (the "**Underwritten Shares**"), in their own name but for the account of the relevant subscribers in the Offering to whom those Underwritten Shares have been allocated:

	<b>Percentage of Underwritten Shares to be subscribed for</b>
<b>Underwriters</b>	
KBC Securities NV/SA.....	50%
Van Lanschot Kempen Wealth Management N.V. ....	50%
<b>Total percentage of the Underwritten Shares to be subscribed for .....</b>	<b>100%</b>

- The Underwriters shall have no obligation to underwrite any of the Underwritten Shares prior to the execution of the Underwriting Agreement (and then only in accordance with the terms and subject to the conditions set forth therein).
- Immediately after receipt of the Underwritten Shares, the Underwriters will deliver such Underwritten Shares to the relevant subscribers in the Offering and the Underwriters shall guarantee to the Issuer the payment of the Offer Price.

- In the Underwriting Agreement, the Issuer will make certain customary representations and warranties and the Issuer will agree to indemnify each of the Underwriters against certain liabilities in connection with the Offering, including liability under the U.S. Securities Act.
- The Underwriting Agreement will provide that each Underwriter shall have the right to terminate the Underwriting Agreement before the realisation of the capital increase in relation to the Offering, upon the occurrence of certain events such as (i) a matter having arisen requiring under Belgian law the publication of a supplement to the Prospectus; (ii) there having been a breach of any of the representations and warranties made by the Issuer; (iii) the Issuer not having complied with the covenants and undertakings set out in the Underwriting Agreement; (iv) there having been or it being likely that there will be a material adverse effect; (v) any of the conditions precedent not having been satisfied, such as the delivery of the launch and closing documents; (vi) the application for trading being withdrawn or refused by Euronext Brussels; or (vii) a force majeure event having occurred. Following termination of the Underwriting Agreement by an Underwriter, the other Underwriter will be authorised but not obliged to further proceed with the Offering and the performance of the Underwriting Agreement without the involvement of the Underwriter who terminated the Underwriting Agreement.

In the event that the Underwriting Agreement is not executed or is executed but subsequently terminated, a supplement to this Prospectus shall be published. After publication of the supplement, the subscriptions for the Offered Shares will automatically be cancelled and withdrawn, and subscribers will not have any claim to delivery of the Offered Shares or to any compensation.

The underwriting commission and the placing commission payable to the Underwriters by the Issuer are expected to be maximum EUR 2,545,469, assuming a placement of the 5,000,000 initially offered New Shares in the Offering (*i.e.*, excluding the exercise in full or in part of the Increase Option and/or the Over-allotment Option) and that the Offer Price is at the midpoint of the Price Range, or EUR 3.412.188, assuming a placement of the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option) and exercise in full by the Stabilization Manager of the Over-allotment Option and that the Offer Price is at the midpoint of the Price Range.

## **15.2 STANDSTILL**

The Issuer is expected to agree pursuant to the Underwriting Agreement (which is expected to be entered into on or about 1 July 2020) that it will not, and it will procure that its affiliates will not, for a period of 360 days from the Closing Date, otherwise than with the prior written consent of the Joint Global Coordinators: (i) issue, offer, sell, contract to sell or otherwise transfer, (attempt to) dispose of, lend, or solicit any offer to buy (or publicly announce such action), directly or indirectly, any Shares or securities of the Issuer that are substantially similar to the Shares, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, Shares or any such substantially similar securities, (ii) grant or issue any options, warrants, convertible securities, other guaranty, or other rights to subscribe for or purchase shares in the Issuer, or enter into any swap, hedge or other arrangement pursuant to which the economic consequences of its ownership of Shares is transferred to any other person or entity, in whole or in part, whether any such transaction is to be

settled by delivery of Shares or such other securities, or cash or otherwise, or (iii) submit to its shareholders or any other body a proposal to effect any of the foregoing. The foregoing undertaking shall not apply in relation to (i) the Offered Shares and the Over-allotment Warrant, (ii) any Shares that may be issued upon exercise of the existing and allocated warrants and conversion of Convertible Bonds as set forth in the Prospectus, (iii) the adaptation of the issue and exercise conditions of the ESOP Warrants in the context of the Offering, (iv) the granting of warrants or options entitling their holders to subscribe for, or acquire, up to maximum 400,000 or securities of the Issuer that are substantially similar to the Shares under a management or employee incentive plan that may be implemented and the securities that may be issued or sold following exercise of such warrants or options, and/or (v) any issue or sale in the context of a merger, (partial) demerger, transfer of a universality or branch of activity or other corporate restructuring, acquisition, or strategic partnership, provided that any Shares issued or sold do not represent more than 10% of the Issuer's share capital at that time.

### **15.3 LOCK-UP**

#### **15.3.1 LOCK-UP PURSUANT TO THE IPO**

The current shareholders, the current warrant holders and the Participating Investors have entered into individual lock-up commitments vis-à-vis the Underwriters (dated June 2020), in respect of (i) any Shares that they held at the date of the lock-up commitment (if any), (ii) any Shares that they will receive as a result of a conversion of the Convertible Bonds that they held at the date of the lock-up commitment (if any), and (iii) any Shares that they will receive as a result of an exercise of any subscription rights of the Issuer held by them at the date of the lock-up commitment (if any), including, for the avoidance of doubt, (x) any of the Shares into which the latter Shares may be converted, exchanged, split or consolidated in the framework of the Offering (but excluding, for the avoidance of doubt, any of the Shares that they may acquire in the Offering at the Offering price, be it pursuant to the Pre-commitments or otherwise) (the **Locked Shares**), and (y) any securities or rights issued or agreed to by the Issuer and held by them at the date of the lock-up commitment (if any) that are convertible into or exercisable or exchangeable for Shares (including the Shares into which such securities or rights may be converted, exercised or exchanged) (together with the Locked Shares, the **Locked Securities**).

Pursuant to the lock-up arrangement, the holders of Locked Securities will not, for a period ending 360 days after the closing of the Offering, (i) directly or indirectly, issue, offer, pledge, exchange, lend, assign by way of security, grant any right "in rem", deliver or market, sell, contract to sell, sell or grant any option, right, warrant or contract to purchase, exercise any option to sell, purchase any option or contract to sell, or otherwise transfer or dispose of any of their Locked Securities, (ii) enter into any swap, any arrangement, any derivative transaction or issue any instruments that transfer (conditionally or unconditionally, now or in the future) to a third party all or part of the economic risk, benefits, rights or ownership of any Locked Securities, or (iii) publicly announce such an intention to effect any such transfer.

The restrictions do not prohibit holders of Locked Securities from (i) accepting a public take-over or tender offer (including by way of cash settlement of Locked Securities) on all the ordinary shares in the Issuer (other than the shares already owned by the offeror or potential offeror or persons affiliated with, acting as intermediary for, or acting in concert with such offeror or such potential offeror) or voting in

favour of a merger proposal, giving an irrevocable commitment to accept such an offer or vote in favour of such a merger proposal, or transferring Locked Securities to an offeror or potential offeror during the period of such an offer; (ii) transferring Locked Securities if required by law, regulation or a court of competent jurisdiction, provided that, if the transfer relates to Locked Shares representing more than 5% of the share capital in the Issuer at the time of closing of the Offering, the transferor acquires within 30 calendar days a number of Shares equivalent to the number of transferred Locked Shares through purchases in the open market, bilateral trades or otherwise; (iii) transferring Locked Securities (x) if the transferor is a legal entity, either to affiliated persons (as defined in article 1:20 of the Belgian Code of Companies and Associations) or to one or more legal successors (who are, or thereby become, affiliates) pursuant to a merger, liquidation, concursus ("*samenloop*"), (partial) de-merger, transfer or contribution of a branch of activity or transfer or contribution of a universality of the transferor, or (y) if the transferor is a natural person, either intra-family, to affiliated persons (as defined in article 1:20 of the Belgian Code of Companies and Associations) or to one or more legal successors pursuant to the death of the transferor, provided in each case that each such transferee shall continue to be bound by the lock-up arrangement for the remainder of the restriction period; (iv) lending a number of its Locked Shares to one of the Joint Global Coordinators in the framework of the Offering, it being understood that the Shares that at the expiry or maturity of the stock lending are redelivered shall become Locked Shares that are subject to the lock-up arrangement for the remainder of the restriction period; (v) transferring Locked Securities pursuant to the Call Option, as disclosed in the prospectus, provided that the transferees under the Call Option shall continue to be bound by the lock-up arrangement for the remainder of the restriction period; (vi) transferring Transaction Warrants, provided that the transferor shall procure that the transferee shall continue to be bound by the lock-up arrangement for the remainder of the restriction period (such clause in the agreement between the transferor and the transferee being a third-party beneficiary provision for the benefit of and accepted by the Joint Global Coordinators); or (vii) in relation to Mr. Stijn Van Rompay as transferor only, transferring Locked Shares if (A) the transferor (together with persons affiliated with, acting as intermediary for, or acting in concert with it (if any)) were to hold less than 30% of the voting securities in the Issuer immediately after the closing of the Offering and (B) in the absence of this exception would be forced to make a mandatory takeover bid on all of the Shares (other than the Shares already owned by the transferor or persons affiliated with, acting as intermediary for, or acting in concert with the transferor) upon acquisition of additional Shares through the exercise of any subscription or option rights held by the transferor, provided that (a) after these transfer(s) and the subsequent acquisition of Shares, the transferor (together with persons affiliated with, acting as intermediary for, or acting in concert with it (if any)) shall own 30% (or slightly less than 30% but in any event above 29.5%) of the voting securities in the Issuer (it is clarified that this will thus result in the decrease of the aggregate number of Locked Shares (on a fully diluted basis) with the difference between (x) the aggregate holding of Locked Shares (on a fully diluted basis) by the transferor (together with persons affiliated with, acting as intermediary for, or acting in concert with it (if any)) in the absence of this exception and (y) the actual aggregate holding of Locked Shares (on a fully diluted basis) by the transferor (together with persons affiliated with, acting as intermediary for, or acting in concert with it (if any)) after such transfer(s)); (b) such transfers shall occur with a view to avoiding the crossing of the mandatory takeover threshold but not earlier than 30 calendar days prior to the envisaged acquisition of Shares through the exercise of any subscription or option rights; (c) the Shares acquired through the exercise of any subscription or option rights shall become Locked Shares that are subject

to the lock-up arrangement for the remainder of the restriction period; and (d) the transfer (individually or taken together with any other transfers) will not violate any applicable laws and regulations.

In addition, transferring Locked Securities as from the 181th day after the first day of trading of the Shares on the regulated market of Euronext Brussels (on an “if-and-when-issued/delivered”-basis) until the end of the restriction period provided that (x) one or more of the current shareholders of the Issuer or of the Participating Investors holding in the aggregate at least 3.5% of the outstanding share capital of the Issuer at the time of the closing of the Offering, shall have requested and obtained the prior written approval of the Joint Global Coordinators, acting reasonably and (y) any such transfer for which such prior written consent has been given, shall solely be effected through a coordinated sale, whereby the following provisions shall apply:

- a. The Participating Investors agree that such a coordinated sale, shall - at the discretion of the Joint Global Coordinators - be coordinated or led by the Joint Global Coordinators.
- b. The Joint Global Coordinators will structure and conduct the coordinated sale in the manner to be agreed upon with the majority of Participating Investors (in terms of voting rights attached to the Locked Securities with which they participate in the coordinated sale) who are proposing to sell Locked Securities, it being understood that all Participating Investors will, at the outset of the coordinated sale process, be invited to participate in the intended size of the coordinated sale on a *pro rata* basis (*i.e.*, *pro rata* to the Locked Securities held by them).
- c. The intended size of the coordinated sale shall relate to at least 3.5% of the outstanding share capital of the Issuer at the time of the closing of the Offering.
- d. All Participating Investors participating in the coordinated sale shall be treated equally, unless agreed otherwise by the Participating Investors participating in the coordinated sale, it being understood that each Participating Investor will accept such terms and conditions of the coordinated sale as agreed to by at least a majority of Participating Investors (in terms of voting rights attached to the Locked Securities with which they participate in the coordinated sale).
- e. The organisation of the coordinated sale shall not give rise to an obligation to publish a prospectus or similar offering document that must be approved by any competent securities law authority or listing authority (such as the FSMA or Euronext Brussels) in order to facilitate the coordinated sale, and the Locked Shares so sold shall not be listed or traded on another market than the regulated market of Euronext Brussels.
- f. Any coordinated sale shall be organised in an expedient manner, without undue delay and in compliance with the applicable laws and regulations and may be conducted in the manner as determined reasonably appropriate by the Joint Global Coordinators in the given circumstances (including through a sale to one or more investors via the regulated market of Euronext Brussels or in over-the-counter transactions or other types of stock offerings), subject to the terms of this provision.

- g. The Joint Global Coordinators shall conduct any coordinated sale against brokerage terms and conditions in line with market practice and to be negotiated in good faith.

Assuming (i) the placement of the maximum number of New Shares (*i.e.*, including the exercise in full of the Increase Option) (ii) that the Offer Price is the midpoint of the Price Range, *i.e.*, EUR 10.75, (iii) the exercise in full by the Stabilization Manager of the Over-allotment Option, (iv) that all Pre-commitments are allocated in full to the Participating Investors, (v) that none of the Adjustment Warrants, Anti-dilution Warrants, Transaction Warrants and ESOP Warrants have been exercised and (vi) that the principal amount as per the expected Closing Date, increased with the unpaid interests accrued during the period starting on the relevant issue date of the Convertible Bonds and ending on the date preceding the expected Closing Date (included), is converted, then immediately after the closing of the Offering and the conversion of the Convertible Bonds, 75.01% of the Issuer's then outstanding Shares will be subject to this lock-up arrangement at the Closing Date.

### **15.3.2 CONVENTIONAL POST-IPO LOCK-UP**

Pursuant to the existing Shareholders' Agreement, the current shareholders of the Issuer and the Issuer have entered into a lock-up arrangement relating to the period after the Offering, in respect of the Shares held by the current Shareholders prior to the Offering (the **Conventionally Locked Securities**). The definition of Conventionally Locked Securities does not include any of the New Shares that may be subscribed for in the Offering (nor, for the avoidance of doubt, any Shares resulting from the conversion of the Convertible Bonds or any new Shares resulting from the exercise of Transaction Warrants or ESOP Warrants). The Shareholders' Agreement will be terminated as of the closing of the Offering, save for the post-IPO lock-up arrangement regarding the Conventionally Locked Securities.

Pursuant to this lock-up arrangement, each current Shareholder will not (i) take any action resulting in, which may result in, or having as goal, the transfer of a right *in rem* or any rights or obligations linked to the Conventionally Locked Securities, with or without consideration, including a sale, gift, contribution, swap, creation of a pledge or any other security interest, dissolution and liquidation, merger, demerger, transfer of (part of) the activity, divorce, death, seizure, the granting of purchase or sale options, and, in general, any acts or promised acts resulting in a certain or contingent event or immediate or future assignments, (ii) announce such an action or (iii) announce any intention thereto, with respect to:

- (a) 66% of the relevant Shareholder's Conventionally Locked Securities: during the period starting on the date of expiry of the last to expire lock-up commitment of such shareholder *vis-à-vis* the Joint Global Coordinators (see Section 15.3.1 (Lock-up pursuant to the IPO)) and ending on the first anniversary of such date; and
- (b) 33% of the relevant Shareholder's Conventionally Locked Securities: during the period starting on the first anniversary of the date of expiry of the last to expire lock-up commitment of such shareholder *vis-à-vis* the Joint Global Coordinators (see Section 15.3.1 (Lock-up pursuant to the IPO)) and ending on the second anniversary of such date.

The lock-up arrangement does not prohibit a holder of Conventionally Locked Securities from (i) transferring Conventionally Locked Securities to its legal successor(s) or other transferees pursuant to (x) its death (in the event the holder concerned is a physical person) or (y) the merger, liquidation, concursus (“*concoors*” / “*samenloop*”), de-merger, transfer or contribution of a branch of activity or transfer or contribution of a universality of or by such holder (in the event the holder concerned is a legal person), provided that in the events referred to in (x) and (y) the legal successor(s) or relevant transferee(s) or contributee(s) shall remain bound by, respectively, adhere to, the lock-up arrangement for its remaining term; (ii) transferring Conventionally Locked Securities to (one of) its affiliates, provided that (x) such affiliate to whom the Conventionally Locked Securities are transferred confirms in writing to the Issuer, prior to such transfer, that it shall be bound by the lock-up arrangement for its remaining term; and (y) the transferee and the transferor undertake towards the Issuer that if the transferee would cease to be an affiliate of the transferor during the term of the lock-up arrangement, the transferee shall prior thereto retransfer the Conventionally Locked Securities to the transferor and such Conventionally Locked Securities shall remain subject to the lock-up arrangement for its remaining term; (iii) accepting a public tender offer (including, for the avoidance of doubt, by way of cash settlement of Conventionally Locked Securities) made to all or substantially all holders of Shares (other than Shares already owned by the offeror or persons affiliated or acting in concert with such offeror) pursuant to the Law of 1 April 2007 on takeover bids or a merger proposal, or making an irrevocable commitment prior to the launch of a tender offer to accept such an offer of such an offeror (or persons affiliated or acting in concert with such offeror) or prior to the announcement of a merger proposal to accept such a merger proposal; (iv) transferring Conventionally Locked Securities further to a court order or as otherwise mandatorily required under any applicable law; (v) transferring to the Joint Global Coordinators any Conventionally Locked Securities that are lent to the Joint Global Coordinators pursuant to a stock lending agreement entered into with such Joint Global Coordinators in the framework of the Offering (see Section 15.4 (Over-allotment Option and price stabilization) (it being understood, however, that the Shares that at the expiry date of such stock lending agreement are delivered to the lending shareholder shall be subject to the lock-up period for its remaining term); (vi) transferring Conventionally Locked Securities pursuant to the Call Option; (vii) transferring Conventionally Locked Securities for which the prior consent of the Issuer has been obtained (the Issuer being entitled to grant, condition, delay or withhold its consent at its sole discretion).

#### **15.4 OVER-ALLOTMENT OPTION AND PRICE STABILIZATION**

In connection with the Offering, KBC Securities NV/SA will act as Stabilization Manager on behalf of the Underwriters and may engage in stabilization transactions aimed at supporting the market price of the Shares during the Stabilization Period. These transactions may stabilize, maintain or otherwise affect the price of the Shares or any options, warrants or rights with respect to, or other interest in, the Shares or other securities of the Issuer for up to 30 calendar days from the Listing Date (not included) (the **Stabilization Period**). These activities may support the market price of the Shares at a level higher than that which might otherwise prevail. Stabilization will not be executed above the Offer Price. Such transactions may be effected, on the regulated market of Euronext Brussels, in the over-the-counter markets or otherwise. The Stabilization Manager and its agents are not required to engage in any of these activities and, as such, there is no assurance that these activities will be undertaken. If undertaken,

the Stabilization Manager or its agents may discontinue any of these activities at any time and they must terminate at the end of the Stabilization Period.

Under the possible stabilization measures, investors may, in addition to the New Shares being offered, be allocated up to 15% of the number of New Shares subscribed for in the Offering (including, for the avoidance of doubt, the number of New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) as Additional Shares as part of the allocation of the Offered Shares to be placed. Within the scope of a possible over-allotment, the Additional Shares will be provided for the account of the Stabilization Manager, acting on behalf of the Underwriters, in the form of a securities loan from Stijn Van Rompay and/or Pieter Van Rompay.

The Issuer is expected to grant to the Stabilization Manager, acting on behalf of the Underwriters, an Over-allotment Option, in the form of a warrant, which will entitle the Stabilization Manager, acting on behalf of the Underwriters, to subscribe for additional new Shares for an aggregate number equal to up to 15% of the number of New Shares subscribed for in the Offering (including, for the avoidance of doubt, the number of New Shares subscribed for pursuant to the effective exercise of the Increase Option, if any) at the Offer Price to cover over-allotments of Additional Shares (if any) or short positions created by such over-allotment, in connection with the Offering.

The Stabilization Manager may elect to reduce any short position by exercising all or part of the Over-allotment Option. The Over-allotment Option will be exercisable during the Stabilization Period. The Over-allotment Option will be exercisable in whole or in part, and in one or in several times, to cover the over-allotment of Additional Shares (if any) or short positions created by such over-allotment. The possibility to over-allot Additional Shares in the Offering and to exercise the Over-allotment Option will exist whether or not the Offering is fully subscribed.

If the Stabilization Manager creates a short position in the Shares in connection with the Offering (*i.e.*, over-allots Additional Shares), it may reduce that short position by purchasing Shares on the market or otherwise, or by exercising all or part of the Over-allotment Option. Purchases of Shares on the market to stabilize the trading price or to reduce a short position may cause the price of the Shares to be higher than it might be in the absence of such purchases. Neither the Issuer, nor the Underwriters make any representation or prediction as to the direction or the magnitude of any effect that the transactions described above may have on the price of the Shares.

Within one week of the end of the Stabilization Period, the following information will be made public: (i) whether or not stabilization was undertaken; (ii) the date on which stabilization started; (iii) the date on which stabilization last occurred; (iv) the price range within which stabilization was carried out, for each of the dates on which stabilization transactions were carried out; (v) the trading venue(s) on which the stabilization transactions were carried out (where applicable) and (vi) the final size of the Offering, including the result of the stabilization and the exercise of the Over-allotment Option and the Increase Option, if any.

## **15.5 OTHER RELATIONSHIPS WITH THE UNDERWRITERS**

In connection with the underwriting of the Offering, each of the Underwriters and any of their respective affiliates, acting as an investor for its own account, may take up Offered Shares in the Offering and in that capacity may retain, purchase or sell for its own account such securities and any Shares or related investments and may offer or sell such Shares or other investments otherwise than in connection with the Offering. Accordingly, references in this Prospectus to Shares being offered or placed should be read as including any offering or placement of Offered Shares to any of the Underwriters or any of their respective affiliates acting in such capacity. None of the Underwriters intend to disclose the extent of any such investment or transactions otherwise than in accordance with any legal or regulatory obligation to do so. In addition, certain of the Underwriters or their affiliates may enter into financing arrangements (including swaps) with investors in connection with which such Underwriters (or their affiliates) may from time to time acquire, hold or dispose of Shares.

Certain of the Underwriters and/or their respective affiliates may in the future, from time to time, engage in commercial banking, investment banking and financial advisory and ancillary activities in the ordinary course of their business with the Issuer or any parties related to it, in respect of which they may in the future receive, customary fees and commissions. As a result of these transactions, these parties may have interests that may not be aligned or could possibly conflict with the interests of investors.

## **15.6 NO PUBLIC OFFERING OUTSIDE BELGIUM**

No public offer is being made and no action has been or will be taken that would, or is intended to, permit a public offering of the Shares, or the possession, circulation or distribution of this Prospectus or any other material relating to the Shares, in any country or jurisdiction, other than Belgium, where any such action for that purpose is required. Accordingly, the Shares may not be offered or sold, directly or indirectly, and neither this Prospectus nor any other offering material or advertisements in connection with the Shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of such country or jurisdiction.

Purchasers of the Shares may be required to pay stamp taxes and other charges in accordance with the laws and practices of the country of purchase in addition to the Offer Price.

## 16 TRANSFER RESTRICTIONS

The Shares have not been and will not be registered under the U.S. Securities Act or the applicable securities laws of any state or other jurisdiction of the United States and may not be offered, sold, pledged or transferred within the United States, except pursuant to an applicable exemption from, or in a transaction not subject to, the registration requirements of the U.S. Securities Act and applicable state securities laws. Terms defined in Rule 144A or Regulation S shall have the same meaning when used in this section.

Each purchaser of the Offered Shares outside the United States in compliance with Regulation S will be deemed to have represented and agreed that it has received a copy of this Prospectus and that:

1. the purchaser is authorized to consummate the purchase of the Offered Shares in compliance with all applicable laws and regulations related to public offerings;
2. the purchaser acknowledges that the Offered Shares have not been and will not be registered under the U.S. Securities Act, or with any securities regulatory authority of any state of the United States, and, subject to certain exceptions, may not be offered or sold within the United States;
3. the purchaser and the person, if any, for whose account or benefit the purchaser is acquiring the Offered Shares, was located outside the United States at the time the buy order for the Offered Shares was originated and continues to be located outside the United States and has not purchased the Offered Shares for the account or benefit of any person in the United States or entered into any arrangement for the transfer of the Offered Shares or any economic interest therein to any person in the United States;
4. the purchaser is not an affiliate of the Issuer or a person acting on behalf of such affiliate;
5. the purchaser is aware of the restrictions on the offer and sale of the Offered Shares pursuant to Regulation S described in this Prospectus;
6. the Offered Shares have not been offered to it by means of any "directed selling efforts" as defined in Regulation S;
7. the purchaser acknowledges that the Issuer shall not recognize any offer, sale, pledge or other transfer of the Offered Shares made other than in compliance with the above-stated restrictions;
8. if it is acquiring any of the Offered Shares as a fiduciary or agent for one or more accounts, the purchaser represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgements, representations and agreements on behalf of each such account; and
9. the purchaser acknowledges that the Issuer, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing acknowledgements, representations

and agreements, and undertakes promptly to notify the Issuer and the Underwriters if, at any time prior to the purchase of the Offered Shares, any of the foregoing ceases to be true.

