

This prospectus (the "Prospectus") relates to the initial offering (the "Offering") to subscribe for up to 1,750,000 new shares in Bone Therapeutics SA (the "Company" or "Bone Therapeutics") within a price range of between € 14.5 and € 16.5 per new share (the "Offer Price Range"). The amount of new shares may be increased by up to 15%, to an amount of 2,012,500 new shares (the "Increase Option", the new shares initially offered and the shares offered as a result of the possible exercise of the Increase Option are jointly being referred to as the "New Shares"). Any decision to exercise the Increase Option will be announced, at the latest, on the date the offer price (the "Offer Price") is announced. Bryan, Garnier & Co Ltd., acting both for itself and on behalf of Kepler Capital Markets and Banque Degroof, (together the "Joint Bookrunners"), has been granted an Over-allotment Option by the Company (the "Over-allotment Option"), exercisable for a period of 30 days from the listing date (the "Listing Date"), corresponding to up to 15% of the New Shares subscribed for in the Offering for the sole purpose of allowing the Joint Bookrunners to cover over-allotments, if any.

The minimum amount set for the Offering is € 17.5 million, below which the Offering will not be completed.

The Offering is conducted as a public offering in Belgium and France to retail investors and a private placement to certain Institutional Investors (meaning qualified and/or institutional investors under applicable laws of the relevant jurisdiction) in certain jurisdictions outside the United States in accordance with Regulation S under the US Securities Act, of 1933, as amended (the "Securities Act"). Private placements may take place in EEA Member States pursuant to another exemption under the Prospectus Directive as implemented in the relevant EEA Member State. The New Shares and the shares of the Company covered by the Over-allotment Option (the "Offered Shares") have not been and will not be registered under the Securities Act, or with any securities regulatory authority of any state or other jurisdiction in the United States, and may not be offered, sold, pledged or otherwise transferred except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and in compliance with any applicable state securities laws. In addition, until 40 days after the commencement of the Offering, an offer, sale or transfer of the Shares within the United States by a broker/dealer (whether or not participating in the Offering) may violate the registration requirements of the Securities Act if such offer or sale is made otherwise than in accordance with an available exemption from registration under the Securities Act.

This Prospectus does not constitute, and neither the Company nor the Joint Bookrunners 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 Company nor the Joint Bookrunners accept any responsibility for any violation by any person, whether or not it is a prospective purchaser of Offered Shares, of any such restriction.

For a description of certain restrictions on transfers of the Offered Shares, see Section 2 "Important information".

This Prospectus contains the minimum disclosure requirements for the share securities note in accordance with Annex III of the Prospectus Regulation. As this Prospectus relates to a public offering and an application for the admission to trading on a regulated market of shares by an issuer which qualifies as SME, the level of disclosure of this Prospectus is proportionate to this type of transaction in accordance with Annex XXV of the Prospectus Regulation.

There is currently no public market for the Company's shares. The Company has applied to have its shares admitted to trading on the regulated markets of Euronext Brussels and Euronext Paris under the trading symbol "BOTHE". The Offered Shares are expected to be delivered in book-entry form on or about 5 February 2015.

Investing in the Offered Shares involves a high degree of risk. An investor is exposed to the risk to lose all or part of his/her investment. Before any investment in shares, the investor must read Section 1 "Risk Factors", in particular the risks related to the description of the Company's business (from page 6 to 10 of the summary and as from page 13 of the Prospectus) and more generally, the risks related to the Offered Shares and the Offering (on page 10 of the summary and from page 26 of the Prospectus). The Company's main assets are intellectual property rights concerning technologies that have not led yet to the commercialisation of any product. The Company has never been profitable.







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## **Summary**

Summaries are made up of disclosure requirements known as "Elements". These Elements are numbered in Sections A - E (A.1 - E.7).

This summary contains all of the Elements required to be included in a summary for this type of securities and company. Because some Elements are not required to be addressed, there may be gaps in the numbering sequence of the Elements.

Even though an Element may be required to be inserted in the summary because of the type of the securities and company, it is possible that no relevant information can be given regarding the element. In this case, a short description of the Element is included in the summery, mentioning "Not applicable".