Each purchaser and each subsequent purchaser of the Offered Shares within the United States purchasing pursuant to an exemption from the registration requirements of the U.S. Securities Act will be deemed to have represented and agreed that it has received a copy of this Prospectus and such other information as it deems necessary to make an informed investment decision and that:

1. the purchaser is authorized to consummate the purchase of the Offered Shares in compliance with all applicable laws and regulations;
2. the purchaser acknowledges that the Offered Shares have not been and will not be registered under the U.S. Securities Act or with any securities regulatory authority of any state of the United States and are subject to restrictions on transfer;
3. the purchaser: (i) is a qualified institutional buyer (as defined in Rule 144A under the U.S. Securities Act); (ii) is aware that the sale to it is being made pursuant to an exemption from the registration requirements of the U.S. Securities Act; and (iii) is acquiring such Offered Shares for its own account or for the account of a qualified institutional buyer;
4. the purchaser is aware that the Offered Shares are being offered in the United States in a transaction not involving any public offering in the United States within the meaning of the U.S. Securities Act;
5. if in the future, the purchaser decides to offer, resell, pledge or otherwise transfer such Offered Shares, or any economic interest therein, such Offered Shares or any economic interest therein may be offered, sold, pledged or otherwise transferred only: (i) to a person whom the beneficial owner and/or any person acting on its behalf reasonably believes is a qualified institutional buyer in a transaction meeting the requirements of Rule 144A, (ii) in compliance with Regulation S under the U.S. Securities Act, (iii) in accordance with Rule 144 under the U.S. Securities Act (if available), or (iv) pursuant to an effective registration statement under the U.S. Securities Act, in each case in accordance with any applicable securities laws of any state of the United States or any other jurisdiction;
6. the purchaser is not an affiliate of the Issuer or a person acting on behalf of such affiliate;
7. the purchaser acknowledges that the Offered Shares are “restricted securities” within the meaning of Rule 144(a)(3) under the U.S. Securities Act and no representation is made as to the availability of the exemption provided by Rule 144 for resales of any Offered Shares;
8. the purchaser will not deposit or cause to be deposited such Offered Shares into any depositary receipt facility established or maintained by a depositary bank other than a Rule 144A restricted depositary receipt facility, so long as such Offered Shares are “restricted securities” within the meaning of Rule 144(a)(3) under the U.S. Securities Act;

9. the purchaser acknowledges that the Issuer shall not recognize any offer, sale, pledge or other transfer of the Offered Shares made other than in compliance with the above-stated restrictions;
10. if it is acquiring any of the Offered Shares as a fiduciary or agent for one or more accounts, the purchaser represents that it has sole investment discretion with respect to each such account and that it has full power to make the foregoing acknowledgements, representations and agreements on behalf of such account; and
11. the purchaser acknowledges that the Issuer, the Underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing acknowledgements, representations and agreements, and undertakes promptly to notify the Issuer and the Underwriters if, at any time prior to the purchase of the Offered Shares, any of the foregoing ceases to be true.

In addition, until the end of the 40<sup>th</sup> calendar day after the commencement of the Offering, an offer or sale of the Shares within the United States by any dealer (whether or not participating in the Offering) may violate the registration requirements of the U.S. Securities Act if such offer or sale is made otherwise than in accordance with Rule 144A or another exemption from registration under the U.S. Securities Act.

Each person in a Member State, other than Belgium, or in the United Kingdom, who receives any communication in respect of, or who acquires any Offered Shares under, the offers contemplated in this Prospectus, will be deemed to have represented, warranted and agreed to and with each of the Underwriters and the Issuer that:

1. it is a “qualified investors” within the meaning of Article 2(e) of the Prospectus Regulation; and
2. in the case of any Offered Shares acquired by it as a financial intermediary, as that term is used in Article 5(1) of the Prospectus Regulation, (i) the Offered Shares acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Member State or in the United Kingdom other than qualified investors within the meaning of Article 2(e) of the Prospectus Regulation, or in other circumstances falling within Article 5(1) of the Prospectus Regulation and the prior consent of the Underwriters has been given to the offer or resale; or (ii) where Offered Shares have been acquired by it on behalf of persons in any Member State or in the United Kingdom other than qualified investors, the offer of those Offered Shares to it is not treated under the Prospectus Regulation as having been made to such persons.

**17 GLOSSARY**

Acute coronary syndrome	A range of conditions associated with sudden, reduced blood flow in the coronary arteries.
Anesthesiologist	A doctor who gives a patient medication so they do not feel pain when they are undergoing surgery.
Anesthetics	A drug used to induce anesthesia, resulting in a temporary loss of sensation or awareness.
Analgesics	An analgesic or painkiller is any member of the group of drugs used to achieve analgesia, relief from pain.
ANDA	An Abbreviated New Drug Application is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.
Angina pectoris	The medical term for chest pain or discomfort due to coronary heart disease (also called as stable angina).
Antifibrinolytic drug	A drug able to stop bleeding by interfering with the bleeding process (fibrinolysis). By inhibiting the fibrinolysis, tranexamic acid promotes the formation of clots.
API	An Active Pharmaceutical Ingredient is the substance of a drug that produces the intended effects. Some drugs, such as combination therapies, have multiple active ingredients to treat different symptoms or act in different ways.
Arrhythmia	An irregular heartbeat.
Artery	A blood vessel that takes blood away from the heart to all parts of the body.
Ascites	Abnormal build-up of fluid in the abdomen.
Atherosclerosis	A build-up of fatty material and cholesterol-containing deposits or plaque inside the arteries.
Atrial fibrillation (Af or AFib)	A quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications.

Atrium of the heart	The atrium is the upper chamber of the heart through which blood enters the ventricles of the heart. There are two atria in the human heart – the left atrium receives blood from the pulmonary (lung) circulation, and the right atrium receives blood from the venae cavae (venous circulation).
Attention Deficit Hyperactivity Disorder (ADHD)	Attention Deficit Hyperactivity Disorder is a chronic mental childhood-onset disorder characterized by developmentally inappropriate and impairing inattention, motor hyperactivity, and impulsivity, with difficulties often continuing into adulthood.
AUC	Area under the curve, definite integral of a curve that describes the variation of a drug concentration in blood as a function of time.
Bioavailability	The drug fraction of the administered dose of a compound that reaches the blood circulation.
Bioequivalence	A term in pharmacokinetics used to assess the expected in vivo biological equivalence of two proprietary preparations of a drug. If two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same.
Black box warning	A black box warning appears on the label of a prescription medication to alert consumers and healthcare providers about safety concerns, such as serious adverse effects or life-threatening risks. A black box warning is the most serious medication warning required by the FDA.
Cardiac pacemaker	The natural pace of the heart. In healthy humans, the concentration of pacemaker cells in the sinoatrial node is the natural pacemaker, and the resultant rhythm is a sinus rhythm.
CDMO	A Contract Development and Manufacturing Organization is a specialized service provider who performs the complete development of the pharmaceutical product, including manufacturing of clinical and submission batches, as well as conduct the stability studies and all required validation work, enabling the contractee to compile the final application to the FDA.
CDO	A Contract Development Organization is a specialized service provider which performs the development of a stable pharmaceutical formulation as well as the development of the analytical methods of a product candidate.
(c)GMP	Current Good Manufacturing Practices are requirements enforced by the FDA and comparable foreign regulatory authorities, relating to manufacturing, quality control, testing, quality assurance and

	<p>corresponding maintenance of records and documents, in order to ensure that a manufactured product is safe for human consumption or use. The “c” stands for "current," reminding manufacturers that they must employ technologies and systems which are up-to-date in order to comply with the regulation.</p>
Cmax	<p>The maximum (or peak) concentration that a compound achieves in a specified compartment of the body (usually in the blood circulation) after the compound has been administered and before the administration of a second dose.</p>
CMC	<p>Chemistry, Manufacturing and Controls, relates to the definition of the product characteristics and product testing in the context of the manufacturing of a pharmaceutical or biologic specific manufacturing process, in order to ensure that the product is safe, effective and consistent between batches.</p>
CMO	<p>A Contract Manufacturing Organization is a specialized service provider which manufactures batches of the pharmaceutical product that are necessary for the contractee’s clinical trials as well as to enable the contractee to generate all of the data and documentation necessary to submit a final application to the FDA.</p>
Congestive heart Failure	<p>A type of heart failure that requires seeking timely medical attention.</p>
CRL	<p>A Complete Response Letter is the letter issued by the FDA, after having evaluated the NDA and having inspected manufacturing facilities where the product candidates and/or its API will be produced, indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA.</p>
CRO	<p>A Contract Research Organization is a specialized service provider that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, commercialization, preclinical research, clinical research, clinical trials management, and pharmacovigilance.</p>
Coronary artery disease	<p>See Coronary heart disease.</p>
Coronary heart disease	<p>What happens when the heart's blood supply is blocked or interrupted by a build-up of fatty substances in the coronary arteries. Over time, the walls of your arteries can become furred up with fatty deposits. Also called Coronary artery disease.</p>

DESI	The Drug Efficacy Study Implementation is the FDA's administrative process to consider the effectiveness of drugs that had been approved only for safety between 1938 and 1962.
Development candidate	A pharmaceutical that is being evaluated by Hyloris in order to assess whether or not it would be a viable product candidate.
Diuretics	Medications which help rid the body of salt and water (also called water pills).
DMF	The Drug Master File is a document prepared by a pharmaceutical manufacturer for submission to the FDA to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products.
Drug (or pharmaceutical)	A drug is defined by the FDA as: <ul style="list-style-type: none"> <li>• A substance recognized by an official pharmacopoeia or formulary</li> <li>• A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease</li> <li>• A substance (other than food) intended to affect the structure or any function of the body</li> <li>• A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device</li> <li>• Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)</li> </ul>
EBIT	Earnings before interests and taxes (also called 'operating profit').
Edema	The build-up of fluid in the body's tissue.
Electrophysiologists	A doctor specializing in abnormal heart rhythms.
FDA	U.S. Food and Drug Administration is a federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.
FDCA	U.S. Federal Food, Drug and Cosmetic Act.
Fibrinogenolysis	A condition involving abnormal production of fibrinogen/fibrin degradation products, degradation of coagulation factors and/or

	degradation of the fibrin present in any pre-existing localized thrombi and hemostatic clots.
Fibrinolysis	A process that prevents blood clots from growing.
GCP	Good Clinical Practices are the regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any products in clinical development. The FDA and its foreign equivalents enforce these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites.
GMP	Good Manufacturing Practices are requirements enforced by the FDA and comparable foreign regulatory authorities, relating to manufacturing, quality control, testing, quality assurance and corresponding maintenance of records and documents, in order to ensure that a manufactured product is safe for human consumption or use.
Heart attack	Occurs when an artery supplying the heart with blood and oxygen becomes blocked but fatty deposits built up over time.
Heart failure	A chronic condition in which the heart is unable to pump sufficiently to maintain blood flow to meet the body's needs.
Hemophilia	Is a rare genetically inherited disorder, mainly occurring in men, where the blood does not clot in a normal manner.
IND	An Investigational New Drug (application) is the means by which a pharmaceutical company obtains permission from the FDA to start human clinical trials and to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved.
Individual mandate (within the meaning of the Affordable Care Act)	Requirement of the Affordable Care Act that most citizens and legal residents of the United States have health insurance, and that people who do not have health insurance must obtain it or pay a penalty.
Intravenous administration (IV)	Administration of a drug directly into the vein of the patient.
IPR	The inter partes review is a procedure for challenging the validity of a United States patent before the U.S. PTO, designed to reduce the costs and time of litigating patents; a jury trial may require millions of dollars to be spent by parties, while an inter partes review can cost only hundreds of thousands of dollars or less in some cases.

IRB	The Institutional Review Board is a group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.
Landscape Review	A (patent) landscape review is a snapshot of the patent situation of a specific technology, either within a given country or region, or globally.
NCE	A New Chemical Entity is an active ingredient that contains no active moiety that has been previously approved by the Agency in an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act or has been previously marketed as a drug in the United States.
NDA	A New Drug Application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. An NDA is made when the sponsor of a new drug believes that enough evidence on the drug's safety and effectiveness has been obtained to meet FDA's requirements for marketing approval. The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. If the NDA is approved, the product may be marketed in the United States.
Nephrotic disorder	A kidney disorder that causes the body to pass too much protein in the urine.
NME	A New Molecular Entity is an active ingredient that has never before been marketed in the United States in any form.
Nociception	The sensory nervous system's response to certain harmful or potentially harmful stimuli. In nociception, intense chemical, mechanical, or thermal stimulation of sensory nerve cells called nociceptors produces a signal that travels along a chain of nerve fibers via the spinal cord to the brain.
Non-opioids	Non-opioid analgesics include various substance classes with different mechanisms of action. In addition to the classical NSAIDs and selective COX-2 inhibitors, substances such as paracetamol, flupirtine and metamizole are also members of this group.

NSAID	Nonsteroidal Anti-Inflammatory Drug is a class of drugs that reduces pain, decreases fever, prevents blood clots, and in higher doses, decreases inflammation. The most prominent members of this group of drugs are acetylsalicylic acid (aspirin), ibuprofen and naproxen, which are all available over the counter in most countries.
Medicare	A national health insurance program in the United States.
Myocardial Infarction	A Myocardial Infarction occurs when blood flow decreases or stops to a part of the heart, causing damage to the heart muscle The most common symptom is chest pain or discomfort which may travel into the shoulder, arm, back, neck or jaw.
Opioids	a class of drugs naturally found in the opium poppy plant and that work in the brain to produce a variety of effects, including the relief of pain with many of these drugs. Opioids can be prescription medications often referred to as painkillers, or they can be so-called street drugs, such as heroin.
Orange Book	The publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book), which identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.
Orphan drug designation (ODD)	An orphan drug designation is a special status granted by the Orphan Drug Act to a drug or biological product to treat a rare disease or condition upon request of a sponsor. For a drug to qualify for orphan designation both the drug and the disease or condition must meet certain criteria specified in the Orphan Drug Act and FDA's implementing regulations. Orphan designation qualifies the sponsor of the drug for various development incentives of the Orphan Drug Act.
Pacemaker	See Cardiac pacemaker.
PDUFA	Prescription Drug User Fee Act.
Peripheral nerves	The peripheral nerves are part of the peripheral nervous system which refers to the nervous system outside the brain and spinal cord. It includes the cranial nerves, spinal nerves and their roots and branches, peripheral nerves, and neuromuscular junctions.
Pharmacodynamics	A branch of pharmacology dedicated to determine the biochemical and physiologic effects of a drug in an organism.

Pharmacokinetics	A branch of pharmacology dedicated to determine how a compound administered a living organism is absorbed, distributed, metabolized, and excreted by the organism (sometimes abbreviated as PK).
Phase 1 study	A clinical study designed to test the safety, side effects, best dose, and formulation method for the drug. These trials are the first stage of testing in human subjects.
Phase 2 study	A clinical study designed to demonstrate clinical efficacy or biological activity ('proof of concept' studies) or to find the optimum dose at which the drug shows biological activity with minimal side-effects ('definite dose-finding' studies).
Phase 3 study	A clinical study designed to assess the effectiveness of the new intervention and, thereby, its value in clinical practice.
Phase 4 study	A Phase 4 study is a post-marketing study usually conducted after marketing authorization is granted and the medicine is in general use. The main objectives of a Phase 4 trial are to evaluate the drug's performance in real life scenarios, to study the long-term risks and benefits of using the drug and/or to discover any rare side effects. A Phase 4 study may be voluntary or imposed by the regulatory authorities.
Placebo-controlled trial	Placebo-controlled trials are a way of testing a medical therapy in which, in addition to a group of subjects that receives the treatment to be evaluated, a separate control group receives a sham "placebo" treatment which is specifically designed to have no real effect.
Platelet aggregation inhibitors	Pharmaceuticals which work in different places of the clotting cascade and prevent platelet adhesion. A platelet aggregation inhibitor is used in the prevention of conditions associated with thrombi, such as stroke and transient ischemic attack.
Pre-IND	A Pre-investigational new drug (application) allows the sponsor-investigator the opportunity to discuss the proposed project and receive guidance directly from the FDA prior to submitting an IND.
Product	A pharmaceutical of Hyloris that has been approved by the relevant authority (FDA for the United States).

Product candidate	A pharmaceutical that is being developed by Hyloris.
Ready-to-use (RTU)	An injectable medicine is Ready-to-use when it requires no further dilution or reconstitution before transfer to an administration device. For example, a liquid with an ampoule, of the required concentration, that only needs to be drawn up into a syringe.
Reference listed drug	A Reference Listed Drug is an approved drug product ( <i>i.e.</i> , the finished dosage form that contains a drug substance, generally, but not necessarily, in association with other active or inactive ingredients) to which new generic versions are compared to show that they are bioequivalent.
Reformulated products	Products that are made available in a new pharmaceutical form, such as transforming an oral tablet into an IV formulation or an oral liquid.
REMS	The Risk Evaluation and Mitigation Strategy is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks.
Renal impairment	A kidney disease in which there is loss of kidney function (also called renal insufficiency or renal failure).
Repurposed products	Products that are based on an existing drug and are approved for a completely new indication.
Sinoatrial node	A group of cells located in the wall of the right atrium of the heart. These cells have the ability to spontaneously produce an electrical impulse that travels through the heart causing it to contract.
Tmax	The time when the maximum concentration of a compound is achieved in the blood circulation.
Solution	A special type of homogeneous mixture composed of two or more substances. In such a mixture, a solute is a substance dissolved in another substance, known as a solvent.
Sponsor	The sponsor is a person, company, institution or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial. The sponsor is responsible for all communications with the FDA. The sponsor does not actually conduct the investigation unless the sponsor is a sponsor-investigator.

Sponsor-investigator	An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed.
Steady state	A state or condition of a system or process (such as one of the energy states of an atom) that does not change in time. In pharmacology, steady state refers to the concentration of drug in the systemic circulation (i.e. in the blood) when the rate of drug elimination is equal to the rate of drug administration.
Stroke	A medical condition in which poor blood flow to the brain results in cell death. There are two main types of stroke: ischemic, due to lack of blood flow, and hemorrhagic, due to bleeding.
Suspension	A heterogeneous mixture that contains solid particles sufficiently large for sedimentation. The particles may be visible to the naked eye.
Topical	A topical medical product is used on the outside of the body.
Torsade des pointes	Torsade de pointes is an uncommon type of disturbance of the heart's rhythm.
U.S. PTO	U.S. Patent and Trademark Office is an agency in the U.S. Department of Commerce that issues patents to inventors and businesses for their inventions, and trademark registration for product and intellectual property identification.
Ventricles	A ventricle is one of two large chambers toward the bottom of the heart that collect and expel blood received from an atrium towards the peripheral beds within the body and lungs.
WAC	Wholesale acquisition cost, which is the manufacturers list price for a drug to wholesalers or direct purchasers in the United States, excluding prompt pay or other discounts, rebates or reductions in price.
WHO	World Health Organization.

# **HYLORIS GROUP**

## **CONSOLIDATED FINANCIAL STATEMENTS**

FOR THE FINANCIAL YEARS ENDED  
DECEMBER 31, 2019, 2018 AND 2017

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## **STATEMENT OF THE BOARD OF DIRECTORS**

On 15 June 2020, Directors of Hyloris Pharmaceuticals SA certifies in the name and on behalf of Hyloris Pharmaceuticals SA, that to the best of their knowledge,

- the consolidated financial statements, established in accordance with International Financial Reporting Standards (“IFRS”) as adopted by the European Union, give a true and fair view of the equity, financial position and financial performance of Hyloris Pharmaceuticals SA and of the entities included in the consolidation as a whole;
- the annual report on the consolidated financial statements includes a fair overview of the development and the performance of the business and the position of Hyloris Pharmaceuticals SA and of the entities included in the consolidation, together with a description of the principal risks and uncertainties to which they are exposed.

# STATUTORY AUDITOR'S REPORT TO THE BOARD OF DIRECTORS OF HYLORIS PHARMACEUTICALS SA ON THE CONSOLIDATED FINANCIAL STATEMENTS AS OF AND FOR THE YEAR ENDED 31 DECEMBER 2019

In the context of the statutory audit of the consolidated financial statements of Hyloris Pharmaceuticals SA ("the Company") and its subsidiaries (jointly "the Group"), we provide you with our statutory auditor's report as at and for the year ended 31 December 2019.

We were appointed as statutory auditor by the general meeting of 31 December 2019, in accordance with the proposal of the board of directors. Our mandate will expire on the date of the general meeting deliberating on the annual accounts for the year ending 31 December 2021. This is the first year we are performing the statutory audit of the Company's consolidated financial statements.

## REPORT ON THE CONSOLIDATED FINANCIAL STATEMENTS

### *UNQUALIFIED OPINION*

We have audited the consolidated financial statements of the Group as of and for the year ended 31 December 2019, prepared in accordance with International Financial Reporting Standards as adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium. These consolidated financial statements comprise the consolidated statement of financial position as at 31 December 2019, the consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the year then ended and notes, comprising a summary of significant accounting policies and other explanatory information. The total of the consolidated statement of financial position amounts to EUR 5.983.000 and the consolidated statement of profit or loss and other comprehensive income shows a loss for the period of EUR 5.768.000.

In our opinion, the consolidated financial statements give a true and fair view of the Group's equity and financial position as at 31 December 2019 and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium.

### *BASIS FOR OUR UNQUALIFIED OPINION*

We conducted our audit in accordance with International Standards on Auditing ("ISAs") as adopted in Belgium. In addition, we have applied the ISAs as issued by the IAASB applicable for the current accounting year while these have not been adopted in Belgium yet. Our responsibilities under those standards are further described in the "Statutory auditors' responsibility for the audit of the consolidated financial statements" section of our report. We have complied with the ethical requirements that are relevant to our audit of the consolidated financial statements in Belgium, including the independence requirements.

We have obtained from the board of directors and the Company's officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### *EMPHASIS OF MATTER – SUBSEQUENT EVENT – CONVERTIBLE BONDS*

We draw attention to Note 28 of the consolidated financial statements, which describes the additional financing resulting from the issuance of convertible bonds by the Company in March and April 2020.

Our opinion is not modified in respect of this matter.

### *EMPHASIS OF MATTER – SUBSEQUENT EVENT – COVID19*

We draw attention to Note 28 of the consolidated financial statements, which describes the uncertainties and the effects of the COVID-19 crisis on the operations and financial situation of the Group.

Our opinion is not modified in respect of this matter.

### *BOARD OF DIRECTORS' RESPONSIBILITIES FOR THE PREPARATION OF THE CONSOLIDATED FINANCIAL STATEMENTS*

The board of directors is responsible for the preparation of these consolidated financial statements that give a true and fair view in accordance with International Financial Reporting Standards as adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium, and for such internal control as board of directors determines, is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the board of directors is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of

accounting unless the board of directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

#### **STATUTORY AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE CONSOLIDATED FINANCIAL STATEMENTS**

Our objectives are to obtain reasonable assurance as to whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of the users taken on the basis of these consolidated financial statements.

When performing our audit we comply with the legal, regulatory and professional requirements applicable to audits of the consolidated financial statements in Belgium. The scope of the statutory audit of the consolidated financial statements does not extend to providing assurance on the future viability of the Group nor on the efficiency or effectivity of how the board of directors has conducted or will conduct the business of the Group.

As part of an audit in accordance with ISAs, we exercise professional judgement and maintain professional skepticism throughout the audit. We also perform the following procedures:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- Obtain an understanding of internal controls relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control;
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by board of directors;
- Conclude on the appropriateness of board of directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditors' report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditors' report. However, future events or conditions may cause the Group to cease to continue as a going concern;
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation;
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the board of directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the board of directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

#### **OTHER LEGAL AND REGULATORY REQUIREMENTS**

##### **INFORMATION ABOUT THE INDEPENDENCE**

Our audit firm and our network have not performed any engagement which is incompatible with the statutory audit of the consolidated financial statements and our audit firm remained independent of the Group during the term of our mandate.

Zaventem, 15 June 2020

KPMG Réviseurs d'Entreprises / Bedrijfsrevisoren  
Statutory Auditor  
represented by

Olivier Declercq  
Réviseur d'Entreprises / Bedrijfsrevisor

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS (in € thousand)	Note	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
<b>Non-current assets</b>		<b>2,245</b>	<b>4,111</b>	<b>3,863</b>	<b>1,060</b>
Intangible assets	9	2,138	3,949	3,825	1,001
Property, plant and equipment		32	30	-	1
Right-of-use assets	10	66	119	35	56
Financial assets		9	12	3	2
<b>Current assets</b>		<b>3,739</b>	<b>3,837</b>	<b>502</b>	<b>285</b>
Trade and other receivables	11	333	1,141	216	38
Other financial assets		-	-	10	13
Current tax assets		-	-	-	4
Other current assets	12	3,200	10	5	6
Cash and cash equivalents	13	205	2,687	271	224
<b>TOTAL ASSETS</b>		<b>5,983</b>	<b>7,948</b>	<b>4,365</b>	<b>1,345</b>
<b>EQUITY AND LIABILITIES</b> (in € thousand)					
	Note	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
<b>Equity attributable to owners of the parent</b>		<b>(10,188)</b>	<b>(2,246)</b>	<b>(4,286)</b>	<b>(2,188)</b>
Share capital	14	89	89	79	67
Share premium	14	23,982	23,982	18,243	18,243
Retained earnings		(36,081)	(28,097)	(24,324)	(20,669)
Other reserves	24	1,822	1,779	1,717	171
<b>Non-controlling interests</b>		<b>-</b>	<b>(2,216)</b>	<b>-</b>	<b>-</b>
<b>Total equity</b>		<b>(10,188)</b>	<b>(4,462)</b>	<b>(4,286)</b>	<b>(2,188)</b>
<b>Non-current liabilities</b>		<b>22</b>	<b>9,309</b>	<b>6,781</b>	<b>2,471</b>
Borrowings	15	22	66	15	35
Other financial liabilities	15		9,243	6,766	2,436
<b>Current liabilities</b>		<b>16,149</b>	<b>3,101</b>	<b>1,870</b>	<b>1,062</b>
Borrowings	15	44	52	20	21
Other financial liabilities	15	13,130	-	-	-
Trade and other liabilities	16	2,927	2,998	1,799	991
Current tax liabilities		47	51	51	49
<b>Total liabilities</b>		<b>16,171</b>	<b>12,410</b>	<b>8,651</b>	<b>3,533</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>5,983</b>	<b>7,948</b>	<b>4,365</b>	<b>1,345</b>

The accompanying notes are an integral part of these Consolidated financial statements.

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED DECEMBER 31

in € thousand	Note	2019	2018	2017
Revenue	18	91	91	213
Other operating income	18	86	-	18
Cost of sales	19	(66)	(65)	(95)
<b>Gross profit</b>		<b>111</b>	<b>26</b>	<b>135</b>
Research and development expenses	19	(4,577)	(4,870)	(2,313)
General and administrative expenses	19	(808)	(622)	(1,657)
Other operating expenses	19	-	(3)	(31)
<b>Operating profit/(loss)</b>		<b>(5,274)</b>	<b>(5,469)</b>	<b>(3,866)</b>
Financial income	21	10	7	257
Financial expenses	21	(518)	(597)	(174)
<b>Profit/(loss) before taxes</b>		<b>(5,782)</b>	<b>(6,059)</b>	<b>(3,783)</b>
Income taxes	22	14	20	66
<b>PROFIT/(LOSS) FOR THE PERIOD</b>		<b>(5,768)</b>	<b>(6,039)</b>	<b>(3,717)</b>
<b>Other comprehensive income</b>		<b>-</b>	<b>-</b>	<b>-</b>
<b>TOTAL COMPREHENSIVE INCOME OF THE PERIOD</b>		<b>(5,768)</b>	<b>(6,039)</b>	<b>(3,717)</b>
Profit/(loss) for the period attributable to the owners of the Company		(5,373)	(5,791)	(3,717)
Profit/(loss) for the period attributable to the non-controlling interests		(395)	(247)	-
Total comprehensive income for the period attributable to the owners of the Company		(5,373)	(5,791)	(3,717)
Total comprehensive income for the period attributable to the non-controlling interests		(395)	(247)	-
Basic and diluted earnings/(loss) per share (in €)	23	(1.49)	(1.71)	(1.27)

The accompanying notes are an integral part of these Consolidated financial statements.

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED DECEMBER 31

	Attributable to equity holders of the Company					Equity attributable to owners of the parent	Non- controlling interests	Total Equity
	Share capital	Share premium	Other reserves		Retained earnings			
			Share- based payment reserve	Other reserves				
<i>(in thousands of euros)</i>								
<b>Balance at January 1, 2017 (note 8.1)</b>	<b>67</b>	<b>18,243</b>	<b>-</b>	<b>171</b>	<b>(20,669)</b>	<b>(2,188)</b>	<b>-</b>	<b>(2,188)</b>
Issuance of shares (note 14.2)	12	-	-	-	-	12	-	12
Acquisition of subsidiary under common control (note 8.2)	-	-	-	-	62	62	-	62
Contribution by shareholder – low-interest loans (net of income tax, note 15.2)	-	-	-	216	-	216	-	216
Share-based payments (note 27)	-	-	1,329	-	-	1,329	-	1,329
Total comprehensive income	-	-	-	-	(3,717)	(3,717)	-	(3,717)
<b>Balance at December 31, 2017</b>	<b>79</b>	<b>18,243</b>	<b>1,329</b>	<b>387</b>	<b>(24,324)</b>	<b>(4,286)</b>	<b>-</b>	<b>(4,286)</b>
Issuance of shares (note 14.2)	10	5,740	-	-	-	5,750	-	5,750
Sale of non-controlling interest (note 8.1)	-	-	-	-	2,218	2,218	(1,968)	250
Contribution by shareholder – low-interest loans (net of income tax, note 15.2)	-	-	-	63	-	63	-	63
Cash settlement of business combination under common control (note 8.2)	-	-	-	-	(200)	(200)	-	(200)
Total comprehensive income	-	-	-	-	(5,791)	(5,791)	(247)	(6,039)
<b>Balance at December 31, 2018</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>450</b>	<b>(28,097)</b>	<b>(2,246)</b>	<b>(2,216)</b>	<b>(4,462)</b>
Contribution by shareholder – low-interest loans (net of income tax, note 15.2)	-	-	-	42	-	42	-	42
Acquisition of non-controlling interest as part of business combination under common control (note 8.1)	-	-	-	-	(2,611)	(2,611)	2,611	-
Total comprehensive income	-	-	-	-	(5,373)	(5,373)	(395)	(5,768)
<b>Balance at December 31, 2019</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>493</b>	<b>(36,081)</b>	<b>(10,188)</b>	<b>-</b>	<b>(10,188)</b>

The accompanying notes are an integral part of these Consolidated financial statements.

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEARS ENDED DECEMBER 31

in € thousand	Note	2019	2018	2017
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>				
Operating result		(5,274)	(5,469)	(3,866)
Adjustments for:				
Depreciation, amortization and impairments	19	3,306	88	65
Equity-settled share-based payment expense	20	-	-	1,329
Changes in working capital:				
Trade and other receivables		808	(925)	(178)
Other current assets		(3,180)	2	257
Trade and Other Payables		(218)	936	777
Other current liabilities		1	-	-
<b>Cash generated from operations</b>		<b>(4,558)</b>	<b>(5,368)</b>	<b>(1,615)</b>
Taxes paid		(3)	(1)	(1)
<b>Net cash generated from operating activities</b>		<b>(4,562)</b>	<b>(5,368)</b>	<b>(1,616)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>				
Interests received		-	-	-
Purchases of property, plant and equipment		(8)	(31)	-
Purchases of Intangible assets	9	(1,222)	-	(2,800)
Sale of non-controlling interest	8.1	-	250	62
Proceeds from other financial assets		3	-	2
Transaction under common control	8.2.	-	(200)	-
<b>Net cash provided by/(used in) investing activities</b>		<b>(1,228)</b>	<b>19</b>	<b>(2,736)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>				
Reimbursements of borrowings and other financial liabilities	15.3	(52)	(43)	(21)
Proceeds from borrowings and other financial liabilities	15.3	3,364	2,060	4,408
Interests paid		(4)	(2)	(1)
Proceeds from issue of equity instruments of the Company (net of issue costs)	14.2	-	5,750	12
<b>Net cash provided by/(used in) financing activities</b>		<b>3,308</b>	<b>7,765</b>	<b>4,398</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		<b>(2,482)</b>	<b>2,416</b>	<b>47</b>
CASH AND CASH EQUIVALENTS at beginning of year		2,687	271	224
CASH AND CASH EQUIVALENTS at end of year		205	2,687	271

The accompanying notes are an integral part of these Consolidated financial statements.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

## 1. GENERAL INFORMATION

Hyloris Pharmaceuticals SA (the “Company” or “Hyloris”) is a limited liability company governed by Belgian law. The address of its registered office is Blvd Gustave Kleyer 17, 4000 Liège, Belgium.

The Company and its subsidiaries (together referred as the “Group”) are focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. Hyloris develops proprietary innovative products it believes offer significant advantages compared to currently available alternatives, with the aim to addressing the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders.

Hyloris’ development strategy focuses on the FDA’s 505(b)(2) regulatory pathway for pharmaceuticals where safety and efficacy of the molecule has been established, with the aim to reduce the clinical burden required to bring a product to the market and to significantly shorten the development timelines, and reduce costs and risks, when compared to traditional NDAs (New Drug Applications) using the FDA’s 505(b)(1) regulatory pathway.

Hyloris has two commercial products (Maxigesic® IV and Sotalol IV) as well 12 product candidates in various stages of development. Hyloris’ products and product candidates can be divided into the following areas:

- Cardiovascular IV Portfolio;
- Reformulation Portfolio (“other reformulations”); and
- Established Market Portfolio (“high-barrier generics”).

The consolidated financial statements were authorized for issue by the Board of Directors on 15 June 2020.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### 2.1. Basis of preparation

These consolidated financial statements of the Group for the year ended December 31, 2019 have been prepared in accordance with IFRS (“International Financial Reporting Standards”) as adopted by the European Union. These include all IFRS standards and IFRIC interpretations issued and effective as at December 31, 2019. No new standards, amendments to standards or interpretations were early adopted.

These consolidated financial statements are presented in euro, which is the Company’s functional currency. All amounts in this document are represented in thousands of euros (€ thousands), unless noted otherwise.

Due to rounding, numbers presented throughout these Consolidated Financial Statements may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures.

These financial statements are prepared on an accrual basis and on the assumption that the entity is in going concern and will continue in operation in the foreseeable future (see also note 3.1 below).

The Group has consistently applied the accounting policies used in the preparation of its opening IFRS statement of financial position on 1 January 2017 throughout all periods presented, unless stated otherwise.

The preparation of financial statements in accordance with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise judgment in the process of applying the Group accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 3.

### Relevant IFRS accounting pronouncements to be adopted as from 2020 onwards

The following IFRS standards, interpretations and amendments that have been issued but that are not yet effective, have not been applied to the first IFRS financial statements closed on 31 December 2019:

Amendments to IFRS 3 – Definition of a Business (effective January 1, 2020, but not yet endorsed in EU): The amendments aim to assist companies to determine whether it has acquired a business or a group of assets.

Amendments to IFRS 9, IAS 39 and IFRS 7 – Interest Rate Benchmark Reform (effective January 1, 2020): The amendments deal with issues affecting financial reporting in the period before the replacement of an existing interest rate benchmark with an alternative interest rate and address the implications for specific hedge accounting requirements.

Amendments to IAS 1 and IAS 8 – Definition of Material (effective January 1, 2020): The amendments clarify the definition of “material” and to align the definition used in the Conceptual Framework and the standards.

The Company does not expect that the above mentioned IFRS pronouncements will have a significant impact on the consolidated financial statements.

## **2.2. Consolidation**

### **Subsidiaries**

Subsidiaries are all entities over which the Group has control. Control is established when the Group is exposed, or has the rights, to variable returns from its involvement with the subsidiary and has the ability to affect those returns through its power over the subsidiary. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

Inter-company transactions, balances and unrealized gains on transactions between group companies are eliminated. Unrealized losses are also eliminated but considered an impairment indicator of the asset transferred.

### **Business combinations**

The acquisition method of accounting is used to account for the acquisition of businesses (meeting the definition of a business in accordance with IFRS 3 Business Combinations) by the Group. The consideration transferred for the acquisition of a business is the fair values of the assets transferred, the liabilities incurred and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration agreement. Acquisition-related costs are expensed as incurred, except if related to the issue of debt or equity securities. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at acquisition date. On an acquisition-by-acquisition basis, the Group recognizes any non-controlling interest in the acquiree at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the net identifiable net assets acquired is recorded as goodwill. If this is less than the fair value of the net assets of the subsidiary in the case of a bargain purchase, the difference is recognized directly in the income statement.

### **Transactions under common control**

For business combinations under common control (also "Transactions under common control"), the Group applies predecessor accounting.

The consideration for each acquisition is measured at the aggregate of the fair values (at the date of acquisition) of assets transferred and liabilities incurred or assumed, and equity instruments issued by the Group in exchange for control of the acquiree. Acquisition-related costs are recognized in profit or loss as incurred.

Where applicable, the consideration for the acquisition includes any asset or liability resulting from a contingent consideration arrangement, measured at its acquisition-date fair value.

The acquiree's identifiable assets, liabilities, and contingent liabilities that meet the conditions for recognition under IFRS are recognized and measured at the carrying amounts as recognized in the acquiree's individual financial statements, but adjusted for any deviations with the accounting policies of the Group.

Any difference between the consideration transferred and the net assets at the acquisition date is recognized in retained earnings.

The Group elected the accounting policy choice to re-present its comparatives and adjust its current reporting period before the date of the transaction as if the transaction had occurred before the start of the earliest period presented. This restatement should not extend to periods during which the entities were not under common control.

### **Non-controlling interests**

On an acquisition-by-acquisition basis, NCI are measured initially at fair value or at their proportionate share of the acquiree's identifiable net assets at the date of acquisition.

Changes in the Group's interest in a subsidiary that do not result in a loss of control are accounted for as equity transactions.

## **2.3. Goodwill**

Goodwill represents the excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the net identifiable net assets acquired at the date of acquisition. Separately recognized goodwill is tested annually for impairment and carried at cost less accumulated impairment losses. Impairment losses on goodwill are not reversed. Gains and losses on the disposal of an entity include the carrying amount of goodwill relating to the entity sold.

## **2.4. Foreign currencies**

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in euro, which is the Group's presentation currency.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at

year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

The principal exchange rate that has been used is the US dollar. The following table presents the exchange rates used for the USD/EUR

<b>1 EUR =</b>	<b>Closing rate</b>	<b>Average rate</b>
December 31, 2019	1.1234	1.1196
December 31, 2018	1.1450	1.1814
December 31, 2017	1.1993	1.1293
January 1, 2017	1.0541	N/A

## **2.5. Intangible assets**

### **Research and development**

#### *Internally-generated research and development*

To assess whether an internally generated intangible asset meets the criteria for recognition, the Company classifies the internal generation of assets into a research phase and a development phase.

No intangible asset arising from research is recognized. Expenditure on research is recognized as an expense when it is incurred.

An intangible asset arising from development is recognized if, and only if, the Company can demonstrate all of the following:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

With respect to the technical feasibility condition, a strong evidence is achieved only when Phase III (i.e. final stage before filing for marketing approval) of the related development project is successfully completed, i.e. when filing for marketing approval from the relevant regulatory authorities. Consequently, internally generated development expenses arising before this point, mainly the cost of clinical trials, are generally expensed as incurred within 'Research and development expenses'.

In some cases (i.e. for generic products), market approval was obtained previously, but additional costs are incurred in order to improve the process for an active ingredient. To the extent that the above criteria are considered as having been met, such expenses are recognized as an asset in the balance sheet within intangible assets as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the above capitalization criteria, in which case the related expenses are recognized as an asset in the balance sheet within intangible assets.

The cost of an internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria. The cost of an internally-generated intangible asset comprises all directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management, including any fees to register legal rights (patent costs) and borrowing costs.

After initial recognition, intangible assets are measured at cost less accumulated amortization and any accumulated impairment losses. Intangible assets are amortized on a straight-line basis over their estimated useful life. Amortization begins when the asset is capable of operating in the manner intended by management, i.e. available for commercialization.

#### *Separately acquired research and development*

Payments for separately acquired research and development are capitalized as intangible assets provided that the following conditions are met: (1) the asset is identifiable, i.e. either separable (if it can be sold, transferred, licensed) or it results from contractual or legal rights; (2) it is probable that the expected future economic benefits that are attributable to the asset will flow to the Group; (3) the Group can control the resource; and (4) the cost of the asset can be measured reliably.

The second condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. The management of the company assesses whether and to which amount milestone payments are to be considered as related to the purchase of an asset (capitalization) or

related to outsourced research and development. The latter will be recognized as a research and development expenses when they occur.

If the development project meets the conditions for capitalization as mentioned above, related upfront and milestone payments to third parties are recognized as intangible assets, and amortized on a straight-line basis over their useful lives beginning when marketing approval is obtained. However, any subsequent expenditure on the relating projects is added to the carrying amount of the intangible asset only if it meets the recognition criteria for capitalizing development costs (see above section Internally-generated research and development).

Payments under research and development arrangements relating to access to technology or to databases and payments made to purchase generics dossiers are also capitalized as the conditions mentioned above are met upon acquisition, and amortized on a straight-line basis over the useful life of the intangible asset. Subsequent expenditure incurred are only capitalized if the expenditure meets the conditions mentioned above for capitalizing development costs.

Subcontracting arrangements, payments for research and development services, and continuous payments under research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term except if as part of the development phase of the underlying assets.

Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses also include upfront and milestone payments, to the amount these payments are assessed to be outsourced research and development and to the amount of the costs effectively occurred.

#### **Other intangible assets acquired separately**

An intangible asset is recognized on the statement of financial position when the following conditions are met: (1) the asset is identifiable, i.e. either separable (if it can be sold, transferred, licensed) or it results from contractual or legal rights; (2) it is probable that the expected future economic benefits that are attributable to the asset will flow to the Group; (3) the Group can control the resource; and (4) the cost of the asset can be measured reliably.

Intangible assets (research and development costs or other intangible assets as referred above) with finite useful lives that are acquired separately are measured at cost less accumulated amortization and accumulated impairment losses. The cost of a separately acquired intangible asset comprises its purchase price, including import duties and non-refundable purchase taxes, after deducting trade discounts and rebates. Any directly attributable cost of preparing the asset for its intended use is also included in the cost of the intangible asset.

#### **Amortization**

After initial recognition, intangible assets are measured at cost less accumulated amortization and any accumulated impairment losses. Intangible assets are amortized on a straight-line basis over their estimated useful life. Amortization begins when the asset is capable of operating in the manner intended by management.

The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis. Intangible assets with indefinite useful lives that are acquired separately are carried at cost less accumulated impairment losses.

Intangible assets are amortized on a systematic basis over their useful life, using the straight-line method, and are presented as Cost of Sale in the Profit or Loss Statement. The applicable useful lives are determined based on the period during which the Company expects to receive benefits from the underlying project. Key factors considered to determine the useful life comprises the duration of the patent protection and access of competitors to the market.

#### **Derecognition**

An intangible asset is derecognized on disposal, or when no future economic benefits are expected from use or disposal. Gains or losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognized in profit or loss when the asset is derecognized.

## **2.6. Property, plant and equipment**

Property, plant and equipment ("PPE") are carried at acquisition cost less any accumulated depreciation and less any accumulated impairment loss. Acquisition cost includes any directly attributable cost of bringing the asset to working condition for its intended use. Borrowing costs that are directly attributable to the acquisition, construction and/or production of a qualifying asset are capitalized as part of the cost of the asset.

Expenditures on repair and maintenance which serve only to maintain, but not increase, the value of PPE are charged to the income statement. However, expenditure on major repair and major maintenance, which increases the future economic benefits that will be generated by the PPE, is identified as a separate element of the acquisition cost. The cost of property, plant and equipment is broken down into major components. These major components, which are replaced at regular intervals and consequently have a useful life that is different from that of the PPE in which they are incorporated, are depreciated over their specific useful lives. In the event of replacement, the component is replaced and removed from the statement of financial position, and the new asset is depreciated up until the next major repair or maintenance.

The depreciable amount is allocated on a systematic basis over the useful life of the asset, using the straight-line method. The depreciable amount is the acquisition cost, less residual value, if any. The applicable useful lives are:

- Furniture and equipment 10 years
- IT equipment 3 years

The useful life of the PPE is reviewed regularly. Each time a significant upgrade is performed, such upgrade extends the useful life of the machine. The cost of the upgrade is added to the carrying amount of the machine and the new carrying amount is depreciated prospectively over the remaining estimated useful life of the machine.

## 2.7. Leases

Leases are recognized as a right-of-use asset and corresponding liability at the date of which the leased asset is available for use by the Group.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (less any lease incentives),
- variable lease payments that are based on an index or rate,
- the exercise price of a purchase option if the group is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the group exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit in the lease, if that rate can be readily determined, or the Group's incremental borrowing rate, i.e. the rate of interest that a lessee would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment.

The group is exposed to potential future increases in variable lease payments based on an index or rate, which are not included in the lease liability until they take effect. When adjustments to lease payments based on an index or rate take effect, the lease liability is reassessed and adjusted against the right-of-use asset.

Each lease payment is allocated between the liability and finance charges so as to achieve a constant rate on the remaining balance of the liability. Finance expenses are recognized immediately in profit or loss, unless they are directly attributable to qualifying assets, in which case they are capitalized.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability,
- any lease payments made at or before the commencement date less any lease incentives received,
- any initial direct costs, and
- an estimate of the costs related to the dismantling and removal of the underlying asset.

If it is reasonably certain that the Group will exercise a purchase option, the asset shall be depreciated on a straight-line basis over its useful life. In all other circumstances the asset is depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term.

For short-term leases (lease term of 12 months or less) or leases of low-value items (mainly IT equipment and small office furniture) to which the Group applies the recognition exemptions available in IFRS 16, lease payments are recognized on a straight-line basis as an expense over the lease term.

## 2.8. Impairment of non-financial assets

Intangible assets with indefinite useful lives and intangible assets not yet available for use are not subject to amortization, but are tested annually for impairment, and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Other assets which are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. To determine the value in use, the forecasted future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

When an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been

determined had no impairment loss been recognized for the asset in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

## 2.9. Revenue recognition

Revenue includes royalty revenue, license revenue and revenue from sale of goods or services.

In accordance with IFRS 15 – Revenue from Contracts with Customers, revenue from the rendering of services is recognized when the Company transfers control over the product to the customer; control of an asset refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, that asset. For the vast majority of contracts, revenue is recognized when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

In addition, the Group has entered into a number of contracts through which it “out-licenses” to customers the IP it developed related to drugs that have not yet received regulatory approval. Generally, under the terms of the license, the licensee can further develop the IP, and manufacture and/or sell the resulting commercialized product. The Group typically receives an upfront fee, milestone payments for specific clinical or other development-based outcomes, and sales-based milestones or royalties as consideration for the license. Some arrangements also include ongoing involvement by the Group, who may provide R&D and/or manufacturing services relating to the licensed IP.

Licenses coupled with other services, such as R&D, must be assessed to determine if the license is distinct (that is, the customer must be able to benefit from the IP on its own or together with other resources that are readily available to the customer, and the Group’s promise to transfer the IP must be separately identifiable from other promises in the contract). If the license is not distinct, then the license is combined with other goods or services into a single performance obligation. Revenue is then recognized as the Group satisfies the combined performance obligation.

A license will either provide:

- A right to access the entity’s intellectual property throughout the license period, which results in revenue that is recognized over time; or
- A right to use the entity’s intellectual property as it exists at the point in time in which the license is granted, which results in revenue that is recognized at a point in time.

For sales- or usage-based royalties that are attributable to a license of IP, the amount is recognized at the later of:

- when the subsequent sale or usage occurs; and
- the satisfaction or partial satisfaction of the performance obligation to which some or all of the sales- or usage-based royalty has been allocated.

## 2.10. Financial assets

The Group classifies its financial assets in the following categories: financial assets at fair value and financial assets at amortized cost. The classification depends on the entity’s business model for managing the financial assets and the contractual terms of the cash flows. Management determines the classification of its financial assets at initial recognition. Currently, the Group holds only financial assets at amortized cost.

Financial assets are not reclassified subsequent to their initial recognition unless the Group changes its business model for managing financial assets, in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.

Trade receivables are initially recognized when they are originated. All other financial assets and financial liabilities are initially recognized when the Group becomes a party to the contractual provisions of the instrument.

At initial recognition, the group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss. A trade receivable without a significant financing component is initially measured at the transaction price.

Financial assets (such as loans, trade and other receivables, cash and cash equivalents) are subsequently measured at amortized cost using the effective interest method, less any impairment if they are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest.

The effective interest method is a method of calculating the amortized cost of a debt instrument and of allocating interest income over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the debt instrument to the net carrying amount on initial recognition.

Trade and other receivables after and within one year are recognized initially at fair value and subsequently measured at amortized cost, i.e. at the net present value of the receivable amount, using the effective interest rate method, less allowances for impairment.

The Group assesses on a forward-looking basis the expected credit losses associated with its financial assets carried at amortized cost. For trade receivables, the group applies the simplified approach permitted by IFRS 9 Financial Instruments, which requires expected lifetime losses to be recognized from initial recognition of the receivables.

The amount of the allowance is deducted from the carrying amount of the asset and is recognized in the income statement within 'sales and marketing expenses'.

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. If the Group neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Group recognizes its retained interest in the asset and an associated liability for amounts it may have to pay. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognizes a collateralized borrowing for the proceeds received.

On de-recognition of a financial asset in its entirety, the difference between the asset's carrying amount and the sum of the consideration received and receivable is recognized in profit or loss.