#### Section A – Introductions and warnings

Element	Disclosure requirement
A.1	Introduction and warnings
	This summary must be read as an introduction to this Prospectus and is provided to aid investors when considering whether to invest in the Offered Shares, but is not a substitute for this Prospectus. Any decision to invest in the Offered Shares should be based on the consideration of this Prospectus as a whole. Following the implementation of the relevant provisions of the Prospectus Directive (Directive 2003/71/EC), no civil liability will attach to the persons responsible for this summary, including any translation thereof, unless it is misleading, inaccurate or inconsistent when read together with the other parts of this Prospectus, or it does not provide, when read together with the other parts of this Prospectus, key information in order to aid investors when considering whether to invest in the Offered Shares. Where a claim relating to this Prospectus is brought before a court in a Member State of the European Economic Area, the plaintiff may, under the national legislation of the Member State where the claim is brought, be required to bear the costs of translating this Prospectus before the legal proceedings are initiated.
A.2	Consent for use of this prospectus for subsequent resale
	Not applicable. The Company does not consent to the use of this Prospectus for the subsequent resale or final placement of securities by financial intermediaries.

#### Section B - Issuer

Element	Disclosure requirement
B.1	Legal and commercial name of the Company
	The legal and commercial name of the Company is Bone Therapeutics SA.
B.2	Registered office and legal form of the Company
	The Company is a limited liability company incorporated in the form of a <i>société anonyme</i> under the laws of Belgium. Bone Therapeutics is registered with the legal entities register (Charleroi) under number 0882.015.654. The Company's registered office is located at rue Adrienne Bolland 8, 6041 Gosselies (Charleroi), Belgium (+32 2 529 59 90).
В.3	Current operations and principal activities of the Company and the principal markets in which it competes
	Bone Therapeutics is a biotechnology company with an advanced pipeline of clinical candidates, founded in 2006, with a unique approach to the discovery, development and commercialisation of bone cell products for bone fracture repair and fracture prevention.
	The Company is creating a new and unique treatment approach (with its two first-in-class products, PREOB® and ALLOB®, which target 5 indications (2 pivotal IIB/III and 3 Phase II) and offer the

potential for additional product extensions) using differentiated bone-forming cells administered via a minimally invasive percutaneous procedure. This procedure is expected to offer significant benefits over the current standard-of-care that often involves heavy surgery and long recovery periods. Solid preclinical foundations support the Company's research and development programs. Phase II clinical programs already demonstrated excellent safety and efficacy results with statistically and clinically relevant benefits, giving the Company a strong rationale to continue clinical development. The Company has extensive knowledge of bone physiology and pathophysiology and collaborates closely with prestigious academic and medical institutions.

In addition, the Company is conducting preclinical research on next generation products such as combined cell-matrix products for large bone defects and maxillofacial applications or enhanced viscosupplementation for osteoarthritis.

The Company aims to be a leading regenerative company providing innovative cell products for conditions with high unmet medical needs (i.e., medical conditions that are not addressed adequately by an existing therapy) in the fields of bone fracture repair and prevention. To achieve this objective, the Company is conducting clinical trials in five identified indications in the fracture repair segment (non-union, delayed-union, spinal fusion) and in the fracture prevention (osteonecrosis and osteoporosis).

#### B.4a Significant recent trends affecting the Company and the industries in which it operates

The area of regenerative medicine in which the Company operates has since several years been characterized by intense academic research. Recently, the academic programs have reached the industry, with the first clinical programs now ongoing and the first products receiving approval for commercialization. According to the Alliance for Regenerative Medicine, nine stem cell products were marketed in 2014. In 2012, seven cell therapy products were approved by regulatory agencies around the world in contrast with five such approvals in the three previous years, and none from 2002 to 2008<sup>1</sup>. An increasing interest can thus be noted in the industry towards regenerative medicine. On the other hand, one can observe that conventional medical approaches (e.g., small proteins, antibodies) are experiencing difficulties when addressing indications related to tissue regeneration (in particular in respect to bone regeneration). Efforts are however expected to continue on all fronts.

The increase in legislative guidance and support for diseases targeted by regenerative medicine is also fuelling the industrial development by bringing a clear regulatory path to market and incentives for clinical development. A recent example is Japan, where a new legislation, which allows for conditional marketing approval after Phase II clinical trials, has been passed in order to accelerate the development of new regenerative medicine therapies that could help address areas of significant unmet medical need. The introduction of regulations, such as Regulation (EC) 1394/2007 defining tissue-engineered products, demonstrates the growing importance of the regenerative medicine field.