Financial assets and financial liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Group currently has a legally enforceable right to set off the amounts and it intends either to settle them on a net basis or to realize the asset and settle the liability simultaneously.

### **2.11. Cash and cash equivalents**

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less. Bank overdrafts are shown within borrowings in current liabilities on the statement of financial position.

### **2.12. Share capital**

Ordinary shares are classified as equity. Where any Group company purchases the company's equity share capital (treasury shares), the consideration paid is deducted from equity attributable to owners of the company until the shares are cancelled or reissued. Incremental costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, from the proceeds.

### **2.13. Government grants**

Government grants are assistance by government, government agencies and similar bodies, whether local, national or international, in the form of transfers of resources to the Company in return for past or future compliance with certain conditions.

The Company recognizes a government grant only when there is reasonable assurance that the Company will comply with the conditions attached to the grant and the grant will be received.

With respect to recoverable cash advances (RCA – "avances récupérables"), the RCA gives rise to a financial liability in the scope of IFRS 9 – Financial Instruments. This financial liability is initially measured at fair value and any difference with the cash to be received from the authorities is treated as a government grant in accordance with IAS 20 – Accounting for Government Grants and Disclosure of Government Assistance. Subsequent to the initial recognition, the financial liability is measured at amortized cost using the effective interest method on the basis of the estimated contractual cash flows with changes in value due to a change in estimated cash flows recognized in profit or loss, in accordance with IFRS 9.

Government grants are recognized in profit or loss on a systematic basis over the periods in which the Company recognizes as expenses the related costs which the grants are intended to compensate. As a result, grants relating to costs that are recognized as intangible assets or property, plant and equipment (grants related to assets or investment grants) are deducted from the carrying amount of the related assets and recognized in the profit or loss statement consistently with the amortization or depreciation expense of the related assets.

Grants that intend to compensate costs are released as income when the subsidized costs are incurred, which is the case for grants relating to research and development costs. The portion of grants not yet released as income is presented as deferred income in the statement of financial position, within the Other current liabilities. In the statement of comprehensive income, government grants are presented as other operating income or financial income depending on the nature of the costs that are compensated.

Government grants that become receivable as compensation for expenses or losses already incurred are recognized in profit or loss of the period in which they become receivable.

### **2.14. Employee benefits**

Employee benefits are all forms of consideration given in exchange for services provided by employees only. Directors and other management personnel who are under service agreements are presented separately in the Notes.

#### **Short-term employee benefits**

Short-term employee benefits are recorded as an expense in the income statement in the period in which the services have been rendered. Any unpaid compensation is included in trade and other liabilities in the statement of financial position.

## 2.15. Share-based payments

A share-based payment is a transaction in which the Company receives goods or services either as consideration for its equity instruments or by incurring liabilities for amounts based on the price of the Company's shares or other equity instruments of the Company. The accounting for share-based payment transactions depends on how the transaction will be settled, that is, by the issuance of equity, cash, or either equity or cash.

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date. The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, if any, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled share-based payment reserve.

## 2.16. Provisions

Provisions are recognized when (I) the Group has a present legal or constructive obligation as a result of past events; (II) it is probable that an outflow of resources will be required to settle the obligation; (III) and the amount can be reliably estimated. Where there are a number of similar obligations, the likelihood that an outflow will be required in settlement is determined by considering the class of obligations as a whole.

Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the provision due to passage of time is recognized as finance cost.

## 2.17. Income taxes

Income tax expense represents the sum of the current income tax and deferred tax.

Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to the tax payable or receivable in respect of previous years. The amount of current tax payable or receivable is the best estimate of the tax amount expected to be paid or received that reflects uncertainty related to income taxes, if any.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Group's subsidiaries operate and generate taxable income. In line with paragraph 46 of IAS 12 Income taxes, management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities. This evaluation is made for tax periods open for audit by the competent authorities.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

Deferred tax is recognized on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements.

However, the deferred tax is not recognized for:

- the initial recognition of goodwill (in case of taxable temporary differences arising);
- the initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss and
- deferred tax is recognized on temporary differences arising on investments in subsidiaries and associates, except for deferred income tax liabilities where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future.

Deferred tax liabilities are recognized for taxable temporary differences.

Deferred tax assets are recognized for deductible temporary differences and tax losses and tax attributes to the extent that it is probable that taxable profits will be available against which those deductible temporary differences can be utilized. Future taxable profits are determined based on the reversal of relevant taxable temporary differences. If the amount of taxable temporary differences is insufficient to recognize a deferred tax asset in full, then future taxable profits, adjusted for reversals of existing temporary differences, are considered, based on the business plans for individual subsidiaries in the Group.

Deferred tax relating to items recognized outside profit or loss is recognized outside profit or loss. Deferred tax items are recognized in correlation to the underlying transaction either in OCI or directly in equity.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered.

Deferred taxes are calculated at the level of each fiscal entity in the Group. The Group is able to offset deferred tax assets and liabilities only if the deferred tax balances relate to income taxes levied by the same taxation authority and it intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

## **2.18. Financial liabilities**

Financial liabilities (including borrowings and trade and other payables) are classified as at amortized cost.

Financial liabilities are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently stated at amortized cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method. Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period.

The effective interest method is a method of calculating the amortized cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial liability to the net carrying amount on initial recognition.

Where the loan is from a shareholder acting in the capacity of a shareholder, the resulting credit (difference between cash received and fair value of the loan) is reflected in equity because the substance of the favorable terms is typically a contribution by a shareholder.

The Group derecognizes a financial liability when its contractual obligations are discharged or cancelled, or expire. The Group also derecognizes a financial liability when its terms are modified and the cash flows of the modified liability are substantially different, in which case a new financial liability based on the modified terms is recognized at fair value.

When a financial liability measured at amortized cost is modified without this resulting in derecognition, a gain or loss is recognized in profit or loss. The gain or loss is calculated as the difference between the original contractual cash flows and the modified cash flows discounted at the original effective interest rate.

## **2.19. Operating segments**

The Group's activities are in one segment. The chief operating decision maker, the Board of Directors, reviews the operating results and operating plans, and make resource allocation decisions on a company-wide basis; therefore, the Group operates as one segment.

## **2.20. Statement of cash flows**

The cash flows of the Group are presented using the indirect method. This method reconciles the movement in cash for the reporting period by adjusting operating result of the year for any non-cash items and changes in working capital, and identifying investing and financing cash flows for the reporting period.

# **3. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

In the application of the Group's accounting policies, which are described above, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The followings are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year:

## **3.1. Going concern**

The 2019 consolidated results of the Group present a negative result, and the consolidated statement of financial position includes a loss carried forward. The Board has examined the statements and accounting standards.

Management has prepared detailed budgets and cash flow forecasts for the years 2020 and 2021. These forecasts reflect the strategy of the Group and include significant expenses and cash outflows in relation to the development of the ongoing clinical programs and pipeline of products candidates. Management acknowledges that uncertainty remains in these cash flow forecasts but believes that the Group has the ability to delay or prioritize research and development projects to avoid that the company is running out of cash.

Based on its current scope of activities, the subscriptions in the Convertible Bonds recorded in March and April 2020 for a total of EUR 15.2 million, and the partial reimbursement of the shareholders loan, the Company estimates that its treasury position as of December 31, 2019, is sufficient to cover its cash requirements until mid of 2021.

After due consideration of the above, taking into account the EUR 15.2 million convertible loan contracted in March and April 2020, its confidence in securing additional future financing (including the irrevocable commitment (conditional to the completion of the Offering) of the investors of the convertible loans to invest an additional amount of EUR 22.7 million in the Company) and the favorable outlook of developments, the Board of Directors is of the opinion that it has an appropriate basis to conclude on the business continuity over the next 12 months from the balance sheet date, and hence it is appropriate to prepare the financial statements on a going concern basis.

The uncertainty raised by the COVID-19 pandemic is not impacting going concern. Although there are a lot of uncertainties, it does not materially impact the Company's ability to continue operations until the mid of 2021.

### **3.2. Business combinations under common control**

The acquisitions of RTU Pharma and Dermax consists of acquisitions of businesses as defined by IFRS 3 – Business Combinations.

Considering that both Hyloris and Dermax and Hyloris and RTU Pharma are controlled by the same group of shareholders, the acquisitions are considered to be transactions under common control (business combination under common control). A business combination under common control is a business combination in which all of the combining entities or businesses are ultimately controlled by the same party or parties both before and after the business combination, and that control is not transitory. As such, considering that both Hyloris and the acquired companies were ultimately controlled by the same parties both before and after the business combinations, the transactions are considered business combinations under common control which falls outside the scope of IFRS 3. Factors considered to conclude the common control situation includes:

- Existence of shareholders agreements;
- The composition of the boards of directors;
- Financing of Dermax operations by Hyloris.

Such transactions under common control are explicitly excluded from the scope of IFRS 3

Considering that there is no other specific guidance on such transactions elsewhere in IFRS, management developed an accounting policy that provides relevant and reliable information in accordance with IAS 8 to account for the acquisitions. As such, Hyloris applies the predecessor approach ('pooling of interests') to the acquisitions and elected for the following accounting policy choice:

- apply book value accounting in recognizing the assets acquired and liabilities assumed using the book values in the financial statements of the acquiree. The difference between the consideration paid and the capital of the acquiree is recognized in retained earnings;
- re-present its comparatives and adjust its current reporting period before the date of the transaction as if the transaction had occurred before the start of the earliest period presented. However, this restatement does not extend to periods during which the entities were not under common control;
- account for the capital increase used as financing of the acquisition as if the acquisition occurred before the start of the earliest period presented as the acquired companies are considered to be part of the Group as from the moment common control is established.

Refer to Note 8 for description of such transactions occurred in 2019 and 2018 for the acquisition of Dermax and RTU respectively.

### **3.3. Share-based payments**

In accordance with IFRS 2 – Share-based Payment, the fair value of the warrants at grant date is recognized as an expense in the consolidated statement of comprehensive income over the vesting period, the period of service. Subsequently, the fair value is not re-measured.

The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions, which are detailed in note 26.

### **3.4. Effective interest rate of shareholders' loans**

The Group was granted several shareholders' loans as disclosed in note 15.2. The shareholders' loans bear a fixed interest rate of 4%, which is considered to be below market rates if the Group would finance itself on the market. As such, based on the principles of IFRS 9 Financial Instruments, the Company remeasured the shareholders' loans at fair value (at the date the loan has been originated or at transition date). Subsequently the loans are measured at amortized cost based on the market-related rate. As such the Group recognizes the interest expense it would need to pay if it would finance itself on the market. The differential between the fair value of the loans and the nominal amount is considered as a capital contribution, which is recognized immediately in equity.

For a reconciliation, we refer to note 15.2.

### **3.5. Recognition of deferred tax assets**

Deferred tax assets are recognized only if management assesses that these tax assets can be offset against taxable income within a foreseeable future.

This judgment is made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives.

Since inception, the Company has reported losses, and as a consequence, the Company has unused tax losses. Therefore, management has concluded that deferred tax assets should not be recognized as of 31 December 2019 considering uncertainties regarding future taxable profits relating to the commercialization of the development projects.

#### 4. TRANSITION TO IFRS

The consolidated financial statements for the period ended 31 December 2019 of the Company are prepared for the first time in accordance with International Financial Reporting Standards as endorsed in the European Union ('IFRS'). Considering that the Company did not prepare consolidated financial statements in accordance with Belgian GAAP ('BeGAAP'), the first-time adoption of IFRS also triggers the preparation of consolidated financial statements for the first time.

The first consolidated IFRS financial statements include comparative information for the period ended 31 December 2017 and 2018. Therefore, an opening IFRS statement of financial position has been prepared as per 1 January 2017, which is the date of transition in accordance with IFRS. Note that IFRS 16 has been applied from the date of transition.

As no consolidated financial statements have been prepared previously in accordance with BeGAAP, no reconciliation can be prepared between the consolidated equity under previous GAAP to the consolidated equity under IFRS at the same dates.

### 5. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

#### 5.1. Overview of financial instruments

The table below summarizes all financial instruments by category in accordance with IFRS 9:

in € thousand	IFRS 9 Category	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Financial assets	At amortized cost	9	12	3	2
Trade receivables	At amortized cost	58	154	186	20
Other financial assets	At amortized cost	-	-	10	13
Cash and cash equivalents	At amortized cost	205	2,687	271	224
<b>Total financial assets</b>		<b>272</b>	<b>2,853</b>	<b>470</b>	<b>260</b>
Non-current financial liabilities					
Lease liabilities	At amortized cost	22	66	15	35
Other financial liabilities	At amortized cost	-	9,243	6,766	2,436
Current financial liabilities					
Lease liabilities	At amortized cost	44	52	20	21
Other financial liabilities	At amortized cost	13,130	-	-	-
Trade and other liabilities					
Trade payables	At amortized cost	2,866	2,056	1,770	976
<b>Total financial liabilities</b>		<b>16,062</b>	<b>11,417</b>	<b>8,571</b>	<b>3,468</b>

Currently, no financial instrument is carried at fair value in the consolidated statement of financial position.

The Company considers that the carrying amounts of financial assets and financial liabilities recognized in the consolidated financial statements approximate their fair values.

#### 5.2. Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk (including currency risk and interest rate risk), credit risk and liquidity risk. There have been no changes in the risk management since last year-end or in any risk management policies.

### 5.3. Foreign exchange risk

The Company is currently exposed to foreign currency risk, mainly relating to positions held in USD.

The exposure to exchange differences of the monetary assets and monetary liabilities of the Group at the end of the reporting period are as follows:

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Assets	173	230	157	173
Liabilities	(3,216)	(3,142)	(3,157)	(1,697)

At December 31, 2019, if the EUR had strengthened/weakened 1% against the USD with all other variables held constant, the impact on the consolidated statement of comprehensive income would have been +/- EUR 31 thousand respectively.

### 5.4. Interest rate risk

The Company is currently not exposed to significant interest rate risk as the interest-bearing financial liabilities bear a fixed interest rate, which are not subject to revision.

### 5.5. Credit risk

Credit risk is the risk that one party to an agreement will cause a financial loss to another party by failing to discharge its obligation. Credit risk covers trade receivables, cash and cash equivalents and short-term deposits.

The Company believes that the credit risk is limited as the Company has currently limited trade receivables considering the limited revenue. Furthermore, the Company is not exposed to any material credit risk with regard to any individual customer of counterparty, as no single customer claims a dominant part of total revenue. As such, no impairment is recognized for these receivables. Cash and cash equivalent and short-term deposits are invested with highly reputable banks and financial institutions.

The maximum credit risk to which the Company is theoretically exposed as at the balance sheet date is the carrying amount of the financial assets.

Based on the ongoing credit evaluation performed, no financial assets were subject to impairment.

### 5.6. Liquidity risk

The Company's main sources of cash inflows are currently obtained through capital increases and external financing through shareholder's loans.

Considering that the loans are with shareholders, the liquidity risk is considered limited as the Company estimates to take mitigating measures as further disclosed in the going concern paragraph in note 3.1.

The following table details the Company's remaining contractual maturity of its financial liabilities with agreed repayment periods. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Company can be required to pay. The tables include both interest and principal cash flows.

31/12/2019 In € thousand	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
Borrowings					
Lease liabilities	44	22	-	-	66
Other financial liabilities					
Loans from shareholders	12,721	-	-	-	12,721
Other loans	409	-	-	-	409
<b>Total</b>	<b>13,174</b>	<b>22</b>	<b>-</b>	<b>-</b>	<b>13,196</b>

31/12/2018 In € thousand	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
Borrowings					
Lease liabilities	52	66	-	-	118
Other financial liabilities					
Loans from shareholders	-	9,243	-	-	9,243

<b>Total</b>	<b>52</b>	<b>9,309</b>	<b>-</b>	<b>-</b>	<b>9,361</b>
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<b>31/12/2017</b> <b>In € thousand</b>	<b>Within one year</b>	<b>&gt;1 and &lt;5 years</b>	<b>&gt;5 and &lt;10 years</b>	<b>&gt;10 years</b>	<b>Total</b>
<b>Borrowings</b>					
Lease liabilities	20	15	-	-	35
<b>Other financial liabilities</b>					
Loans from shareholders	-	6,766			6,766
<b>Total</b>	<b>20</b>	<b>6,781</b>	<b>-</b>	<b>-</b>	<b>6,801</b>

<b>01/01/2017</b> <b>In € thousand</b>	<b>Within one year</b>	<b>&gt;1 and &lt;5 years</b>	<b>&gt;5 and &lt;10 years</b>	<b>&gt;10 years</b>	<b>Total</b>
<b>Borrowings</b>					
Lease liabilities	21	35	-	-	56
<b>Other financial liabilities</b>					
Loans from shareholders	-	2,436			2,436
<b>Total</b>	<b>21</b>	<b>2,471</b>	<b>-</b>	<b>-</b>	<b>2,492</b>

## 6. OPERATING SEGMENTS

According to IFRS 8, reportable operating segments are identified based on the “management approach”. This approach stipulates external segment reporting based on the Group’s internal organizational and management structure and on internal financial reporting to the chief operating decision maker.

The Group’s activities are managed and operated in one segment, pharmaceuticals. There is no other significant class of business, either individual or in aggregate. As such, the chief operating decision maker reviews the operating results and operating plans and makes resource allocation decisions on a company wide basis.

The revenue generated currently relates to royalties generated from one third party customer, Altha Thera.

### 6.1. Geographical information

Revenue reported in the consolidated statement of profit or loss and other comprehensive income and non-current assets recorded in the consolidated statement of financial position are located in Belgium, country of domicile of the Company.

## 7. LIST OF CONSOLIDATED COMPANIES AS AT DECEMBER 31, 2019

<b>Company name</b>	<b>Company number</b>	<b>Location</b>	<b>% financial interest</b>
Hyloris Pharmaceuticals SA	BE 0674.494.151	Blvd Gustave Kleyer 17, 4000 Liège	Parent
Hyloris Developments SA	BE 0542.737.368	Blvd Gustave Kleyer 17, 4000 Liège	99.99%
RTU Pharma SA	BE 0669.738.676	Blvd Gustave Kleyer 17, 4000 Liège	100.00%
Dermax SA	BE 0667.730.677	Blvd Gustave Kleyer 17, 4000 Liège	100.00%

The voting rights equal the percentage of financial interest held.

## 8. BUSINESS COMBINATIONS UNDER COMMON CONTROL

### 8.1. 2019 Acquisition

On December 31, 2019, the Company acquired Dermax for a total consideration of EUR 18,260 thousand. The consideration is fully settled in equity instruments (issue of 855,409 shares). The consideration settled in equity instruments was determined based on a pre-money valuation of the company resulting from the weighted average of a discounted cash flow approach and EBITDA multiple approach minus net debt. This valuation was confirmed by the board of directors of Hyloris and was in accordance with the report as provided by the external auditor (i.e. PKF-VMB Réviseurs d'Entreprises SCRL) of the Company.

Dermax is a company founded in Liège in December 2016 and similarly as the Company focused on 505 (b)(2) approvals as well as complex generics. It is specialized in the development of products in various therapeutic areas such as antibiotic for skin-related diseases, hormone therapy and anti-viral medicine and has on-going discussion with third-parties that could result in addition of new products in the pipeline. Dermax is a strategic contributor to the future success of Hyloris through the addition of a strong network of partners which will reinforce the group in the future.

Considering that both the Company and Dermax were ultimately controlled by the same parties both before and after the business combination, the acquisition is considered as a business combination under common control which falls outside the scope of IFRS 3 (see also note 3.2. above). At incorporation of Dermax in December 2016, Stijn Van Rompay and Thomas Jacobsen, who are key management and shareholders of Hyloris, were the only shareholders of Dermax. The other shareholders entered the capital of Dermax during the capital increase done in 2018. As such, Hyloris' ultimate controlling party did not hold the majority of the shares in Dermax, but the other shareholders agreed to take any decisions with prior approval of Hyloris' ultimate controlling party. Furthermore, Dermax' management and board of directors consisted of Stijn Van Rompay and Thomas Jacobsen, who are key management of Hyloris. Hyloris' involvement was not only limited to the shares held and the shared management, but Hyloris also granted financing for the activities of Dermax.

As the acquisition is considered a common control transaction, the business combination is not in scope of IFRS 3 Business Combinations. Based on this, the Group selected the accounting policy choice to account for the acquisition by applying the predecessor approach. The application of the predecessor approach to the acquisition of Dermax consisted of the following accounting steps:

- Restated and adjust the comparative statements as if the acquisition had occurred before the start of the earliest period presented. This restatement should not extend to periods during which the entities were not under common control. Based on this, Dermax has been included in these consolidated financial statements as from January 1st, 2017.
- Considering that, accounting wise, Dermax is included in these financial statements as from January 1st, 2017, the share issue done legally in December 2019 to finance the acquisition (see note 14.2) is also accounted for as from the start of the earliest period presented.
- As Hyloris' controlling shareholders only held part of the shares of Dermax till December 2019, the Group recognized non-controlling interests (52.94%) for the shares in Dermax not held by Hyloris' shareholders as from October 30th 2018, date at which the non-controlling interests entered into the equity of Dermax. The capital increase was subscribed by Hyloris in cash (EUR 250 thousand). As such, this is presented under the investing activities in the consolidated statement of cash flows in 2018.
- At the date of the legal acquisition (i.e. December 31, 2019), the balance of non-controlling interests is reclassified to the Group retained earnings.

Acquisition-related costs were not significant and included only notary fees.

## 8.2. 2018 Acquisition

In September 2018, the Company acquired RTU Pharma for a total consideration of EUR 200 thousand. The consideration was settled in cash.

Considering that both the Company and RTU Pharma were ultimately controlled by the same parties both before and after the business combination, the acquisition was considered as a business combination under common control which falls outside the scope of IFRS 3 (see note 3.2. above). As such, Hyloris' ultimate controlling party was also the 100% controlling party of RTU Pharma. Furthermore, RTU Pharma's board of directors was the same as the board of directors of Hyloris. Hyloris' involvement was not only limited to the shares held and the shared management, but Hyloris also granted financing for the activities of RTU Pharma.

As the acquisition is a transaction under common control, no goodwill nor gain on a bargain purchase was recognized, but the investment is recognized immediately in equity (EUR 200 thousand).

Acquisition-related costs were not significant and included only notary fees.

As such, the Group applied the predecessor approach, which implies that the comparative statements have been restated and adjusted as if the transaction had occurred before the start of the earliest period presented. This restatement should not extend to periods during which the entities were not under common control. Based on this, RTU Pharma has been included in these consolidated financial statements as from its incorporation in 2017. As such, the cash paid the incorporation of RTU Pharma in 2017 has been presented as investing activity in the consolidated statement of cash flows.

See note 8.1. for the details of the accounting based on the predecessor approach.

## 9. INTANGIBLE ASSETS

in € thousands	Development costs	Assets Purchase	In Licencing	Total
<b>Year ended December 31, 2019</b>				
Opening carrying amount	245	3 704	-	3 949
Additions	461	400	401	1 262
Borrowing costs capitalized	5	168	-	173
Amortization expense		(43)		(43)
Impairment losses	-	(3 203)		(3 203)
<b>Closing carrying amount</b>	<b>712</b>	<b>1 026</b>	<b>401</b>	<b>2 138</b>
<b>At December 31, 2019</b>				
Cost	712	4 458	401	5 570
Accumulated amortization and impairment		(3 432)		(3 432)
<b>Carrying amount</b>	<b>712</b>	<b>1 026</b>	<b>401</b>	<b>2 138</b>

in € thousands	Development costs	Assets Purchase	In Licencing	Total
<b>Year ended December 31, 2018</b>				
Opening carrying amount	245	3 580	-	3 825
Additions		0		0
Borrowing costs capitalized	-	168		168
Amortization expense		(44)		(44)
<b>Closing carrying amount</b>	<b>245</b>	<b>3 704</b>	<b>-</b>	<b>3 949</b>
<b>At December 31, 2018</b>				
Cost	245	3 890		4 135
Accumulated amortization and impairment		(185)		(185)
<b>Carrying amount</b>	<b>245</b>	<b>3 704</b>		<b>3 949</b>

in € thousands	Development costs	Assets Purchase	In Licencing	Total
<b>Year ended December 31, 2017</b>				
Opening carrying amount	245	756	-	1 001
Additions		2 800		2 800
Borrowing costs capitalized		67		67
Amortization expense		(43)		(43)
<b>Closing carrying amount</b>	<b>245</b>	<b>3 580</b>	<b>-</b>	<b>3 825</b>
<b>At December 31, 2017</b>				
Cost	245	3 722		3 967
Accumulated amortization and impairment		(141)		(141)
<b>Carrying amount</b>	<b>245</b>	<b>3 580</b>	<b>-</b>	<b>3 825</b>

In 2019, the Company acquired intangible assets for a total of EUR 1.3 million, of which (i) EUR 461 thousand related to the development costs of product-candidates that have reached the development phase (namely Tranexamic RTU, Maxigesic® and HY-EMP-16), (ii) EUR 400 thousand of assets purchase (product candidate HY-REF-075) and (iii) EUR 401 thousand of in-

licensing of product candidates. In-licensing acquisition were related to the product candidate Fusidic Acid Cream for an amount of EUR 175 thousand, several product candidates of our Cardiovascular IV portfolio for an amount of EUR 134 thousand and EUR 91 thousand related to the product candidate Atomoxetine Liquid.

In 2018, there were no acquisition of intangibles. The additions of EUR 2,800 thousand in 2017 was relating to the acquisition of HY-REF-028, the development of which, following market information and the decision of Hyloris management, has been put on hold and fully impaired in 2019 (see note 19).

Borrowing costs are calculated on 'Assets Purchase' and on Capitalized Development costs using a 6% annual interest rate, in line with the weighted average borrowing rate applicable to the Group.

The intangible assets are not amortized until the moment they are available for use as intended by management, i.e. ready for commercialization. The company is amortizing since 2014 the development costs of Sotalol IV, an asset for which regulatory approval had been obtained. The development costs of Sotalol IV have a remaining useful life of 6 years.

The amortization expenses are included in "Cost of sales" in the consolidated statement of profit or loss and other comprehensive income.

The main on-going development projects recognized as intangible assets are broken down by portfolio and which are not yet amortized are as follows:

<b>in € thousand</b>	<b>December 31, 2019</b>	<b>December 31, 2018</b>	<b>December 31, 2017</b>	<b>January 1, 2017</b>
Cardiovascular Portfolio	134			
Established Market Portfolio	249			
Reformulation Portfolio	1,549	3,700	3,532	665
<b>Total Intangible assets not yet amortized</b>	<b>1,932</b>	<b>3,700</b>	<b>3,532</b>	<b>665</b>
Intangible assets for which amortization already started	206	249	293	336
<b>Carrying amount – Intangible assets</b>	<b>2,138</b>	<b>3,949</b>	<b>3,825</b>	<b>1,001</b>

Therefore, as long as the assets are not amortized, they are tested for impairment losses on an annual basis or more frequently if specific indicators require it. The impairment test conducted is performed by product and consists in measuring the recoverable amount. The recoverable amount of the product is estimated based on the forecasted future cash flows discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. The time horizon used for the impairment testing is based on the period during which the Company expects to generate cash flows from the project, which period does not exceed 10 years in the management estimates.

The impairment losses are included in the Research and Development expenses in the consolidated statement of profit or loss and other comprehensive income.

Based on the impairment tests conducted at year-end, except for the impairment loss recorded on product-candidate HY-REF-028 (refer to comment above), the recoverable amount of the different products was estimated to be higher than their carrying amount and no impairment was required. The main assumptions used are the discount rate and the probability of success. As defined in section 2.8, the discount rate reflecting current market assessments of the time value of money and the risks specific to the asset, and which was used for the impairment test, is estimated at 12.77%.

The main variables that lead to a discount rate of 12.77% are:

- a risk free rate of 0.09% (corresponding to the 10-year OLO rate as of December 31, 2019)
- a beta factor of 1.31
- a market risk rate of 5.96%
- a Company specific risk premium of 7%
- a cost of debt before tax of 6%

Probability of success (PoS) rate varies from 100% for the commercial products of the Company to 60% for the less developed products of the Company.

We tested the sensitivity analysis of the impairment tests by increasing the discount rate by 4%, leading the discount rate to 16.77%. We cumulatively decreased the probability of success up to 40%, leading the PoS to 60% and 20% respectively for the commercial products and product in developments. None of these assumptions resulted to an impairment loss.

No intangible assets have been pledged in the context of financial liabilities.

## 10. RIGHT-OF-USE ASSETS

<b>in € thousand</b>	<b>Land and buildings</b>	<b>Vehicles and equipment</b>	<b>Total</b>
<b>Year ended December 31, 2019</b>			
Opening carrying amount	88	31	119
Depreciation expense	(36)	(16)	(53)
<b>Closing carrying amount</b>	<b>51</b>	<b>15</b>	<b>66</b>
<b>At December 31, 2019</b>			
Cost	109	66	175
Accumulated depreciation and impairment	(58)	(51)	(109)
<b>Carrying amount</b>	<b>51</b>	<b>15</b>	<b>66</b>

<b>in € thousand</b>	<b>Land and buildings</b>	<b>Vehicles and equipment</b>	<b>Total</b>
<b>Year ended December 31, 2018</b>			
Opening carrying amount	7	28	35
Additions	109	17	126
Depreciation expense	(29)	(14)	(43)
<b>Closing carrying amount</b>	<b>88</b>	<b>31</b>	<b>119</b>
<b>At December 31, 2018</b>			
Cost	109	66	175
Accumulated depreciation and impairment	(21)	(35)	(56)
<b>Carrying amount</b>	<b>88</b>	<b>31</b>	<b>119</b>

<b>in € thousand</b>	<b>Land and buildings</b>	<b>Vehicles and equipment</b>	<b>Total</b>
<b>Year ended December 31, 2017</b>			
Opening carrying amount	16	40	56
Depreciation expense	(9)	(12)	(21)
<b>Closing carrying amount</b>	<b>7</b>	<b>28</b>	<b>35</b>
<b>At December 31, 2017</b>			
Cost	27	48	75
Accumulated depreciation and impairment	(19)	(21)	(40)
<b>Carrying amount</b>	<b>7</b>	<b>28</b>	<b>35</b>

The Group leases its headquarter building and some company cars. The contracts do not include any purchase options. The lease term considered for the building is three years, while for the company cars the lease term ranges between 4 and 5 years.

The amounts recognized in profit or loss can be summarized as follows:

<b>In € thousand</b>	<b>2019</b>	<b>2018</b>	<b>2017</b>
Depreciation expense of right-of-use assets	(53)	(43)	(21)
Interest expense on lease liabilities	(4)	(2)	(1)
Expenses relating to low-value leases	(1)	(1)	(1)
<b>Total amount recognized in profit or loss</b>	<b>(58)</b>	<b>(45)</b>	<b>(23)</b>

of which as:

General and administrative expenses (note 19)	(54)	(44)	(22)
Financial expenses (note 21)	(4)	(2)	(1)

The depreciation expenses are all presented as "General and administrative expenses".

The Group has lease contracts that include termination options. These options are negotiated by management to provide flexibility in managing the leased assets and align with the Group's business needs.

The undiscounted potential future rental payments relating to periods following the exercise date of termination options that are not included in the lease term amount to EUR 223 thousand.

## 11. TRADE RECEIVABLES AND OTHER RECEIVABLES

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Trade receivables	58	154	186	20
Less: allowance for impairment of trade receivables	-	-	-	-
<b>Trade receivables - net</b>	<b>58</b>	<b>154</b>	<b>186</b>	<b>20</b>
Prepayments	-	-	-	-
Other amounts receivable	275	987	30	17
<b>Prepaid expenses and other receivables</b>	<b>275</b>	<b>987</b>	<b>30</b>	<b>17</b>
<b>Trade and other receivables - Current</b>	<b>333</b>	<b>1,141</b>	<b>216</b>	<b>38</b>

An impairment analysis of trade receivables is done on an individual level, and there are no individual significant impairments.

The carrying amount of the Group's trade receivables (gross) is denominated in EURO.

During the year, the payment terms for the receivables have neither deteriorated nor been renegotiated. The maximum credit risk exposure at the end of the reporting period is the carrying value of each caption of receivables mentioned above. The Group does not hold any collateral as security.

Other amounts receivable mainly includes recoverable VAT.

## 12. OTHER CURRENT ASSETS

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Pre-paid R&D expenses	3,150	-	-	-
Other pre-paid expenses	50	10	5	6
Accrued income	-	-	-	-
<b>Other current assets</b>	<b>3,200</b>	<b>10</b>	<b>5</b>	<b>6</b>

Pre-paid R&D expenses relate to payments made by the Company for research and development projects conducted by third parties and will be recorded in profit and loss when incurred.

Pre-paid R&D expenses of EUR 3,150 thousand in 2019 related to:

- EUR 2,000 thousand: On 28 June 2019, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group, a related party of Hyloris) entered into a "development agreement" with Dermax, pursuant to which GSP agreed to carry out all development activities required for the acquisition/ registration of ANDA/NDA approval for the product HY-REF-038 in vial and prefilled syringes forms.
- EUR 800 thousand: development agreement with Stasisport Pharma (a subsidiary of the Alter Pharma group, a related party of Hyloris) to run the clinical development of the Fusidic Acid cream product candidate
- EUR 350 thousand: On 21 December 2018, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group, a related party of Hyloris) entered into an Asset purchase and development agreement with Hyloris Developments, pursuant to which GSP assigned and transferred to Hyloris Developments all intellectual property rights, title and interests in a product that has since been discontinued. In consideration of the amount paid by Hyloris, GSP will develop the (patentable) product, will be responsible for the patent application and for the submission of the NDA with the FDA. In 2019, Hyloris made a pre-payment of EUR 350,000. As of 31 December 2019, no decision was made on the selection

of a new product, hence no expenses have been incurred yet on that project. Therefore, the full amount paid is recognized as pre-paid R&D expenses. An outstanding milestone payment of EUR 150 thousand will only be due upon completion of the formulation of the product.

### 13. CASH AND CASH EQUIVALENTS

The net cash position as presented in the consolidated statement of cash flows is as follows:

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Cash at bank and in hand	205	2,687	271	224
Short-term bank deposits	-	-	-	-
<b>Total cash and cash equivalents</b>	<b>205</b>	<b>2,687</b>	<b>271</b>	<b>224</b>

The carrying amount of the cash and cash equivalents is a reasonable approximation of their fair value.

### 14. SHARE CAPITAL AND SHARE PREMIUM

#### 14.1. Capital management

The Company manages its capital to maintain a strong level of capital in order to sustain development of the business and confidence of creditors while optimizing return on capital for shareholders. This ensures that entities in the Group will be able to continue as going concerns while maximizing the return to stakeholders through the optimization of its debt and equity balance. Also refer to Note 3.1 for further details on going concern.

The Group is not subject to any externally imposed capital requirements except those provided for by law. The Group's management reviews the capital structure of the Group on a regular basis. As part of this review, management considers the cost of capital and the risks associated with each class of capital. The Group's objectives, policies and processes for managing capital have remained unchanged over the past few years.

#### 14.2. Share capital and share premium

The shares are fully paid up and have no nominal value.

All shares rank equally with regard to the Company's residual assets. Holders of these shares are entitled to dividends as declared from time to time and are entitled to one vote per share at general meetings of the Company.

The following capital transactions have taken place since January 1st, 2017:

Date	Transaction	Increase of share capital (incl. share premium) (€)	Number of securities issued	Issue price / share (rounded, incl. share premium) (€)	Number of Shares after the transaction
7 June 2012	Incorporation	50,000	10,000 Shares	5.00	10,000
31 March 2017	Capital increase	11,500	2,300 Shares	5.00	12,300
12 May 2017	Share split	-		-	3,075,000
12 May 2017	Warrants issue	-	300,000 Transaction Warrants	-	3,075,000
31 May 2018	Capital increase	2,750,000	248,711 Shares	11.06	3,323,711
31 May 2018	Warrants issue	-	5 Adjustment Warrants	-	3,323,711
31 May 2018	Warrants issue	-	5 Anti-dilution Warrants	-	3,323,711
31 May 2018	Capital increase	3,000,000	271,322 Shares	11.06	3,595,033
31 December 2019	Capital increase	18,259,783	855,409 Shares	21.35	4,450,442
31 December 2019	Warrants issue	-	90,825 ESOP Warrants	-	4,450,442
31 March 2020	Convertible bonds issue	-	500 Convertible Bonds	-	4,450,442
8 June 2020	Share split	-	-	-	17,801,768

Accounting wise, the share issue of December 2019 was accounted for as from the date of establishment of common control in Dermax, as disclosed in note 8.1.

## 15. BORROWINGS AND OTHER FINANCIAL LIABILITIES

### 15.1. Borrowings

In € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Bank borrowings	-	-	-	-
Lease liabilities	66	118	35	56
Other borrowings	-	-	-	-
<b>Total borrowings</b>	<b>66</b>	<b>118</b>	<b>35</b>	<b>56</b>
of which as:				
Non-current borrowings	22	66	15	35
Current borrowings	44	52	20	21

For more details on the leases, we refer to note 10 on "Right-of-use assets".

The weighted average incremental borrowing rate used for the measurement of the lease liabilities is 1.60%.

The Group is not subject to financial covenants.

The underlying leased assets act as pledge in the context of the lease liabilities.

### 15.2. Other financial liabilities

The other financial liabilities can be detailed as follows:

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Loans from shareholders	12,721	9,243	6,766	2,436
Recoverable cash advance	409	-	-	-
<b>Other financial liabilities</b>	<b>13,130</b>	<b>9,243</b>	<b>6,766</b>	<b>2,436</b>
of which as:				
Non-current other financial liabilities	-	9,243	6,766	2,436
Current other financial liabilities	13,130	-	-	-

#### *Loans from shareholders*

The loans from shareholders are unsecured and bear a fixed nominal interest rate of 4% which are payable when the principal is due at the end of 2020, unless agreed otherwise between the parties. The Company reassessed the interest rate under the shareholders loan agreements and considered that a 6% interest rate represented a fair estimate at which it could obtain similar loans based on benchmarking obtained from peer companies with a similar profile and the rate applied in its pre-IPO convertible bonds.

#### *Sensitivity analysis of the shareholders loans*

A variance of 1% of the interest rate will have a EUR 127 thousand impact on the statement of profit or loss of the Company (on an annual basis).

#### *Recoverable cash advance*

The recoverable cash advance ('RCA') received by the Company from the Walloon Region which gives rise to a financial liability in the scope of IFRS 9 Financial Instruments as the advance needs to be settled by paying back the cash received or transfer all relating intellectual property rights and titles. As at year-end December 31, 2019, the research program for which the advance was granted was abandoned due to unsatisfactory results. The Company judges that the financial liability of the effectively received EUR 488 thousand will be settled by paying back the unutilized cash received for an amount of EUR 409 thousand. Subsequent to the initial recognition, the financial liability is measured at amortized cost using the effective interest method on the

basis of the estimated contractual cash flows with changes in value due to a change in estimated cash flows recognized in profit or loss, in accordance with IFRS 9.

The following table gives an overview of the difference between the fair value of the shareholder's loans and their nominal value and the subsequent impact to profit or loss:

	Nominal amount, incl. accrued interests	Fair value at initial recognition	Difference between fair value and nominal value	Deferred taxes	Total impact	Equity		Income statement
						Contribution by shareholder, gross	Deferred tax impact in equity	
<b>In € thousand</b>								
<b>Balance at January 1, 2017</b>	<b>2,665</b>	<b>2,436</b>	<b>228</b>	<b>(57)</b>	<b>171</b>	<b>228</b>	<b>(57)</b>	<b>-</b>
Capital contribution			245	(61)	183	288	(72)	(33)
<b>Balance at December 31, 2017</b>	<b>7,289</b>	<b>6,816</b>	<b>473</b>	<b>(118)</b>	<b>355</b>	<b>516</b>	<b>(129)</b>	<b>(33)</b>
Capital contribution			(49)	12	(37)	84	(21)	(99)
<b>Balance at December 31, 2018</b>	<b>9,660</b>	<b>9,236</b>	<b>424</b>	<b>(106)</b>	<b>318</b>	<b>600</b>	<b>(150)</b>	<b>(132)</b>
Capital contribution			(139)	35	(104)	57	(14)	(147)
<b>Balance at December 31, 2019</b>	<b>13,012</b>	<b>12,727</b>	<b>285</b>	<b>(71)</b>	<b>214</b>	<b>657</b>	<b>(164)</b>	<b>(279)</b>

### 15.3. Liquidity and cash flow reconciliation

The maturity table of the borrowings and the other financial liabilities is presented in note 5 on the liquidity risk.

The following tables reconcile the movements of the financial liabilities to the cash flows arising from financing activities:

31/12/2019 In € thousand	Non-cash movements							Closing carrying amount
	Opening carrying amount	Cash flows	Acquisition	Capital contribution (note 15.2)	Re-classes	Accrued interests and exchange differences		
<b>Non-current financial liabilities</b>								
Lease liabilities	66	-	-	-	(44)	-	-	22
Other financial liabilities	9,243	-	-	-	(9,243)	-	-	-
<b>Current financial liabilities</b>								
Lease liabilities	52	(52)	-	-	44	-	-	44
Other financial liabilities	-	3,364	-	(57)	9,243	580	-	13,130
<b>Total liabilities from financing activities</b>	<b>9,361</b>	<b>3,312</b>	<b>-</b>	<b>(57)</b>	<b>-</b>	<b>580</b>	<b>-</b>	<b>13,196</b>
Presented in the statement of cash flows (financing activities) as follows:								
Proceeds from borrowings and other financial liabilities		3,364						
Repayment of borrowings and other financial liabilities		(52)						

31/12/2018 In € thousand	Non-cash movements							Closing carrying amount
	Opening carrying amount	Cash flows	Acquisition	Capital contribution (note 15.2)	Re-classes	Accrued interests and exchange differences		
<b>Non-current financial liabilities</b>								
Lease liabilities	15	-	126	-	(75)	-	-	66

Other financial liabilities	6,766	2,060	-	(84)	-	500	9,243
<b>Current financial liabilities</b>							
Lease liabilities	20	(43)	-	-	75	-	52
Other financial liabilities	-	-	-	-	-	-	-
<b>Total liabilities from financing activities</b>	<b>6,801</b>	<b>2,017</b>	<b>126</b>	<b>(84)</b>	<b>-</b>	<b>500</b>	<b>9,361</b>
Presented in the statement of cash flows (financing activities) as follows:							
Proceeds from borrowings and other financial liabilities		2,060					
Repayment of borrowings and other financial liabilities		(43)					

31/12/2017 In € thousand	Non-cash movements						Closing carrying amount
	Opening carrying amount	Cash flows	Acquisition	Capital contribution (note 15.2)	Re-classes	Accrued interests and exchange differences	
<b>Non-current financial liabilities</b>							
Lease liabilities	35	-	-	-	(20)	-	15
Other financial liabilities	2,436	4,408	-	(288)	-	(210)	6,766
<b>Current financial liabilities</b>							
Lease liabilities	21	(21)	-	-	20	-	20
Other financial liabilities	-	-	-	-	-	-	-
<b>Total liabilities from financing activities</b>	<b>2,492</b>	<b>4,387</b>	<b>-</b>	<b>(288)</b>	<b>-</b>	<b>(210)</b>	<b>6,801</b>
Presented in the statement of cash flows (financing activities) as follows:							
Proceeds from borrowings and other financial liabilities		4,408					
Repayment of borrowings and other financial liabilities		(21)					

## 16. TRADE AND OTHER LIABILITIES

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Trade payables	2,866	2,056	1,770	976
Employee benefit liabilities	52	26	30	15
Other payables	8	916	-	-
<b>Trade and other liabilities - Current</b>	<b>2,927</b>	<b>2,998</b>	<b>1,799</b>	<b>991</b>

The trade payables relate mainly to the R&D activities and increased significantly in 2019 in line with the increase in R&D activities and relates mainly to outstanding invoices for pre-paid R&D expenses related to product candidate HY-REF-038 and Fusidic Acid Cream.

The fair value of trade payables approximates their carrying amount.

Other payables relate to VAT payables.

Liquidity and currency risk are detailed in note 5 above.

## 17. DEFERRED TAXES

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset and when the deferred taxes relate to the same fiscal authority. The deferred tax assets and liabilities are attributable to the following items:

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
---------------	-------------------	-------------------	-------------------	-----------------

	Deferred tax asset	Deferred tax liability						
Intangible assets	503	-	1,829	-	802	-	320	-
Leases	-	-	-	-	-	-	-	-
Inventories	-	-	-	-	-	-	27	-
Financial liabilities	-	(71)	-	(106)	-	(118)	-	(57)
Others	-	-	-	-	5	-	45	-
Tax losses	1,990	-	673	-	355	-	166	-
<b>Total deferred tax assets &amp; liabilities</b>	<b>2,493</b>	<b>(71)</b>	<b>2,502</b>	<b>(106)</b>	<b>1,163</b>	<b>(118)</b>	<b>558</b>	<b>(57)</b>
Net deferred tax assets not recognized	(2,422)	-	(2,396)	-	(1,044)	-	(501)	-
Offsetting	(71)	71	(106)	106	(118)	118	(57)	57
<b>Total deferred tax assets &amp; liabilities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>

The deferred tax liability on the financial liabilities relates to the initial recognition of the loans from shareholders at fair value and has been recorded through equity following the underlying. This deferred tax liability is however offset by the same amount of deferred tax assets recognized through the income statement.

Deferred tax assets have not been recognized in respect of the following items, because it is not probable that future taxable profits are available against which the Group can use the benefits of therefrom:

in € thousand	December 31, 2019	December 31, 2018	December 31, 2017	January 1, 2017
Deductible temporary differences	1,727	6,890	2,757	1,339
Tax losses	7,960	2,694	1,420	664
<b>Total</b>	<b>9,687</b>	<b>9,584</b>	<b>4,177</b>	<b>2,003</b>

The deductible temporary differences disclosed above would reverse over a period ranging between 5 to 10 years.

The tax losses carried forward, however, are available indefinitely.

## 18. REVENUE AND OTHER OPERATING INCOME

Currently, the Group generates only limited revenue as its main projects are in the development pipeline and are not yet commercialized. The limited revenue currently presented in the consolidated statement of comprehensive income relates to royalty income from our commercialized product, Sotalol IV.

The other operating income relates mostly to the Recoverable Cash Advance (RCA) received from the Walloon Region. The income recognized by the Company corresponds to the amount of expenses allocated to the research program partially financed by the RCA.

## 19. EXPENSES BY NATURE

Expenses by nature represent an alternative disclosure for amounts included in the consolidated statement of comprehensive income. They are classified under "Cost of sales", "Research and development expenses", "General and administrative expenses" and "Other operating expenses" in respect of the years ended December 31:

In € thousand	2019	2018	2017
Amortization expense of intangible assets (note 9)	(43)	(44)	(43)
Impairment losses on intangible assets (note 9)	(3,203)	-	-
Depreciation expense of property, plant and equipment	(7)	(1)	(1)
Depreciation expense of right-of-use assets (note 10)	(53)	(43)	(21)
Employee benefit expenses (note 20)	<b>(377)</b>	<b>(306)</b>	<b>(180)</b>
Management consultancy fees	(353)	(394)	(313)
Share based payments	-	-	(1,329)
Legal & paralegal fees	(253)	(122)	(82)

Office expenses	(101)	(31)	(14)
Out-sourced R&D	(971)	(4,573)	(1,983)
Travel expenses	(34)	(11)	(1)
Other expenses	(55)	(34)	(129)
<b>Total operating expenses</b>	<b>(5,451)</b>	<b>(5,560)</b>	<b>(4,096)</b>
of which as:			
Cost of sales	(66)	(65)	(95)
Research and development expense	(4,577)	(4,870)	(2,313)
General and administrative expenses	(808)	(622)	(1,657)
Other operating expenses	-	(3)	(31)

The employee benefit expenses include both employees and contractors as detailed in note 20.

Legal & paralegal fees have increased as a result of potential finance transactions (IPO) which are considered.

Hyloris' research and development expenses decreased by 14.3%, from EUR 4,870 thousand for the year ended December 31, 2018 to EUR 4,577 thousand for the year ended December 31, 2019.

In 2019, an impairment loss for a total of EUR 3,203 thousand was recognized in research and development expenses, as a result of the full impairment of one of Hyloris' product candidate development projects following unfavorable market information relating to that product candidate and Hyloris' decision to change its development focus towards other product candidates with higher expected profitability. Impairment loss included the acquisition costs for EUR 2,800 thousand and borrowing costs capitalized for EUR 403 thousand.

The net variance excluding the impairment loss amounted to EUR 3,496 thousand. This decrease was principally driven by (i) higher research and development costs on 2018 and by (ii) the fact three product candidates that were in the research phase in 2018 entered the development phase in 2019 (Maxigesic® IV, HY-EMP-016 and Tranexamic Acid RTU). In 2019, the Company capitalized developments costs for a total of EUR 0.5 million. The Company did not capitalize development costs prior to 2019.

Hyloris' research and development expenses increased by 110.5% in 2018, from EUR 2,313 thousand for the year ended December 31, 2017 to EUR 4,870 thousand for the year ended December 31, 2018. This increase was principally driven by Hyloris' increased product R&D activities.

Total R&D expenditure can be detailed as follows:

In € thousand	2019	2018	2017
Research and development costs	(1,374)	(4,870)	(2,313)
Impairment of assets	(3,203)	-	-
<b>Total R&amp;D costs</b>	<b>(4,577)</b>	<b>(4,870)</b>	<b>(2,313)</b>

## 20. EMPLOYEE BENEFIT EXPENSES

In € thousand	2019	2018	2017
Wages and salaries	(277)	(204)	(116)
Social security costs	(58)	(43)	(29)
Defined contribution costs	(9)	(6)	(5)
Other employee benefit expenses	(33)	(53)	(30)
<b>Total employee benefit expense</b>	<b>(377)</b>	<b>(306)</b>	<b>(180)</b>

in full-time equivalents	2019	2018	2017
Average number of total employees	9.7	8.8	7.0
Of which:			
- employees	5.5	4.8	3.0
- management	4.2	4.0	4.0

## 21. FINANCIAL RESULT

The various items comprising the net finance cost are as follows:

In € thousand	2019	2018	2017
Interest income on current assets	-	-	-
Exchange differences	10	7	257
<b>Financial income</b>	<b>10</b>	<b>7</b>	<b>257</b>
Interest expense on lease liabilities	(4)	(2)	(1)
Interest expense on other financial liabilities	(407)	(332)	(143)
<b>Interest expense</b>	<b>(411)</b>	<b>(334)</b>	<b>(144)</b>
Bank fees	(4)	(5)	(2)
Exchange differences	(103)	(252)	(27)
Other	-	(6)	(2)
<b>Total financial expenses</b>	<b>(518)</b>	<b>(597)</b>	<b>(174)</b>

We refer to note 9 for the capitalized borrowing costs.