#### **B.5** Description of the Group and the Company's position within the Group

The Company's main business is conducted through the Company (as described in B.3) itself and through its affiliate SCTS (Skeletal Cell Therapy Support).

SCTS is a service company dedicated to provide infrastructure, logistics and manufacturing services to the Company.

SCTS is part of the Walloon Cell Therapy Platform ("PWTC").

#### B.6 Relationship with major shareholders

At the date of the Prospectus, the principal direct shareholders of the Company are Jacques Reymann (15.57%), Theodorus II SA (11.61%), S.R.I.W. SA (10.11%), Christian Boon Falleur (6.33%), Sambrinvest Spin-off/Spin-out SA (5.53%) and JJ Verdickt & consorts (5.06%). The Company has issued convertible bonds which were subscribed by existing shareholders of the Company and by certain new investors. As the number of shares to be issued upon conversion of the bonds will depend on the Offer Price, the dilution caused by the conversion of the bonds upon completion of the Offering is unknown at the date of this Prospectus. It is expected that SFPI SA (Société Fédérale de Participations et d'Investissement) and Sofipôle SA (Société Wallonne pour le

 $<sup>^{1}\,</sup>$  The Alliance for Regenerative Medicine Annual Report March 2013.

Financement des Infrastructures des Poles de Compétitivité), as two of the main subscribers of the convertible bonds, will upon conversion of the bonds and participation to the Offering in line with their commitment become significant shareholders ( $\geq$  5%) of the Company.

The following direct or indirect relationships exist between the Company and its significant shareholders: the Company (and SCTS) have obtained a number of loan facilities through regional investment offices, such as Sambrinvest SA, Fond de Capital à Risque SA, Novallia SA and Sofipôle SA. The amounts to be reimbursed in accordance with these loan facilities (as per 30 September 2014) amount to  $\in$  2,881,000 for the Company (of which  $\in$  469,000 to Novallia SA and  $\in$  2,385,000 to Sambrinvest SA) and to  $\in$  870,000 for SCTS (of which  $\in$  500,000 to Novallia SA and  $\in$  370,000 to Fonds de Capital à Risque SA).

#### B.7 Selected key historical financial information

The following table includes information relating to the Company's statement of comprehensive income for the financial years ended 31 December 2013 and 2012 and for the nine months period ended 30 September 2014 and 2013.

	-	Year ended 31 December		
30/09/14	30/09/13	2013	2012	
0	0	0	0	
2,644	2,418	3,394	3,057	
2,644	2,418	3,394	3,057	
(5,523)	(4,647)	(6,816)	(6,371)	
(865)	(502)	(621)	(348)	
(3,743)	(2,731)	(4,043)	(3,662)	
110	96	150	172	
(201)	(115)	(190)	(189)	
(63)	()	(1)	(3)	
0	31	19	(17)	
(3,897)	(2,720)	(4,066)	(3,698)	
0	0	0	0	
(3,897)	(2,720)	(4,066)	(3,698)	
0	0	0	0	
(3.897)	(2.720)	(4.066)	(3,698)	
	90 (3,897)	0 0 2,644 2,418 2,644 2,418 (5,523) (4,647) (865) (502) (3,743) (2,731)  110 96 (201) (115) (63) () 0 31 (3,897) (2,720) 0 0 (3,897) (2,720)	ended         Decem           30/09/14         30/09/13         2013           0         0         0           2,644         2,418         3,394           2,644         2,418         3,394           (5,523)         (4,647)         (6,816)           (865)         (502)         (621)           (3,743)         (2,731)         (4,043)           110         96         150           (201)         (115)         (190)           (63)         ()         (1)           0         31         19           (3,897)         (2,720)         (4,066)           0         0         0           0         0         0	

The table below shows the balance sheet on 1 January 2012, 31 December 2012, 31 December 2013 and 30 September 2014.