## 22. INCOME TAX EXPENSE

### 22.1 Amounts recognized to profit and loss

The income tax (charged)/credited to the income statement during the year is as follows:

In € thousand	2019	2018	2017
Current tax (expense)/income	-	(1)	(6)
Deferred tax (expense)/income	14	21	72
<b>Total tax income</b>	<b>14</b>	<b>20</b>	<b>66</b>

### 22.2 Reconciliation of effective tax

The income tax expense can be reconciled as follows:

In € thousand	2019	2018	2017
<b>Loss before income tax</b>	<b>(5,782)</b>	<b>(6,059)</b>	<b>(3,783)</b>
Income tax expense calculated at domestic tax rates	1,446	1,515	946
Disallowed expenses	-	(16)	(2)
Effect of unused tax losses not recognized as deferred tax assets	(1,432)	(1,478)	(877)
<b>Total tax income</b>	<b>14</b>	<b>20</b>	<b>66</b>

## 23. EARNINGS PER SHARE

Basic earnings per share amounts are calculated by dividing net profit for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share amounts are calculated by dividing the net profit attributable to ordinary equity holders of the parent (after adjusting for the effects of all dilutive potential ordinary shares) by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

No effects of dilution affect the net profit attributable to ordinary equity holders of the Group. The table below reflects the income and share data used in the basic and diluted earnings per share computations:

In € thousand	2019	2018	2017
<b>Basic earnings</b>			
Loss from continuing operations attributable to owners of the Company	(5,373)	(5,791)	(3,717)
<b>Diluted earnings</b>			
Dilution effect of share-based payments	-	-	-
<b>Loss from continuing operations attributable to owners of the parent, after dilution effect</b>	<b>(5,373)</b>	<b>(5,791)</b>	<b>(3,717)</b>

*Earning par share based on the existing number of ordinary shares*

	2019	2018	2017
Weighted average existing number of ordinary shares outstanding during the period	3,597,377	3,379,896	2,933,219
Basic earnings per share (in €)	(1.49)	(1.71)	(1.27)
Diluted earnings per share (in €)	(1.49)	(1.71)	(1.27)

*Earning per share based on the number of shares as adjusted for the common control of Dermax SA*

In €	2019	2018	2017
Weighted average number of ordinary shares outstanding during the period as adjusted for the common control of Dermax SA	4,450,442	4,236,143	3,789,818
Basic earnings per share (in €)	(1.21)	(1.37)	(0.98)
Diluted earnings per share (in €)	(1.21)	(1.37)	(0.98)

As the Company is suffering operating losses, the stock options have an anti-dilutive effect. As such, there is no difference between basic and diluted earnings per ordinary share. There are no other instruments that could potentially dilute earnings per share in the future.

## 24. SHARE-BASED PAYMENTS

The Company has a stock option scheme for the employees, consultants and directors of the Company and its subsidiaries for rendered services. In accordance with the terms of the plan, as approved by shareholders, employees may be granted options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

Each employee share option converts into one ordinary share of the Company on exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry.

The following share-based payment arrangements were in existence during the current and prior years:

	Expiry Date	Exercise Price per stock option (€)	Fair value at grant date (€)	Options per December 31, 2019	Options per December 31, 2018	Options per December 31, 2017
<b>PLAN 2017</b>						
Options	4/05/2022	9.44	4.43	300,000	300,000	300,000
<b>PLAN 2019</b>						
Options	31/12/2024	21.35	9.88	78,250	-	-

The 2017 plan is fully vested immediately as no vesting conditions were required.

The 2019 plan is only subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). This plan has no impact on the income statement 2019, as the options have been granted on 31 December 2019. The Company offered 78,250 options to the beneficiaries. 29,500 options were accepted on 31 December 2019. The remaining options offered were accepted after the reporting date.

The following reconciles the options outstanding at the beginning and end of the year:

	Average exercise price (€)	Number of options
<b>Opening balance at January 1, 2017</b>	-	-
Granted	9.44	300,000
<b>Closing balance at December 31, 2017</b>	<b>9.44</b>	<b>300,000</b>
<b>Closing balance at December 31, 2018</b>	<b>9.44</b>	<b>300,000</b>
Granted	21.35	29,500
<b>Closing balance at December 31, 2019</b>	<b>10.51</b>	<b>329,500</b>

The 300,000 Transaction warrants are exercisable during the periods set out in the terms and conditions thereof, including notably an annual window during the 60 calendar days preceding the Annual General Shareholders' Meeting to be held in that year, and immediate exercisability in the event of an IPO of the Company. However, in the Shareholders' Agreement, all holders have committed not to exercise their Transaction Warrants (i) during the 60 calendar days' period prior to the Annual General Shareholders' Meeting to be held in 2020 regarding the financial year 2019 and (ii) from the first day of trading of the Shares on Euronext Brussels until closing of the Offering, without prejudice to the right of each holder of Transaction Warrants to exercise its Transaction Warrant(s) as from the closing of the Offering in accordance with the terms and conditions of the Transaction Warrants.

The fair value of the stock options has been determined based on the Black Scholes model. Expected volatility is based on the historical share price volatility over the past 5 years of listed peer companies.

Below is an overview of all the parameters used in this model:

	PLAN 2017	PLAN 2019
Share price (€)	9.44	21.35
Exercise Price (€)	9.44	21.35
Expected volatility of the shares (%)	55%	55%
Expected dividends yield (%)	0%	0%
Risk free interest rate (%)	0.60%	0.10%

## 25. CONTINGENCIES

At closing 2019, the Group was not involved in any claim or dispute incidental to the activities of the Group (nor in 2018 and 2017).

## 26. COMMITMENTS AND CONTINGENT LIABILITIES

Hyloris has contractual commitments and contingent liabilities for a maximum amount of EUR 3.4 million (among which EUR 0.25 million and USD 3.2 million converted in EUR at a rate of 1,1234) related to asset purchase, licenses and development agreements recorded under intangible assets. The amounts are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted.

The accounting treatment of the contractual commitments and contingent liabilities will vary per nature of triggering event. Development milestones up until commercialization will be expensed. Sales related commitments such as royalties, profit sharing and sales milestones will be expensed when incurred.

The following table details the total maximum contractual commitments (milestone payments only) at 31 December 2019 per product candidates if such products are successfully marketed (in'€000):

Product-Candidate	\$	€	Converted in €
HY-REF-004	225		200
Metolazone IV	1.750		1.558
Dofetilide IV	400		356
Atomoxetine Liquid	250		223
HY-CVS-073	625		556
To be assigned		150	150
HY-CVS-074	325		289
HY-REF-075		100	100
<b>TOTAL</b>	<b>3.575</b>	<b>250</b>	<b>3.432</b>

As of 31 December 2019, out of the total value of €3.4 million, \$1.8 million (or €1.6 million) should be considered as contingent liabilities as they are not triggered by a performance obligation from the counterparty (\$1.3 million for Metolazone IV, \$0.3 million for Atomoxetine Liquid and \$0.2 million for HY-REF-004).

Contingent liabilities attached to profit split and royalties which percentage varies based on achieved profit and/or sales are not considered in the above table as no maximum amount can be determined.

## 27. RELATED PARTY TRANSACTIONS

The reference shareholder is Stijn Van Rompay.

As part of the business, the Company has entered into several transactions with related parties.

Balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated on consolidation and are not disclosed in this note. Details of transactions between the Group and other related parties are disclosed below.

The related parties presented below are identified as:

- Shareholders; Mr Stijn Van Rompay, an executive member of the board of the Company, CEO and reference shareholder of the Company; GRNR Invest BVBA, an entity controlled by Thomas Jacobsen, an Executive member of the board of the Company; Pieter Van Rompay (Sibling of Mr Stijn Van Rompay.);
- The Alter Pharma group and its subsidiaries, in which Hyloris' Chief Executive Officer, Mr. Stijn Van Rompay, and board member and executive director, Mr. Thomas Jacobsen, have material ownership interests.
- Executive Management Team as defined in section 27.2

### 27.1. Transactions with related parties

The following table presents the total amount of services purchased from entities controlled by or related to members of the Executive Management Team:

in € thousand	Type of services	2019	2018	2017
Other related parties	Licensing	175	-	-
	Asset Purchase	750	-	2,800
	Development agreement	2,801	13	37
<b>Total</b>		<b>3,726</b>	<b>13</b>	<b>2,837</b>

The above mentioned Licensing refers to the License agreement with Stasisport Pharma (a subsidiary of the Alter Pharma group) and relates to the granted personal, sub-licensable and exclusive right to use all available development data and registration documents concerning Fusidic Acid Cream, in order to obtain (one or multiple) marketing authorizations for Fusidic Acid Cream in Canada, and to subsequently market, sell and distribute Fusidic Acid Cream in that territory.

The Asset Purchase of EUR 750 thousand in 2019 are related to:

- EUR 350 thousand: an Asset purchase and development agreement with GSP (a subsidiary of the Alter Pharma group), pursuant to which GSP assigned and transferred all (intellectual property) rights, title and interests in a product that, whereof the final selection still has to be made, as well as in all related data and documentation. The balance can be offset against another existing project in place between Hyloris, GSP or an affiliated company of GSP. Therefore, the full amount is recognized as pre-paid R&D.
- EUR 400 thousand: an Asset purchase and development agreement with Nordic Specialty Pharma BVBA (NSP, a subsidiary of the Alter Pharma group), pursuant to which NSP divest all of its rights with respect to HY-REF-075 (a

product currently being developed by NSP for the United States market and subject to NSP's approval any market, that will accept the US Formulation.

The Development agreement of EUR 2,800 thousand are to pre-paid expenses related to

- EUR 2,000 thousand: Development Agreement with Generic Specialty Pharma Ltd (GSP, a subsidiary of the Alter Pharma group), pursuant to which GSP agreed to carry out all development activities required for (the acquisition/ registration of ANDA/NDA approval for) the product HY-REF-038.
- EUR 800 thousand: Development Agreement with Stasisport Pharma (a subsidiary of the Alter Pharma group) to run the clinical development of the Fusidic Acid cream product candidate.

The Development transaction of EUR 2,800 thousand in 2017 relates to an Asset purchase and development agreement with GSP, pursuant to which GSP assigned and transferred to Hyloris Developments all (intellectual property) rights, title and interests in the product HY-REF-028. The development of this product candidate has been put on hold in 2019 (see note 19).

At year-end, the following trade payables were outstanding:

in € thousand	Type of services	December 2019	31, December 2018	31, December 2017
Other related parties	Licensing	175	-	-
	Asset Purchase	-	-	-
	Development Agreement	1,700	-	-
<b>Total</b>		<b>1,875</b>	<b>-</b>	<b>-</b>

The outstanding trade payables related to the Licensing is an outstanding payable to Stasisport Pharma (a subsidiary of the Alter Pharma group), concerning the License Agreement for Fusidic Acid Cream.

The outstanding trade payables related to the Development Agreement is an outstanding payable €1.4 million to GSP, concerning the development Agreement for product HY-REF-038 and €0.3 million related to Fusidic Acid Cream asset due to Stasisport Pharma.

The following loans from related parties were outstanding at the end of year:

in € thousand	December 2019	31, December 2018	31, December 2017
Loans from shareholders (excluding accrued interest)	11,651	8,535	6,434
<b>Total</b>	<b>11,651</b>	<b>8,535</b>	<b>6,434</b>

The reference Shareholder and CEO Stijn Van Rompay has an outstanding amount (principal loan) of EUR 9,652 thousand as per December 31, 2019. Pieter Van Rompay, Shareholder and sibling of Stijn Van Rompay has an outstanding amount (principal loan) of EUR 1,422 thousand as per December 31, 2019.

GRNR Invest BVBA, entity controlled by Thomas Jacobsen, Shareholder and executive director, has an outstanding amount (principal loan) of EUR 377 thousand as per December 31, 2019.

As per December 31, 2019 Stijn Van Rompay and his spouse have an outstanding amount (principal loan) of EUR 201 thousand as per December 31, 2019.

As per December 31, 2018 Stijn Van Rompay, Pieter Van Rompay and Thomas Jacobsen respectively have amounts outstanding (loan principals) of EUR 6,917 thousand, EUR 1,170 thousand and EUR 448 thousand. The amount outstanding related to loan from Thomas Jacobsen was repaid during 2019 (incl. accrued interests).

As per December 31, 2017 Stijn Van Rompay, Pieter Van Rompay and Thomas Jacobsen respectively have amounts outstanding (loan principals) of EUR 5,160 thousand, EUR 921 thousand and EUR 352 thousand.

The amounts outstanding are unsecured and will be settled in cash. No guarantees have been given or received.

The above loans bear fixed interest rates (nominal rate of 4% and effective interest rate of 6%). The amount of accrued interest at year-end amounted to EUR 1,069 thousand for 2019 (2018: EUR 708 thousand; 2017: EUR 332 thousand). For information related to the reimbursement of the shareholders loans, reference is made to Note 28.

#### Contractual commitments

Hyloris has contractual commitments for a maximum amount of EUR 0.25 million with related parties related to licenses and development agreements recorded under intangible assets. The amounts are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting

specified sales targets, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted.

The following table details the total maximum contractual commitments (milestone payments only) at 31 December 2019 per product candidates if such products are successfully marketed (in'€000). The profit split and royalties, which percentage varies based on achieved profit, are not included in the table:

Product-Candidate	Related party	€
To be assigned	Neogen	150
HY-REF-075	Nordic Speciality Pharma	100
<b>TOTAL</b>		<b>250</b>

## 27.2. Executive Management Team

Executive management team personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Group. As of 31 December 2019, members of the Executive Management Team are:

- Mr Stijn Van Rompay, an executive member of the board of the Company, CEO and reference shareholder of the Company; SVR Management.
- Jacobsen Management, an entity controlled by Thomas Jacobsen, an executive member of the board of the Company
- Humara Kinetics LLC, an entity controlled by Edward J Maloney, Chief Business Development Officer
- Maurizio Passanisi, Chief Clinical Officer<sup>204</sup>
- LOF Consulting, an entity controlled by Antoine Carlhian, Chief Financial Officer<sup>205</sup>

The table below presents the compensation of all members of Executive Management Team by type of compensation:

in € thousand	2019	2018	2017
Short-term compensation (including management fees)	350	338	361
Post-employment benefits	2	2	2
Other long-term benefits	-	-	-
Share-based payments	-	-	1,329
<b>Total</b>	<b>352</b>	<b>340</b>	<b>1,692</b>

As of 31 December 2019, members of the Executive Management Team owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct. (%)	Number (#)	Pct. (%)
Mr. Stijn Van Rompay (CEO)	1,609,516	36.17%	230,024	62.89%
Mr. Edward Maloney (CBDO)	107,207	2.41%	-	-
Mr. Antoine Carlhian (CFO) <sup>(1)</sup>	-	-	10,000	2.73%
Mr. Maurizio Passanisi (CCLO) <sup>(2)</sup>	47,631	1.07%	11,500	3.14%
Mr. Thomas Jacobsen (Executive director)	859,440	19.31%	40,878	11.18%
<b>TOTAL</b>	<b>2,623,794</b>	<b>58.96%</b>	<b>292,402</b>	<b>79.95%</b>

Note:

(1) Mr. Carlhian left the Company on 30 April 2020

(2) Mr. Passanisi will leave the Company on 3 July 2020 (i.e., shortly after the Offering, and is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

Total outstanding shares and warrants existing as of 31 December 2019 are respectively 4,450,442 and 365,750.

## 28. EVENTS AFTER THE END OF THE REPORTING PERIOD

### Shareholders loans

<sup>204</sup> Mr. Passanisi will leave the Company on 3 July 2020 (i.e., shortly after the Offering, and is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

<sup>205</sup> Mr. Carlhian left the Company on 30 April 2020

Since year end 2019 and the closing of the Convertible Bonds occurred on 31 March 2020, the Company financed its operations through shareholders loans. Over the first quarter 2020, Hyloris received additional loans from its shareholders for a total amount of EUR 3.25 million. In 2020, the Issuer repaid EUR 7.5 million of the outstanding shareholders loans. Following amendments to the shareholders loans agreements signed in May 2020, the remaining amount of the shareholders loans will be reimbursed at the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.

#### *Convertible bonds*

On March 31, 2020, the Company issued automatically convertible bonds for an aggregate nominal amount of EUR 10,800 thousand. On 30 April 2020, the Company issued additional convertible bonds of a nominal amount of EUR 4,350 thousand, bringing the total subscription to EUR 15,150 thousand (the "Bonds"). The Bonds are issued in registered form. Each Bond has a nominal value of EUR 50 thousand. The Bonds bear interest as from their issue date, at the rate of 6% per annum. The Bonds will automatically be converted into Shares at the earliest date between (i) the closing date of an IPO, (ii) the occurrence of an exit event, and (iii) 31 March 2022.

#### *COVID-19*

On March 11, 2020 the World Health Organization declared the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. The length or severity of this pandemic cannot be predicted, but the Group anticipates that there may be a potential impact from COVID-19 on the planned development activities of the Group.

With COVID-19 continuing to spread in Europe and in the United States, the business operations of the Group could be delayed or interrupted, particularly if a large portion of its employees become ill. COVID-19 may also affect employees of third-party organizations (such as CRO's and CMO's) located in affected geographies that the Group relies upon to carry out its preclinical and clinical trials. The spread of COVID-19, or another infectious disease, could also negatively affect the operations at its third-party suppliers, which could result in delays or disruptions in the supply of drug product used in its preclinical and clinical trials. In addition, the Group is taking temporary precautionary measures intended to help minimize the risk of the virus to its employees, including temporarily requiring all employees to work remotely, suspending all travel worldwide for its employees.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be potentially affected by the COVID-19 pandemic. Most of the Group's and CRO's clinical trial sites are located in the United States, currently being afflicted by COVID-19.

Some factors from the COVID-19 outbreak that the Group believes would affect enrollment in its trials at least on a temporary basis include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of physicians serving as Group's clinical trial investigators, hospitals serving as its clinical trial sites and hospital staff supporting the conduct of its clinical trials;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product used in our trials; and
- employee absences that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

The impact of COVID-19 on the Company's business and operations are uncertain and will depend on future developments, which are highly uncertain and cannot be predicted. The Company is of the opinion that although there are lot of uncertainties, it does not materially impact the Company's ability to continue operations. As of the date of authorization for issue of the consolidated financial statements, we have encountered some delays in the development of our product-candidates (such as delayed patient enrolment in the current clinical trials), but we do not believe this will result in major deviation in our planned activities and in the assumptions of our business plan. Also note that reference is made to the potential impact of COVID-19 in our assessment of the going concern (refer to Note 3.1).

There were no other subsequent events that occur between 2019 year-end and the date of the Prospectus.

## **29. AUDIT FEES**

The total audit fees for the statutory and consolidated financial statements for the period ended 31 December 2019 amounted to EUR 34,000. The total audit fees for the consolidated financial statements for the periods ended 31 December 2018, 2017 and 2016 amounted to EUR 24,000.

# HYLORIS GROUP

## CONDENSED CONSOLIDATED FINANCIAL STATEMENTS FOR THE 3-MONTH PERIOD ENDED MARCH 31, 2020 AND 2019

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# STATUTORY AUDITORS' REPORT TO THE BOARD OF DIRECTORS OF HYLORIS PHARMACEUTICALS SA ON THE REVIEW OF THE CONDENSED CONSOLIDATED INTERIM FINANCIAL INFORMATION AS AT 31 MARCH 2020 AND FOR THE THREE-MONTH PERIOD THEN ENDED

## INTRODUCTION

As statutory auditor of Hyloris Pharmaceuticals SA, we provide you with our review report on the condensed consolidated interim financial information as at 31 March 2020 and for the three-month period then ended.

We have reviewed the accompanying condensed consolidated statement of financial position of Hyloris Pharmaceuticals SA as at 31 March 2020, the condensed consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the three-month period then ended, and notes to the interim financial information ("the condensed consolidated interim financial information"). The board of directors is responsible for the preparation and presentation of this condensed consolidated interim financial information in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union. Our responsibility is to express a conclusion on this condensed consolidated interim financial information based on our review.

## SCOPE OF REVIEW

We conducted our review in accordance with the International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

## CONCLUSION

Based on our review, nothing has come to our attention that causes us to believe that the accompanying condensed consolidated interim financial information as at 31 March 2020 and for the three-month period then ended is not prepared, in all material respects, in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union.

## EMPHASIS OF MATTER – SUBSEQUENT EVENT – CONVERTIBLE BONDS

We draw attention to Note 19 of the consolidated financial statements, which describes the additional financing resulting from the convertible bonds contracted by the Company in April 2020.

Our conclusion is not modified in respect of this matter.

Zaventem, 15 June 2020

KPMG Réviseurs d'Entreprises  
Statutory auditor  
represented by

Olivier Declercq  
Réviseur d'Entreprises

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS (in € thousand)	Note	March 31, 2020	December 31, 2019
<b>Non-current assets</b>		<b>2,468</b>	<b>2,245</b>
Intangible assets	6	2,374	2,138
Property, plant and equipment		30	32
Right-of-use assets		55	66
Financial assets		9	9
<b>Current assets</b>		<b>18,025</b>	<b>3,739</b>
Trade and other receivables	7	1,742	333
Other financial assets	8	3,230	-
Current tax assets		-	-
Other current assets	8	1,840	3,200
Cash and cash equivalents		11,213	205
<b>TOTAL ASSETS</b>		<b>20,493</b>	<b>5,983</b>

EQUITY AND LIABILITIES (in € thousand)	Note	March 31, 2020	December 31, 2019
<b>Equity attributable to owners of the parent</b>		<b>(8,425)</b>	<b>(10,188)</b>
Share capital		89	89
Share premium		23,982	23,982
Retained earnings		(37,661)	(36,081)
Other reserves		5,165	1,822
<b>Non-current liabilities</b>		<b>10,682</b>	<b>22</b>
Borrowings	9	12	22
Other financial liabilities	9	10,671	-
<b>Current liabilities</b>		<b>18,235</b>	<b>16,149</b>
Borrowings	9	43	44
Other financial liabilities	9	16,112	13,130
Trade and other liabilities	10	2,033	2,927
Current tax liabilities		47	47
<b>Total liabilities</b>		<b>28,918</b>	<b>16,171</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>20,493</b>	<b>5,983</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

## CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE 3-MONTH PERIOD ENDED MARCH 31

in € thousand	Note	2020	2019
Revenue	11	63	40
Other operating income		-	-
Cost of sales	12	(20)	(23)
<b>Gross profit</b>		<b>44</b>	<b>18</b>
Research and development expenses	12	(784)	(443)
General and administrative expenses	12	(523)	(136)
Other operating expenses	12	-	-
<b>Operating profit/(loss)</b>		<b>(1,264)</b>	<b>(561)</b>
Financial income		9	99
Financial expenses	13	(325)	(223)
<b>Profit/(loss) before taxes</b>		<b>(1,579)</b>	<b>(685)</b>
Income taxes		(1)	-
<b>PROFIT/(LOSS) FOR THE PERIOD</b>		<b>(1,580)</b>	<b>(685)</b>
<b>Other comprehensive income</b>		<b>-</b>	<b>-</b>
<b>TOTAL COMPREHENSIVE INCOME OF THE PERIOD</b>		<b>(1,580)</b>	<b>(685)</b>
Profit/(loss) for the period attributable to the owners of the Company		(1,580)	(579)
Profit/(loss) for the period attributable to the non-controlling interests			(106)
Total comprehensive income for the period attributable to the owners of the Company		(1,580)	(579)
Total comprehensive income for the period attributable to the non-controlling interests		-	(106)
Basic and diluted earnings/(loss) per share (in €)	14	(0.36)	(0.16)

The accompanying notes are an integral part of these condensed consolidated financial statements.

**CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**  
FOR THE 3-MONTH PERIOD ENDED MARCH 31, 2020

	Attributable to equity holders of the Company					Equity attributable to owners of the parent	Non-controlling interests	Total Equity
	Share capital	Share premium	Other reserves		Retained earnings			
			Share-based payment reserve	Other reserves				
<i>(in thousands of euros)</i>								
<b>Balance at December 31, 2018</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>450</b>	<b>(28,097)</b>	<b>(2,246)</b>	<b>(2,216)</b>	<b>(4,462)</b>
Issuance of shares	-	-	-	-	-	-	-	-
Contribution by shareholder	-	-	-	14	-	14	-	14
Total comprehensive income	-	-	-	-	(579)	(579)	(106)	(685)
<b>Balance at March 31, 2019</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>464</b>	<b>(28,676)</b>	<b>(2,811)</b>	<b>(2,322)</b>	<b>(5,133)</b>
<b>Balance at December 31, 2019</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>493</b>	<b>(36,081)</b>	<b>(10,188)</b>	<b>-</b>	<b>(10,188)</b>
Share-based payments	-	-	113	-	-	113	-	113
Initial recognition of convertible bond at fair value (note 9)	-	-	-	3,230	-	3,230	-	3,230
Total comprehensive income	-	-	-	-	(1,580)	(1,580)	-	(1,580)
<b>Balance at March 31, 2020</b>	<b>89</b>	<b>23,982</b>	<b>1,443</b>	<b>3,723</b>	<b>(37,661)</b>	<b>(8,425)</b>	<b>-</b>	<b>(8,425)</b>

The accompanying notes are an integral part of these condensed consolidated financial statements.

## CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE 3-MONTH PERIOD ENDED MARCH 31

in € thousand	Note	2020	2019
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Operating result		(1,264)	(561)
Adjustments for:			
Depreciation, amortization and impairments		24	29
Equity-settled share-based payment expense	15	113	-
Changes in working capital:			
Trade and other receivables		(1,409)	945
Other current assets		1,369	(248)
Trade and Other Payables		(1,277)	(841)
Other current liabilities		-	1
<b>Cash generated from operations</b>		<b>(2,443)</b>	<b>(675)</b>
Taxes paid		(1)	-
<b>Net cash generated from operating activities</b>		<b>(2,444)</b>	<b>(675)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Interests received		-	-
Purchases of property, plant and equipment		-	-
Purchases of Intangible assets		(240)	(35)
Proceeds from other financial assets		-	3
<b>Net cash provided by/(used in) investing activities</b>		<b>(240)</b>	<b>(32)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Reimbursements of borrowings and other financial liabilities		(11)	(13)
Proceeds from borrowings and other financial liabilities	9	13,702	546
Interests paid		-	-
<b>Net cash provided by/(used in) financing activities</b>		<b>13,691</b>	<b>533</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		<b>11,008</b>	<b>(175)</b>
CASH AND CASH EQUIVALENTS at beginning of the period		205	2,687
CASH AND CASH EQUIVALENTS at end of the period		11,213	2,512

The accompanying notes are an integral part of these condensed consolidated financial statements.

# NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## 1. GENERAL INFORMATION

Hyloris Pharmaceuticals SA (the “Company” or “Hyloris”) is a limited liability company governed by Belgian law. The address of its registered office is Blvd Gustave Kleyer 17, 4000 Liège, Belgium.

The Company and its subsidiaries (together referred as the “Group”) are focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. Hyloris develops proprietary innovative products it believes offer significant advantages compared to currently available alternatives, with the aim to addressing the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders.

Hyloris’ development strategy focuses on the FDA’s 505(b)(2) regulatory pathway for pharmaceuticals where safety and efficacy of the molecule has been established, with the aim to reduce the clinical burden required to bring a product to the market and to significantly shorten the development timelines, and reduce costs and risks, when compared to traditional NDAs (New Drug Applications) using the FDA’s 505(b)(1) regulatory pathway.

Hyloris has two commercial products (Maxigesic<sup>®</sup> IV and Sotalol IV) as well 12 product candidates in various stages of development. Hyloris’ products and product candidates can be divided into the following areas:

- Cardiovascular IV Portfolio;
- Reformulation Portfolio (“other reformulations”); and
- Established Market Portfolio (“high-barrier generics”).

The condensed consolidated financial statements were authorized for issue by the Board of Directors on 15 June 2020.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### 2.1. Basis of preparation

The Group’s condensed consolidated financial statements for the 3-month period ended March 31, 2019 have been prepared in accordance with International Accounting Standard 34 – *Interim Financial Reporting* as endorsed by the European Union (“IFRS”) and should be read in conjunction with the Group’s last annual consolidated financial statements as at and for the year ended 31 December 2019 (‘last annual financial statements’).

They do not include all of the information required for a complete set of financial statements prepared in accordance with IFRS Standards. However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group’s financial position and performance since the last annual financial statements.

These interim financial statements were authorised for issue by the Company’s board of directors on 15 June 2020.

The same accounting policies, presentation and methods of computation have been applied in these condensed financial statements as were applied in the preparation of the Group’s financial statements for the year ended December 31, 2019, except for the impact of the adoption of new Standards and Interpretations as described below:

- Amendments to IFRS 3 – *Definition of a Business* (effective January 1, 2020): The amendments aim to assist companies to determine whether it has acquired a business or a group of assets.
- Amendments to IFRS 9, IAS 39 and IFRS 7 – *Interest Rate Benchmark Reform* (effective January 1, 2020): The amendments deal with issues affecting financial reporting in the period before the replacement of an existing interest rate benchmark with an alternative interest rate and address the implications for specific hedge accounting requirements.
- Amendments to IAS 1 and IAS 8 – *Definition of Material* (effective January 1, 2020): The amendments clarify the definition of “material” and to align the definition used in the Conceptual Framework and the standards.

Following the issuance of convertible bonds in March 2020, a new accounting policy has been defined and disclosed in note 3.3.

These condensed consolidated financial statements are presented in euro, which is the Company’s functional currency. All amounts in this document are represented in thousands of euros (€ thousands), unless noted otherwise.

Due to rounding, numbers presented throughout these condensed consolidated financial statements may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures.

These financial statements are prepared on an accrual basis and on the assumption that the entity is in going concern and will continue in operation in the foreseeable future (see also note 3.1 below).

The preparation of financial statements in accordance with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise judgment in the process of applying the Group accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in note 3.

### **3. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

In the application of the Group's accounting policies, which are described above, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The followings are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year:

#### **3.1. Going concern**

The 2019 consolidated results of the Group present a negative result, and the consolidated statement of financial position includes a loss carried forward. The Board has examined the statements and accounting standards.

Management has prepared detailed budgets and cash flow forecasts for the years 2020 and 2021. These forecasts reflect the strategy of the Group and include significant expenses and cash outflows in relation to the development of the ongoing clinical programs and pipeline of products candidates. Management acknowledges that uncertainty remains in these cash flow forecasts but believes that the Group has the ability to delay or prioritize research and development projects to avoid that the company is running out of cash.

Based on its current scope of activities, the subscriptions in the Convertible Bonds recorded in March and April 2020 for a total of EUR 15 million, and the partial reimbursement of the shareholders loan, the Company estimates that its treasury position as of December 31, 2019, is sufficient to cover its cash requirements until mid of 2021.

After due consideration of the above, taking into account the EUR 15.2 million convertible loan contracted in March and April 2020, its confidence in securing additional future financing (including the irrevocable commitment (conditional to the completion of the offering) of the investors of the convertible loans to invest an additional amount of EUR 22.7 million in the Company) and the favorable outlook of developments, the Board of Directors is of the opinion that it has an appropriate basis to conclude on the business continuity over the next 12 months from the balance sheet date, and hence it is appropriate to prepare the financial statements on a going concern basis.

The uncertainty raised by the COVID-19 pandemic is not impacting going concern. Although there are lot of uncertainties, it does not materially impact the Company's ability to continue operations until the mid of 2021.

#### **3.2. Share-based payments**

In accordance with IFRS 2 – Share-based Payment, the fair value of the warrants at grant date is recognized as an expense in the consolidated statement of comprehensive income over the vesting period, the period of service. Subsequently, the fair value is not re-measured.

The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions, which are detailed in note 15.

#### **3.3. Automatically convertible bonds**

On March 31, 2020, the Company issued automatically convertible bonds for an amount of EUR 10,800 thousand. On 30 April 2020, the Company issued additional convertible bonds of an amount of EUR 4,350 thousand (refer to Note 19 Subsequent event), bringing the total subscription to EUR 15,150 thousand. The bonds bear interest at a rate of 6% per annum. At IPO date, the bonds will automatically be converted into a variable number of new shares equal to a fraction whereby the numerator is equal to 100 per cent of the nominal value of the Bonds, and the denominator is equal to 70% of the offer price of the IPO. If the IPO would not take place, the bonds would have been automatically converted on 31 March 2022 into new shares at a fixed conversion ratio of EUR 21.35 per share.

Management concluded that the automatically convertible bonds are hybrid financial instruments containing a host debt instrument and an embedded derivative instrument to be separated as not closely related to the host contract. Whereas the debt instrument is subsequently measured at amortized cost using the effective interest rate method, the derivative is measured at fair value with changes in fair value recognized in profit or loss. Management also concluded that the difference between the initial value of the two instruments (the debt instrument and the derivative) and the proceeds from the bonds is a transaction between the shareholders and the bondholders in their capacity as future shareholders of the Company. As a result, this difference has been recognized in equity (EUR 3.2 million).

The transaction costs amounting to EUR 169 thousand that have been incurred on the issuance of the bonds have been allocated to the debt component and the equity component on the basis of their relative initial values.

#### **3.4. Effective interest rate of shareholders' loans**

In previous years, the Group was granted several shareholders' loans as disclosed in note 9.2. The shareholders' loans bear a fixed interest rate of 4%, which is considered to be below market rates if the Group would finance itself on the market. As such, based on the principles of IFRS 9 Financial Instruments, the Company remeasured the shareholders' loans at fair value (at the date the loan has been originated or at transition date). Subsequently the loans are measured at amortized cost based on the market-related rate. As such the Group recognizes the interest expense it would need to pay if it would finance itself on the market. The differential between the fair value of the loans and the nominal amount is considered as a capital contribution, which is recognized immediately in equity.

### 3.5. Recognition of deferred tax assets

Deferred tax assets are recognized only if management assesses that these tax assets can be offset against taxable income within a foreseeable future.

This judgment is made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives.

Since inception, the Company has reported losses, and as a consequence, the Company has unused tax losses. Therefore, management has concluded that deferred tax assets should not be recognized as of March 31, 2020 considering uncertainties regarding future taxable profits relating to the commercialization of the development projects.

## 4. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

### 4.1. Overview of financial instruments

The table below summarizes all financial instruments by category in accordance with IFRS 9:

in € thousand	IFRS 9 Category	March 31, 2020	December 31, 2019
Financial assets	At amortized cost	9	9
Trade receivables	At amortized cost	1,742	58
Other financial assets	At fair value through P&L	3,230	-
Cash and cash equivalents	At amortized cost	11,213	205
<b>Total financial assets</b>		<b>16,194</b>	<b>272</b>
Non-current financial liabilities			
Lease liabilities	At amortized cost	12	22
Other financial liabilities	At amortized cost	10,671	-
Current financial liabilities			
Lease liabilities	At amortized cost	43	44
Other financial liabilities	At amortized cost	16,112	13,130
Trade and other liabilities			
Trade payables	At amortized cost	1,751	2,866
<b>Total financial liabilities</b>		<b>28,589</b>	<b>16,062</b>

Currently, only the embedded derivative relating to the convertible bond which is recognized as a financial asset is carried at fair value in the consolidated statement of financial position.

The Company considers that the carrying amounts of financial assets and financial liabilities recognized in the consolidated financial statements approximate their fair values, considering the current nature of the shareholder's loans and the recent issue of the convertible bond.

## 5. OPERATING SEGMENTS

According to IFRS 8, reportable operating segments are identified based on the "management approach". This approach stipulates external segment reporting based on the Group's internal organizational and management structure and on internal financial reporting to the chief operating decision maker.

The Group's activities are managed and operated in one segment, pharmaceuticals. There is no other significant class of business, either individual or in aggregate. As such, the chief operating decision maker reviews the operating results and operating plans and makes resource allocation decisions on a company wide basis.

The revenue generated currently relates to royalties generated from one third party customer, AltaThera as well as a revenue related to the sales of an Asset to Alter Pharma group in 2020.

## 5.1. Geographical information

Revenue reported in the consolidated statement of profit or loss and other comprehensive income and non-current assets recorded in the consolidated statement of financial position are located in Belgium, country of domicile of the Company.

## 6. INTANGIBLE ASSETS

In 2020, the significant movements in intangible assets are related to additions of EUR 240 thousand, mainly relating to own product candidates (Tranexamic RTU and HY-EMP-016).

The Group incurred EUR 784 thousand of research and development expenses in the 3-month period ended March 31, 2020 (2019: EUR 443 thousand) that have been recorded under the caption "Research and development expenses".

Capitalized borrowing costs were computed on capitalized development costs using a 6% interest rate as applied to the Convertible Bonds. The intangible assets relating to capitalized development are not amortized until the moment they are available for use as intended by management, i.e. ready for commercialization. The development costs of Sotalol IV, for which amortization already started, have a remaining useful life of 6 years.

As long as the assets are not amortized, they are tested for any impairment losses on an annual basis or more frequently if specific indicators require it. The impairment test conducted is performed by product and consists in measuring the recoverable amount. No impairment loss has been recognized during the period.

No intangible assets have been pledged in the context of financial liabilities.

## 7. TRADE RECEIVABLES AND OTHER RECEIVABLES

in € thousand	March 31, 2020	December 31, 2019
Trade receivables	1,742	58
Less: allowance for impairment of trade receivables	-	-
<b>Trade receivables - net</b>	<b>1,742</b>	<b>58</b>
Prepayments	-	-
Other receivables	-	275
<b>Prepaid expenses and other receivables</b>	<b>-</b>	<b>275</b>
<b>Trade and other receivables - Current</b>	<b>1,742</b>	<b>333</b>

The trade receivables at closing March 2020 relates mostly to the sales of an asset (HY-REF-038 in vial form) to the Alter Pharma group, a related party of Hyloris, for €1.74 million (corresponding to the contractual value of €1.4 million plus VAT payment received in May 2020) and to royalties earned during the first quarter of 2020.

An impairment analysis of trade receivables is done on an individual level, and there are no individual significant impairments.

The carrying amount of the Group's trade receivables (gross) is denominated in EURO.

During the period, the payment terms for the receivables have neither deteriorated nor been renegotiated. The maximum credit risk exposure at the end of the reporting period is the carrying value of each caption of receivables mentioned above. The Group does not hold any collateral as security.

Other receivables mainly include recoverable VAT.

## 8. OTHER ASSETS

in € thousand	March 31, 2020	December 31, 2019
<b>Other financial assets</b>	<b>3,230</b>	<b>-</b>

<b>Pre-paid R&amp;D expenses</b>	<b>1,837</b>	<b>3,150</b>
<b>Other pre-paid expenses</b>	<b>4</b>	<b>50</b>
<b>Other current assets</b>	<b>1,840</b>	<b>3,200</b>

#### *Other financial assets*

On March 31, 2020, the Company issued automatically convertible bonds for an aggregate nominal amount of EUR 10,800 thousand (fair valued at March 31, 2020 to €10,671 thousand). The Bonds bear interest as from their issue date, at the rate of 6% per annum.

The Bonds will automatically be converted into Shares at the earliest date between (i) the closing date of an IPO, (ii) the occurrence of an exit event, and (iii) 31 March 2022. This means that the exact number of shares to be issued upon conversion of the Bonds is unknown at the date of issuance.

The embedded conversion option does not meet the definition of equity because the number of shares to be issued at conversion date depends of the share price at that date. Therefore, the embedded conversion option is recognized separately as a derivative financial asset presented under other current financial assets (initial recognition at fair value) and subsequently measured at fair value through profit or loss for an amount of EUR 3,230 thousand.

#### *Other current assets*

Pre-paid R&D expenses relate to payments made by the Company for research and development projects conducted by third parties and will be recorded in profit and loss when incurred. The decrease of EUR 1.4 million compared to 31 December 2019, related to the sale of the vial-form of HY-REF-038 to Alter Pharma. This transaction is accounted for as an asset deal with Alter Pharma as Alter Pharma takes over all rights and obligations associated with the asset transferred. As of the date of the sale, Hyloris had not incurred any expenses on the assets transferred.

Pre-paid R&D expenses of EUR 1,837 thousand per March 31, 2020 relate mostly to:

- EUR 800 thousand: development agreement with Stasisport Pharma (a subsidiary of the Alter Pharma group, a related party of Hyloris) to run the clinical development of the Fusidic Acid cream product candidate
- EUR 600 thousand: development Agreement with Generic Specialty Pharma Ltd (GSP, a subsidiary of the Alter Pharma group and a related party of Hyloris), pursuant to which GSP agreed to carry out all development activities required for (the acquisition/ registration of ANDA/NDA approval for) the product HY-REF-038 in the form of prefilled syringes.
- EUR 350 thousand: On 21 December 2018, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group, a related party of Hyloris) entered into an Asset purchase and development agreement with Hyloris Developments, pursuant to which GSP assigned and transferred to Hyloris Developments all intellectual property rights, title and interests in a product that has since been discontinued. In consideration of the amount paid by Hyloris, GSP will develop the (patentable) product, will be responsible for the patent application and for the submission of the NDA with the FDA. In 2019, Hyloris made a pre-payment of EUR 350,000. As of 31 March 2020, no decision was made on the selection of a new product, hence no expenses have been incurred yet on that project. Therefore, the full amount paid is recognized as pre-paid R&D expenses. An outstanding milestone payment of EUR 150 thousand will only be due upon completion of the formulation of the product.
- EUR 67 thousand prepayments made to AltaThera on smaller projects.

## **9. BORROWINGS AND OTHER FINANCIAL LIABILITIES**

### **9.1 Borrowings**

<b>In € thousand</b>	<b>March 31, 2020</b>	<b>December 31, 2019</b>
Bank borrowings	-	-
Lease liabilities	55	66
Other borrowings	-	-
<b>Total borrowings</b>	<b>55</b>	<b>66</b>
of which as:		
Non-current borrowings	12	22
Current borrowings	43	44

The Group is not subject to financial covenants. The underlying leased assets act as pledge in the context of the lease liabilities.

## 9.2 Other financial liabilities

The other financial liabilities can be detailed as follows:

<b>in € thousand</b>	<b>March 31, 2020</b>	<b>December 31, 2019</b>
Convertible bond	10,671	-
Loans from shareholders	15,703	12,721
Other loans (recoverable cash advances)	409	409
<b>Other financial liabilities</b>	<b>26,783</b>	<b>13,130</b>
of which as:		
Non-current other financial liabilities	10,671	-
Current other financial liabilities	16,112	13,130

### *Convertible bond*

On March 31, 2020, the Company issued automatically convertible bonds for an aggregate nominal amount of EUR 10,800 thousand (fair valued at March 31, 2020 to €10,671 thousand). On 30 April 2020, the Company issued additional convertible bonds of a nominal amount of EUR 4,350 thousand (refer to Note 19 Subsequent event), bringing the total subscription to EUR 15,150 thousand (the "Bonds"). The Bonds are issued in registered form. Each Bond has a nominal value of EUR 50 thousand. The Bonds bear interest as from their issue date, at the rate of 6% per annum.

The Bonds will automatically be converted into Shares at the earliest date between (i) the closing date of an IPO, (ii) the occurrence of an exit event, and (iii) 31 March 2022.

If the IPO occurs within 18 months from the issue date, the number of Shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 100 per cent of the nominal value of the Bonds, and the denominator is equal to 70% of the offer price of the IPO. This means that the exact number of shares to be issued upon conversion of the Bonds is unknown at the date of issuance.

If the IPO occurs after 18 months from the issue date, the number of shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 100 per cent of the nominal value of the Bonds, and the denominator is equal to 65% of the offer price of the IPO. This means that the exact number of shares to be issued upon conversion of the Bonds is unknown at the date of issuance.

If the conversion occurs at maturity date, the number of shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to the nominal value of the Bonds, and the denominator is equal to EUR 21.35.

Each investor subscribing to the Bonds has committed to subscribe to shares in the offering for an amount equal to the amount subscribed to in Bonds.

Although Bonds will automatically be converted into equity of the Company, the number of shares to be issued is variable in the event the conversion occurs on the closing date of an IPO. As a result, the Bonds will not be classified as equity instruments of the Company before the Bonds are converted into shares.

The embedded conversion option does not meet the definition of equity because the number of shares to be issued at conversion date depends of the share price at that date. Therefore, the embedded conversion option is recognized separately as a derivative financial asset presented under other current financial assets (initial recognition at fair value) and subsequently measured at fair value through profit or loss for an amount of EUR 3,230 thousand.

### *Loans from shareholders*

The loans from shareholders are unsecured and bear a fixed nominal interest rate of 4% which are payable when the principal is due at the end of 2020, unless agreed otherwise between the parties. In its IFRS financial statements, the Company reassessed the interest rate under the shareholders loan agreements and considered that a 6% interest rate represented a fair estimate at which it could obtain similar loans based on benchmarking obtained from peer companies with a similar profile and the rate applied in its pre-IPO convertible bonds.

Over the first quarter of 2020, the Company received additional loans from its shareholders for a total of EUR 3.3 million and made repayments of EUR 0.6 million.

### *Recoverable cash advance*

The recoverable cash advance ('RCA') received by the Company from the Walloon Region which gives rise to a financial liability in the scope of IFRS 9 Financial Instruments as the advance needs to be settled by paying back the cash received or transfer all relating intellectual property rights and titles. As at March 31 2020, the research program for which the advance was granted was

abandoned due to unsatisfactory results. The Company judges that the financial liability of the effectively received EUR 488 thousand will be settled by paying back the unutilized cash received for an amount of EUR 409 thousand.

## 10. TRADE AND OTHER LIABILITIES

in € thousand	March 31, 2020	December 31, 2019
Trade payables	1,751	2,866
Employee benefit liabilities	58	52
Other payables	224	8
<b>Trade and other liabilities - Current</b>	<b>2,033</b>	<b>2,927</b>

The trade payables relate mainly to the research and development activities.

The fair value of trade payables approximates their carrying amount.

Other payables relate to VAT payables.

## 11. REVENUE

The revenue for the 3-month period ended March 31, 2020 related to the royalties received from Alta Thera, our US distributor of Sotalol IV in the US.

## 12. EXPENSES BY NATURE

Expenses by nature represent an alternative disclosure for amounts included in the consolidated statement of comprehensive income. They are classified under "Cost of sales", "Research and development expenses", "General and administrative expenses" and "Other operating expenses" in respect of the 3-months period ended March 31:

In € thousand	Q1/2020	Q1/2019
Amortization expense of intangible assets	11	14
Impairment losses on intangible assets	-	-
Depreciation expense of property, plant and equipment	2	2
Depreciation expense of right-of-use assets	11	13
Employee benefit expenses and Management fees	316	166
Share based payments	113	-
Legal & paralegal fees	35	11
Office expenses	30	5
Out-sourced R&D	695	382
Travel expenses	10	3
Other expenses	103	6
<b>Total operating expenses</b>	<b>1,327</b>	<b>602</b>
of which as:		-
Cost of sales	20	23
Research and development expense	784	443
General and administrative expenses	523	136
Other operating expenses	-	-

Hyloris' research and development expenses increased by 77%, from EUR 443 thousand Q1 2019 to EUR 784 thousand Q1 2020. The increase was principally driven additional out-sourced R&D expenses related to existing product-candidates.

Hyloris' General and administrative expenses increased by 284%, from EUR 136 thousand Q1 2019 to EUR 523 thousand Q1 2020. The increase was principally driven by the cost of to the share-based payments over the vesting period (refer to Note 15), additional staff in Q1 2020 as well an increase of fees linked to the IPO process such as audit, legal, consultants' fees.

## 13. FINANCIAL RESULT

The various items comprising the net finance cost are as follows:

<b>In € thousand</b>	<b>Q1/2020</b>	<b>Q1/2019</b>
Interest income on current assets	-	17
Exchange differences	9	82
<b>Financial income</b>	<b>9</b>	<b>99</b>
Interest expense on lease liabilities	-	-
Interest expense on other financial liabilities	(191)	(112)
<b>Interest expense</b>	<b>(191)</b>	<b>(112)</b>
Bank fees	(4)	(3)
Exchange differences	(90)	(108)
Fair value adjustment	(40)	-
<b>Total financial expenses</b>	<b>(325)</b>	<b>(223)</b>

## 14. EARNINGS PER SHARE

Basic earnings per share amounts are calculated by dividing net profit for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share amounts are calculated by dividing the net profit attributable to ordinary equity holders of the parent (after adjusting for the effects of all dilutive potential ordinary shares) by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

No effects of dilution affect the net profit attributable to ordinary equity holders of the Group. The table below reflects the income and share data used in the basic and diluted earnings per share computations for the 3-months period ended March 31:

<b>In € thousand</b>	<b>Q1/2020</b>	<b>Q1/2019</b>
<b>Basic earnings</b>		
Profit from continuing operations attributable to owners of the parent	(1,580)	(579)
<b>Diluted earnings</b>		
Dilution effect of share-based payments	-	-
<b>Profit from continuing operations attributable to owners of the parent, after dilution effect</b>	<b>(1,580)</b>	<b>(579)</b>

*Earning par share based on the existing number of ordinary shares*

<b>Number of shares</b>	<b>Q1/2020</b>	<b>Q1/2019</b>
Weighted average number of ordinary shares outstanding during the period	4,450,442	3,595,033
Basic earnings per share	(0.36)	(0.16)
Diluted earnings per share	(0.36)	(0.16)

*Earning per share based on the number of shares as adjusted for the common control of Dermax SA*

<b>Number of shares</b>	<b>Q1/2020</b>	<b>Q1/2019</b>
-------------------------	----------------	----------------

Weighted average number of ordinary shares outstanding during the period as adjusted for the common control of Dermax SA	4,450,442	4,450,442
Basic earnings per share	(0.36)	(0.13)
Diluted earnings per share	(0.36)	(0.13)

As the Company is suffering operating losses, the stock options and convertible bond have an anti-dilutive effect. As such, there is no difference between basic and diluted earnings per ordinary share. There are no other instruments that could potentially dilute earnings per share in the future.