	9 month period ended	Year ended	Year ended	Opening balance
ASSETS (in thousands of euros)	30/09/14	31/12/13	31/12/12	01/01/12
Non-current assets	4,230	4,724	2,650	2,004
Intangible assets	42	60	19	4
Property, plant and equipment	2,074	2,869	1,277	1,137
Investments in associates	282	282	263	280
Financial assets	181	180	163	59
Deferred tax assets	1,652	1,333	927	523

Current assets	8,741	8,087	11,767	13,049
Trade and other receivables	6,861	5,513	6,834	7,220
Other financial assets	0	0	0	203
Other current assets	145	134	112	67
Cash and cash equivalents	1,735	2,440	4,822	5,559
TOTAL ASSETS	12,971	12,811	14,418	15,053
	9 month period ended	Year ended	Year ended	Opening balance
EQUITY AND LIABILITIES (in thousands of euros)	30/09/14	31/12/13	31/12/12	01/01/12
Equity				
Equity attributable to owners of the Company	(1,810)	63	2,637	3,812
Share capital	10,466	9,288	8,417	6,943
Share premium	7,480	6,635	6,014	4,966
Retained earnings	(19,757)	(15,860)	(11,794)	(8,097)
Non-controlling interests	0	0	0	0
Total equity	(1,810)	63	2,637	3,812
Non-current liabilities	6,570	6,502	5,926	4,840
Financial liabilities	5,082	5,052	4,115	3,090
Deferred tax liabilities	0	0	0	0
Other non-current liabilities	1,488	1,450	1,811	1,750
Current liabilities	8,212	6,246	5,854	6,400
Financial liabilities	3,340	509	192	152
Trade and other payables	1.852	1,458	1,116	789
Current tax liabilities	0	0	0	0
Other current liabilities	3,020	4,279	4,546	5,459
Total Kabilidas	14 792	12.740	11.700	11 241
Total liabilities	14,782	12,748	11,780	11,241
TOTAL EQUITY AND LIABILITIES	12,971	12,811	14,418	15,053
The following table sets forth the Company's consolid 31 December 2013 and 2012 as well as the nine month	period ended		iber 2014 a Year ei	nd 2013. nded 31
(in thousands of euros)		ded	Dece	mber
(in thousands of euros)		ded 30/09/13	Dece: 2013	mber 2012
(in thousands of euros)  CASH FLOW FROM OPERATING ACTIVITIES	en			
	en			2012
CASH FLOW FROM OPERATING ACTIVITIES	enc 30/09/14	30/09/13	2013	

	NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(705)	(1,148)	(2,381)	(737)
	CASH AND CASH EQUIVALENTS at beginning of year CASH AND CASH EQUIVALENTS at end of year	2,440 <b>1,735</b>	4,822 <b>3,674</b>	4,822 2,440	5,559 4,822
B.8	Selected key pro forma financial information  Not applicable. No pro forma information has been included.	d in this Pr	ospectus.		
B.9	Profit forecast or estimate  Not applicable. No profit forecast has been included in this	Prospectus	S.		
B.10	Description of the nature of any qualifications in the a information  Not applicable. There are no qualifications to the audit repo	•			
B.11	Working capital  On the date of this Prospectus, the Company is of the opin cash and cash equivalents on 30 September 2014 and the December 2014 and 8 January 2015 (in aggregate € 10.35 to cover the working capital needs for a period of at Prospectus.	ne proceed million), it	s of the is has suffic	sue of bon	ds of 18 g capital

## **Section C – Securities**

Element	Disclosure requirement			
C.1	Type and class of the securities being offered and admitted to trading			
	The shares offered to investors in the context of the Offering (the " <b>Offered Shares</b> ") are ordinary shares of the Company, without nominal value. The shares are in dematerialised form.			
	The following code has been assigned to the shares of the Company: ISIN: BE0974280126			
C.2	Currency of the Offered Shares			
	The currency of the Offered Shares is euro.			
C.3	Number of shares issued			
	On the date of this Prospectus, the Company's share capital is represented by 3,458,240 shares, each representing an identical fraction of the Company's share capital.			
	The Company has issued 304,760 warrants which give right to subscribe to an equal number of Shares. On the date of this Prospectus, 159,800 warrants have been granted.			
	The Company has issued automatically convertible bonds for a total amount of $\in$ 10,350,000 which will automatically convert, on completion of the Offering, into a number of Shares equal to a fraction, whereby the numerator is equal to 166.5% of the nominal value of the bonds, and the denominator is equal to the Offer Price.			
C.4	Rights attached to the Offered Shares			
	All Offered Shares will have the same rights and benefits attached to them as the Company's other ordinary shares and will be issued with coupons 1 and following attached.			
	The Offered Shares are entitled to dividends, if and when declared, for the financial year ended on 31 December 2014.			

C.5	Restrictions on the free transferability of the Shares
	The Company's shares are freely transferable, subject to any contractual restrictions and any restrictions imposed on the Company's existing shareholders by the Royal Decree of 17 May 2007 on Primary Market Practices.
C.6	Application for admission to trading on a regulated market and identity of all the regulated markets where the Offered Shares are or are to be traded
	An application has been made to have the Company's shares (including the Offered Shares) listed on the regulated market of Euronext Brussels and the regulated market of Euronext Paris under the symbol "BOTHE". Trading of the Offered Shares on Euronext Brussels and Euronext Paris is expected to commence on or about 6 February 2015.
C.7	Dividend policy
	Following the Offering, the Company's dividend policy will be determined by, and may change from time to time by determination of the Board of Directors. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the Board of Directors, from time to time.
	The Company does not intend to pay dividends for the foreseeable future.

## Section D - Risk Factors

Element	Disclosure requirement
D.1	Key Risk Factors related to the Company's business  Risk factors inherent to the sector
	Research programmes and product candidates of the Company must undergo rigorous preclinical tests and clinical trials, of which the start, timing of completion, number and results are uncertain and could substantially delay or prevent the products from reaching the market. Clinical trials may be delayed for a variety of reasons, including, but not limited to, delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable terms with prospective clinical research organisations, contract manufacturing organisations and clinical trial sites, in obtaining approval of the Competent Authority, in recruiting suitable patients to participate in a trial, in having patients complete a trial, in obtaining sufficient supplies of clinical trial materials or clinical sites dropping out of a trial and in the availability to the Company of appropriate clinical trial insurances. In particular, the clinical trials related to orthopaedics require longer follow-up periods of up to 24 months.
	Uncertain outcome of clinical trials. The Company's cell products are highly innovative and are based on the differentiation of human bone marrow cells with a view to producing osteoblastic bone-forming cells. If serious adverse side effects are identified for any product candidate, the Company may need to abandon or limit its development of that product candidate, which may delay, limit or prevent marketing approval, or, if approval is received for the product candidate, require it to be taken off the market, require it to include safety warnings or otherwise limit its sales. Important unpredicted side effects from any of the Company's product candidates could arise either during clinical development or, if approved by the Competent Authorities, after the approved product has been commercialised.
	<ul> <li>Nearly all aspects of the Company's activities are subject to substantial regulation. The international biopharmaceutical industry is highly regulated by government bodies ("Competent Authorities") imposing substantial requirements on almost all aspects of the Company's activities, notably on manufacturing, preclinical and clinical trials, labelling, marketing, sales, handling, transport and storage, record keeping, promotion and pricing. The standards imposed by a Competent Authority and the approval procedure for clinical trials may vary from country to country.</li> </ul>
	<ul> <li>If the Company obtains regulatory approval for a product candidate, the product will remain subject to on-going regulatory obligations. Once commercialised, products may be subject to</li> </ul>

post-authorisation safety studies or other pharmacovigilance or biovigilance activities, may be subject to limitations on their uses or may be withdrawn from the market for various reasons, including if they are shown to be unsafe or ineffective, or when used in a larger population that may be different from the trial population studied prior to introducing the product on the market.

The future commercial success of the Company's product candidates will depend on the degree of market acceptance of its products among third party payers, doctors, patients and the medical community in general. To date, the Company has no product authorised for commercialisation, the Company's products candidates are at different stages of development (in different phases of clinical trials) and the Company may never have a product that is commercially successful.

#### Risk factors inherent to the Company

- The Company is at an early stage of its development and has not yet commercialised any of its products. Successful products require significant development and investment, including testing to demonstrate their safety, their efficacy and their cost-effectiveness prior to commercialisation. Furthermore, problems encountered in connection with the development and utilisation of new technologies and the competitive environment in which the Company operates, might limit the Company's ability to develop commercially successful products. In addition, The Company does not anticipate generating revenue from sales of commercially successful products for the foreseeable future.
- The Company may need substantial additional funding which may not be available on acceptable terms when needed if at all. These future financing needs will depend on many factors, including the progress, costs and timing of its clinical trials, the costs and timing of obtaining regulatory approval, the costs of obtaining, maintaining and enforcing its patents and other intellectual property rights, the costs and timing of maintaining or obtaining manufacturing approval for its products and product candidates, the costs and timing of establishing sales and marketing capabilities.