## 15. SHARE-BASED PAYMENTS

The Company has a stock option scheme for the employees, consultants and directors of the Company and its subsidiaries for rendered services. In accordance with the terms of the plan, as approved by shareholders, employees may be granted options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

Each employee share option converts into one ordinary share of the Company on exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry.

The following share-based payment arrangements were in existence during the current and prior periods:

	Expiry Date	Exercise Price per stock option (€)	Fair value at grant date (€)	Options per March 31, 2020	Options per December 31, 2019
<b>PLAN 2017</b>					
Options	4/05/2022	9.44	4.43	300,000	300,000
<b>PLAN 2019</b>					
Options	31/12/2024	21.35	9.88	78,250	78,250

The 2017 plan is fully vested immediately as no vesting conditions were required.

The 2019 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). The Company offered 78,250 options to the beneficiaries. As of 31 March 2020, all options offered were accepted.

The following reconciles the options and RSU's outstanding at the beginning and end of the year:

	Average exercise price (€)	Number of options
<b>Closing balance at December 31, 2018</b>	<b>9.44</b>	<b>300,000</b>
Warrants accepted in December 2019	21.35	29,500
<b>Closing balance at December 31, 2019</b>	<b>10.51</b>	<b>329,500</b>
Warrants accepted in Q1 2020	21.35	48,750
<b>Closing balance at March 31, 2020</b>	<b>11.90</b>	<b>378,250</b>

The 300,000 Transaction warrants are exercisable during the periods set out in the terms and conditions thereof, including notably an annual window during the 60 calendar days preceding the Annual General Shareholders' Meeting to be held in that year, and immediate exercisability in the event of an IPO of the Company. However, in the Shareholders' Agreement, all holders have committed not to exercise their Transaction Warrants (i) during the 60 calendar days' period prior to the Annual General Shareholders' Meeting to be held in 2020 regarding the financial year 2019 and (ii) from the first day of trading of the Shares on Euronext Brussels until closing of the Offering, without prejudice to the right of each holder of Transaction Warrants to exercise its Transaction Warrant(s) as from the closing of the Offering in accordance with the terms and conditions of the Transaction Warrants.

The fair value of the stock options has been determined based on the Black Scholes model. Expected volatility is based on the historical share price volatility over the past 5 years of listed peer companies.

Below is an overview of all the parameters used in this model:

	PLAN 2017	PLAN 2019
Share price (€)	9.44	21.35
Exercise Price (€)	9.44	21.35
Expected volatility of the shares (%)	55%	55%
Expected dividends yield (%)	0%	0%
Risk free interest rate (%)	0.60%	0.10%

## 16. CONTINGENCIES

As of March 31st 2020, the Group was not involved in any claim or dispute incidental to the activities of the Group (nor in 2019, 2018 and 2017).

## 17. COMMITMENTS AND CONTINGENT LIABILITIES

End of March 2020, Hyloris had contractual commitments and contingent liabilities for a maximum amount of EUR 4.3 million (among which EUR 0,25 million and \$4.4 million converted in EUR at a rate of 1.0956) related to asset purchase, licenses and developments agreements recorded under intangible assets. The amounts due to the counterparties are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted.

The following table details the total maximum contractual commitments and contingent liabilities at 31 March 2020 per product candidates if such products are successfully marketed (in'€000):

Product-Candidate	\$	€	Converted in €
HY-REF-004	225	-	205
Metolazone IV	1 750	-	1 597
Dofetilide IV	1 267	-	1 157
Atomoxetine Liquid	250	-	228
HY-CVS-073	625	-	570
To be assigned	0	150	150
HY-CVS-074	325	-	297
HY-REF-075	0	100	100
<b>TOTAL</b>	<b>4 442</b>	<b>250</b>	<b>4 305</b>

As of 31 March 2020, out of the total value of €4.3 million, \$1.8 million (or €1.6 million) should be considered as contingent liabilities as they are not triggered by a performance obligation from the counterparty (\$1.3 million for Metolazone IV, \$0.3 million for Atomoxetine Liquid and \$0.2 million for HY-REF-004).

Contingent liabilities attached to profit split and royalties which percentage varies based on achieved profit and/or sales are not considered in the above table as **no maximum amount can be determined**.

## 18. RELATED PARTY TRANSACTIONS

The reference shareholder is Stijn Van Rompay.

As part of the business, the Company has entered into several transactions with related parties.

Balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated on consolidation and are not disclosed in this note. Details of transactions between the Group and other related parties are disclosed below.

The related parties presented below are identified as:

- Shareholders; Mr Stijn Van Rompay, an executive member of the board of the Company, CEO and reference shareholder of the Company; GRNR Invest BVBA, an entity controlled by Thomas Jacobsen, an Executive member of the board of the Company; Pieter Van Rompay (Sibling of Mr Stijn Van Rompay.);
- The Alter Pharma group and its subsidiaries, in which Hyloris' Chief Executive Officer, Mr. Stijn Van Rompay, and board member and executive director, Mr. Thomas Jacobsen, have material ownership interests.

- Executive Management Team as defined in section 18.2 hereunder.

## 18.1. TRANSACTIONS WITH RELATED PARTIES

The following table presents the total amount of transactions made with entities controlled by or related to key management and the transactions occurred during the first quarter of 2020. The underlying assets of the transactions made with related parties are presented as intangibles or prepaid expenses in the Consolidated Statement of Financial Position.

in € thousand	Nature of assets	December 31, 2019	Transactions of the period	March 31, 2020
Other related parties	Licensing	175	-	175
	Asset Purchase	750	-	750
	Development services	2,801	(1,381)	1,420
<b>Total</b>		<b>3,726</b>	<b>(1,381)</b>	<b>2,345</b>

For the description of the transactions made as at December 31, 2019, we refer to Note 27.1. During the first quarter of 2020, the Company sold the vial form of HY-REF-038 to Alter Pharma for an amount of EUR 1.4 million (cfr Note 8).

At March 31, 2020, there were no outstanding trade payables related to transactions with related parties:

in € thousand	Type of services	March 31, 2020	December 31, 2019
Other related parties	Licensing	-	175
	Asset Purchase	-	-
	Development Agreement	-	1,700
<b>Total</b>		<b>-</b>	<b>1,875</b>

At March 31, 2020, there were outstanding trade receivables related to transactions with related parties:

in € thousand	Type of services	March 31, 2020	December 31, 2019
Other related parties	Licensing	-	-
	Sale of Asset	1,694	-
<b>Total</b>		<b>1,694</b>	<b>-</b>

The outstanding trade receivables related to the Development/Asset Sales is an outstanding receivable, concerning the Asset Sales to Alter Pharma, which Hyloris assigned and transferred all (intellectual property) rights, title and interests in a product.

The following loans from related parties were outstanding at the end of the first quarter 2020:

in € thousand	March 31, 2020	December 31, 2019
Loans from shareholders (excluding accrued interest)	14,506	11,651
<b>Total</b>	<b>14,506</b>	<b>11,651</b>

The reference Shareholder and CEO Stijn Van Rompay has an outstanding amount (principal loan) of EUR 9,253 thousand as per March 31, 2020.

Pieter Van Rompay, Shareholder and sibling of Stijn Van Rompay has an outstanding amount (principal loan) of EUR 2,221 thousand as per March 31, 2020.

GRNR Invest BVBA, entity controlled by Thomas Jacobsen, Shareholder and executive director, has an outstanding amount (principal loan) of EUR 2,094 thousand as per March 31, 2020.

Stijn Van Rompay and his spouse have an outstanding amount (principal loan) of EUR 197 thousand as per March 31, 2020.

Ellen Delimon, spouse of Stijn Van Rompay has an outstanding amount (principal loan) of EUR 739 thousand, as per March 31, 2020.

As per December 31, 2019 Stijn Van Rompay, Pieter Van Rompay, GRNR Invest BVBA, entity controlled by Thomas Jacobsen, Stijn Van Rompay and his spouse respectively amount outstanding (loan principals) of EUR 9,652 thousand, EUR 1,422 thousand, EUR 377 thousand and EUR 201 thousand.

The amounts outstanding are unsecured and will be settled in cash. No guarantees have been given or received.

The above loans bear fixed interest rates (nominal rate of 4% and effective interest rate of 6%). The amount of accrued interest at March 31, 2020 amounted to EUR 1,196 thousand.

For information on the reimbursement of the shareholders loans, reference is made to Note 19.

#### *Contractual commitments*

Hyloris has contractual commitments for a maximum amount of EUR 0.25 million with related parties related to licenses and development agreements recorded under intangible assets. The amounts are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted.

The following table details the total maximum contractual commitments (milestone payments only) at 31 March 2020 per product candidates if such products are successfully marketed (in'€000). The profit split and royalties, which percentage varies based on achieved profit, are not included in the table:

<b>Product-Candidate</b>	<b>Related party</b>	<b>€</b>
To be assigned	Neogen	150
HY-REF-075	Nordic Speciality Pharma	100
<b>TOTAL</b>		<b>250</b>

## **18.2. EXECUTIVE MANAGEMENT TEAM**

Executive management team personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Group. As of 31 March 2020, members of the Executive Management Team are:

- Mr Stijn Van Rompay, an executive member of the board of the Company, CEO and reference shareholder of the Company; SVR Management.
- Jacobsen Management, an entity controlled by Thomas Jacobsen, an executive member of the board of the Company
- Humara Kinetics LLC, an entity controlled by Edward J Maloney, Chief Business Development Officer
- Maurizio Passanisi, Chief Clinical Officer<sup>206</sup>
- LOF Consulting, an entity controlled by Antoine Carlhian, Chief Financial Officer<sup>207</sup>
- Heralut, an entity controlled by Koenraad Van der Elst, Chief Legal Officer

The table below presents the compensation of all members of Executive Management Team by type of compensation:

<b>in € thousand</b>	<b>Q1 2020</b>	<b>Q1 2019</b>
Short-term compensation	159	77
Post-employment benefits	1	1
Other long-term benefits	-	-
Share-based payments	-	-
<b>Total</b>	<b>160</b>	<b>78</b>

<sup>206</sup> Mr. Passanisi will leave the Company on 3 July 2020 (i.e., shortly after the Offering, and is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

<sup>207</sup> Mr. Carlhian left the Company on 30 April 2020.

As of 31 March 2020, members of the Executive Management Team owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct. (%)	Number (#)	Pct. (%)
Mr. Stijn Van Rompay (CEO)	1,609,516	36.17%	230,024	60.81%
Mr. Edward Maloney (CBDO)	107,207	2.41%	-	-
Mr Koenraad Van der Elst (CLO)	-	-	12,500	3.30%
Mr. Antoine Carlhian (CFO) <sup>(1)</sup>	-	-	10,000	2.64%
Mr. Maurizio Passanisi (CCLO) <sup>(2)</sup>	47,631	1.07%	11,500	3.04%
Mr. Thomas Jacobsen (Executive director)	859,440	19.31%	40,878	10.81%
<b>TOTAL</b>	<b>2,623,794</b>	<b>58.96%</b>	<b>304,902</b>	<b>80.61%</b>

Note:

(1) Mr. Carlhian left the Company on 30 April 2020.

(2) Mr. Passanisi will leave the Company on 3 July 2020 (i.e., shortly after the Offering, and is not presented as a member of the Executive Management for purposes of this Prospectus (Section 10.4.4 (Composition of the Executive Management)).

Total outstanding shares and warrants existing as of 31 March 2020 are respectively 4,450,442 and 378,250.

In March and April 2020, Mr Van Rompay and Mr Van der Elst subscribed to the Convertible Bonds issued by the Company for respectively EUR 1.0 million and EUR 0.1 million.

## 19. EVENTS AFTER THE END OF THE REPORTING PERIOD

Since 31 March 2020, the Company recorded additional subscriptions to the Convertible Bonds for a total principal amount of EUR 4.4 million, leading the total subscription of the Convertible Bonds to EUR 15.2 million.

The Company also reimbursed some of the shareholders loans in April and June 2020 for a total of EUR 7.5 million. Following amendment to the shareholders loans agreements signed in May 2020, the remaining amount of the shareholders loans will be reimbursed at the earlier of 31 December 2022, or if and when Hyloris generates a positive EBIT.

On March 11, 2020 the World Health Organization declared the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. The length or severity of this pandemic cannot be predicted, but the Group anticipates that there may be a potential impact from COVID-19 on the planned development activities of the Group.

With COVID-19 continuing to spread in Europe and in the United States, the business operations of the Group could be delayed or interrupted, particularly if a large portion of its employees become ill. COVID-19 may also affect employees of third-party organizations (such as CRO's and CMO's) located in affected geographies that the Group relies upon to carry out its preclinical and clinical trials. The spread of COVID-19, or another infectious disease, could also negatively affect the operations at its third-party suppliers, which could result in delays or disruptions in the supply of drug product used in its preclinical and clinical trials. In addition, the Group is taking temporary precautionary measures intended to help minimize the risk of the virus to its employees, including temporarily requiring all employees to work remotely, suspending all travel worldwide for its employees.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by the COVID-19 pandemic. Most of the Group's and CRO's clinical trial sites are located in the United States, currently being afflicted by COVID-19.

Some factors from the COVID-19 outbreak that the Group believes will potentially affect enrollment in its trials at least on a temporary basis include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of physicians serving as Group's clinical trial investigators, hospitals serving as its clinical trial sites and hospital staff supporting the conduct of its clinical trials;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product used in our trials; and
- employee absences that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

The impact of COVID-19 on the Company's business and operations are uncertain at the date of the Prospectus and will depend on future developments, which are highly uncertain and cannot be predicted. The Company is of the opinion that although there are lot of uncertainties, it does not materially impact the Company's ability to continue operations. As of the date of authorization for issue of the consolidated financial statements, we have encountered some delays in the development of our product-candidates (such as delayed patient enrolment in the current clinical trials), but we do not believe this will result in major deviation

in our planned activities and in the assumptions of our business plan. Also note that reference is made to the potential impact of COVID-19 in our assessment of the going concern (refer to Note 3.1).

# SUMMARY STATUTORY FINANCIAL STATEMENTS

## STATUTORY BALANCE SHEET AFTER APPROPRIATION

(in €)	2019	2018
<b>ASSETS</b>		
<b>FIXED ASSETS</b>	<b>36.538.011</b>	<b>14.924.605</b>
<b>II. Intangible fixed assets</b>		
<b>III. Tangible fixed assets</b>		
<b>IV. Financial fixed assets</b>	<b>36.538.011</b>	<b>14.924.605</b>
Related companies - Participations	22.674.782	4.414.999
Related companies - Receivables	13.863.229	10.509.606
<b>CURRENT ASSETS</b>	<b>763.197</b>	<b>949.251</b>
<b>VII. Amounts receivable within one year</b>	<b>24.016</b>	<b>139.419</b>
Trade debtors	8.449	135.973
Others amounts receivable	15.567	3.446
<b>VIII. Investment</b>		
<b>IX. Cash at bank and in hand</b>	<b>4.526</b>	<b>552.713</b>
<b>X. Deferred charges and accrued income</b>	<b>734.655</b>	<b>257.119</b>
<b>TOTAL ASSETS</b>	<b>37.301.208</b>	<b>15.873.856</b>
<b>CAPITAL AND RESERVES</b>	<b>23.950.531</b>	<b>6.126.249</b>
<b>I. Capital</b>	<b>89.009</b>	<b>71.901</b>
Issued capital	89.009	71.901
Uncalled capital (-)		
<b>II. Share Premium</b>	<b>23.982.274</b>	<b>5.739.599</b>
<b>IV. Reserves</b>	<b>5.000</b>	<b>5.000</b>
Legal Reserve	5.000	5.000
<b>V. Accumulated profits (losses)</b>	<b>-125.752</b>	<b>309.749</b>
<b>PROVISIONS AND DEFERRED TAXES</b>		
<b>CREDITORS</b>	<b>13.350.677</b>	<b>9.747.607</b>
<b>VIII. Amounts payable after more than one year</b>		<b>8.964.827</b>
Other financial loans		8.964.827
<b>IX. Amounts payable within one year</b>	<b>12.080.965</b>	<b>86.259</b>
Current portion of amounts payable after one year	8.964.827	
Other financial loans	2.978.163	
Suppliers	90.651	35.739
Taxes	47.324	50.520
<b>X. Accrued charges and deferred income</b>	<b>1.269.712</b>	<b>696.521</b>
<b>TOTAL LIABILITIES</b>	<b>37.301.208</b>	<b>15.873.856</b>

## STATUTORY INCOME STATEMENT

(in €)	2019	2018
<b>Operating income</b>	<b>50.882</b>	<b>33.333</b>
Turnover		
Capitalization of development costs		
Other operating income	50.882	33.333
Non recurring operating income		
<b>Operating charges</b>	<b>-536.253</b>	<b>-493.613</b>
Supplies and goods		
Services and other goods	-535.170	-492.355
Remuneration; social security and pensions		
Depreciation of and other amounts written off formations expenses; intangible and tangible fixed assets (-)		
Write-downs on inventories, on orders in progress and on trade receivables (appropriations -; write-backs +)		
Provisions for liabilities and charges (appropriations -; use and write-backs +)		
Other operating charges (-)	-1.083	-1.258
Non recurring operating expenses		
<b>Operating profit (loss)</b>	<b>-485.371</b>	<b>-460.280</b>
<b>Financial income</b>	<b>444.432</b>	<b>204.627</b>
Income from financial fixed assets	444.387	203.332
Other financial income	45	1.295
<b>Financial charges (-)</b>	<b>-394.562</b>	<b>-202.140</b>
Interest on financial debts	-383.735	-174.543
Other financial charges	-10.827	-27.597
<b>Profit (Loss) for the period before taxes (-)</b>	<b>-435.501</b>	<b>-457.793</b>
<b>Income taxes (-) (+)</b>		
<b>Profit (loss) for the period available for appropriation</b>	<b>-435.501</b>	<b>-457.793</b>

# EXTRACT FROM HYLORIS SA SEPARATE (NON-CONSOLIDATED) FINANCIAL STATEMENTS PREPARED IN ACCORDANCE WITH BELGIAN GAAP

The preceding information is extracted from the separate Belgian GAAP financial statements of Hyloris Pharmaceuticals SA and is included as required by article 105 of the Belgian Company Code. The separate financial statements, together with the annual report of the Board of Directors to the general assembly of shareholders as well as the auditors' report, will be filed with the National Bank of Belgium within the legally foreseen time limits. These documents are also available on request at Hyloris Pharmaceuticals SA, Blvd Gustave Kleyer 17, 4000 Liège, Belgium.

The statutory auditor's report is unqualified and certifies that the non-consolidated financial statements of Hyloris Pharmaceuticals SA prepared in accordance with Belgian GAAP for the year ended December 31, 2019 (full financial year) give a true and fair view of the financial position and results of Hyloris Pharmaceuticals SA in accordance with the legal and regulatory dispositions applicable in Belgium.

## Statutory Notes

### Statement of financial fixed assets

(in €)	2019	2018
<b>Related companies - Participations</b>		
Acquisition value at the end of the preceding period		4.414.999
Movements during the period		
Acquisitions, included produced fixed assets	18.259.783	
Acquisition value at the end of the period	22.674.782	
Depreciation and amounts written down at end of the preceding period		
Movements during the period		
Recorded		
Depreciation and amounts written down at end of the period		
<b>Net book value at the end of the period</b>	<b>22.674.782</b>	
<b>Related companies - Receivables</b>		
Net book value at the end of preceding period		10.509.607
Movements during the period		
Additions	3.353.622	
Reimbursement		
<b>Net book value at the end of the period</b>	<b>13.863.229</b>	

Company	Participation held				Data extracted from the last available annual accounts			
	Nature	Direct		By subsidiaries	Annual Accounts at	Currency Code	Capital	Net Profit or Loss
		Number	%					
<b>Hyloris Developments SA</b> Blvd Gustave Kleyer 17 4000 Liège Belgium 0542.737.368	Shares	74.066	99,99%	0,00%	31/12/2019	EUR	4.600.423	-4.079.956
<b>RTU Pharma SA</b> Blvd Gustave Kleyer 17 4000 Liège Belgium					31/12/2019	EUR	-526.053	-69.350

0669.738.676	Shares	62.000	100%	0,00%				
<b>Dermax SA</b> Blvd Gustave Kleyer 17 4000 Liège Belgium 0667.730.677					31/12/2019	EUR	- 3.249.978	-742.845
	Shares	65.875	100%	0%				

### Deferred Charges and accrued income

(in €)	2019
<b>Deferred Charges and accrued income</b>	
Interest earned on receivables from related companies	696.242

### Statement of capital

(in €)	2019	2018
Issued capital	89.009	71.901
	<b>Amounts</b>	<b>Number of Shares</b>
<b>Changes during the year</b>		
Capital increase by Contribution of Kind (Shares)	17.108	855.409
<b>Structure of the capital</b>		
Different categories of shares		
Registered	XXXXXXXXXX	
Dematerialized	XXXXXXXXXX	4.450.442
<b>Commitment to issue shares</b>	<b>2019</b>	
Following the exercise of conversion rights		
Amount of convertible loans outstanding		
Amount of capital to subscribe		
Maximum corresponding number of shares to be issued		
Following the exercise of subscription rights		
Amount of convertible loans outstanding	378.250	
Amount of capital to subscribe	4.502.278	
Maximum corresponding number of shares to be issued	378.250	

### Statement of amounts payable

(in €)	2019
<b>Analysis by current position of amounts initially payable after more than one year, maturing in 1 year</b>	
Other debts (Shareholder loans)	11.942.990
<b>Other debt</b>	
<b>Tax, wage and social amounts payable</b>	
<b>Taxes</b>	
Estimated taxes payable	47.325
<b>Accrued charges and deferred income</b>	
Accrued Interests	719.711
Accrued Management fees	550.000

## Operating results

(in €)	2019	2018
<b>Other operating income</b>		
Subsidies and recoverable cash advance received from the Walloon Region		
<b>Operating charges</b>		
<b>Employees recorded in the personnel register</b>		
Total number at the closing date		
Average number of employees calculated in full-time equivalents		
Number of actual worked hours		
<b>Personnel costs</b>		
Remuneration and direct social benefits		
Employer's social security contributions		
Employer's premiums for extra statutory insurances		
Other personnel costs (+)/(-)		
Pensions		
<b>Impairment of trade receivables</b>		
<b>Write-downs</b>		
On trade receivables		
Record		
Withdrawal		
<b>Provisions for risks and charges</b>		
Addition		
Use of and withdrawal		
<b>Other operating charges</b>		
Taxes related to operations		
Other charges	1.083	1.258
<b>Hired temporary staff and persons placed at the enterprise's disposal</b>		
Total number at the closing date		
Average number calculated as full-time equivalents		
Number of actual worked hours		
Charges to the enterprise		

### Financial results

(in €)	2019	2018
Interest income	444.387	203.332
Other financial income	45	1.295
Interest charges	383.735	174.543
Unrealized Exchange rate differences	9.506	24.472
Other financial charges	1.321	3.125

### Income Tax

(in €)	2019
<b>Status of tax losses carried forward</b>	
Accumulated tax losses deductible from future taxable profits	886.597

### The total amount of value added tax and taxes borne by third parties

(in €)	2019	2018
<b>The total amount of value added tax and taxes borne by third parties</b>		
<b>The total amount of value added tax charged</b>		
To the enterprise (deductible)	57.412	74.697
By the enterprise	12.859	35.230
<b>Amounts retained on behalf of third parties</b>		
Withholding taxes	3.012	

### Relations with related companies

(in €)	2019	2018
<b>Financial Fixed assets</b>	<b>36.538.011</b>	<b>14.924.605</b>
Participations	22.674.782	4.414.999
Subordinated receivables		
Other receivables	13.863.229	10.509.606
<b>Receivables</b>	<b>734.561</b>	<b>388.928</b>
More than a year		
Up to one year	734.561	388.928
<b>Other investments</b>		
<b>Payables</b>		
<b>Other financial engagements</b>		
<b>Financial results</b>	<b>444.387</b>	<b>203.076</b>
Income from financial fixed assets	444.387	203.076
<b>Disposals of fixed assets</b>		

*Financial relationship with Amount of direct and indirect remunerations and pensions, included in the income statement, as long as this disclosure does not concern exclusively or mainly, the situation of a single identifiable person*

(in €)	2019
To former non-executive directors	169.600

*Financial relationship with auditors*

(in €)	2019
<b>Auditor's fees</b>	24.000
Auditor's special missions fees	
Fees for special missions executed by related parties to the Auditor	

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