If the necessary funds are not available, the Company may need to seek funds through collaborations and licensing arrangements, which may require it to reduce or relinquish significant rights to its research programmes and product candidates, to grant licences on its technologies to partners or third parties or enter into new collaboration agreements, the terms could be less favourable to the Company than those it might have obtained in a different context.

- The Company's business environment is characterised by rapid technological change and complexity which could limit or eliminate the market opportunity for its product candidates.
- If the Company fails to comply with its obligations under the agreement pursuant to which it licenses intellectual property rights from third parties, or otherwise experiences disruptions to its business relationships with its licensors, the Company could lose the rights to intellectual property that is important to its business. The Company's activities are dependent at least in part on the use of intellectual property rights which are for some projects not owned by it, but have been granted to it pursuant to license agreements and which are important to the business. In particular, for its clinical programs, the Company has been granted an exclusive worldwide license from a third party regarding the PREOB® technology for which it has entered into a sub-license manufacturing agreement with its affiliate SCTS, whereby the Company is granted a back-license.
- The Company may not be able to protect and/or enforce its intellectual property rights in all key countries or territories. Competitors may use the Company's technologies in jurisdictions where the Company or its licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where the Company has patent protection but where enforcement is not as well developed as in the European Union, United States or Japan. These products may compete with the Company's products in jurisdictions where the Company or its licensors do not have any issued patents and the Company's patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Moreover, it cannot be excluded that the debate on the patentability of elements of the human body could lead to a situation whereby the technology developed by or licensed to the Company can no longer be protected by patents or

- that such patents cannot be enforced against third parties.
- The Company has a strong collaborative relationship with its affiliate SCTS through a Group of Economic Interest (*Groupement d'Interêt Economique*), a service provider for cell product manufacturing, in particular in the bone field and which collaborates with the Company on production, quality control and assurance and storage and distribution of cell products.
- The manufacturing of the Company's products may be more costly than expected. To be able to supply the products at acceptable prices, the Company will have to control its costs and work continuously on the optimization of the manufacturing processes to prolong shelf-life, increase product stability and reduce processing time to increase the span over which the Company can transport the product.
- The Company is subject to competition for its skilled personnel and challenges in identifying and retaining key personnel could impair the Company's ability to conduct and grow its operations effectively. The services of the Company's management team are critical to the successful implementation of its business, research, product development and regulatory strategies. Members of the Company's management team may terminate their employment or services with the Company at any time with relatively short notice. Two key members of the Company's management team, i.e., the Company's chief executive officer, Mr Enrico Bastianelli, and the Company's chief medical officer, Pr. Valérie Gangji, are married. In general, conflicts between key managers may result in the Company losing the services of a manager or otherwise affect the cohesion within the management team.
- The Company has obtained significant grants and subsidies. The terms of certain of these agreements may hamper the Company in its flexibility to choose a convenient location for its activities. The subsidies granted to the Company may prohibit the granting, by way of license, transfer or otherwise, any right to use the results, respectively the patents without the prior consent of the Region. In addition, under the patent subsidies the Company may lose all or part of its right to any further funding in the event that the Company ceases to qualify as a "small or medium-sized enterprise". Changes in regional financing and grant policies or a shift in regional investment priorities may reduce or jeopardise the Company's ability to obtain nondilutive financing and grants. Also, future growth of the Company, whether or not including geographical expansion, could limit the Company's eligibility to obtain similar non-dilutive financing or grants. If the necessary funds are not available, the Company may need to seek funds through collaborations and licensing arrangements, which may require it to reduce or relinquish significant rights to its research programmes and product candidates, to grant licences on its technologies to partners or third parties or enter into new collaboration agreements, the terms could be less favourable to the Company than those it might have obtained in a different context. If adequate funds are not available on commercially acceptable terms when needed, the Company may be forced to delay, reduce or terminate the development or commercialisation of all or part of its product candidates or it may be unable to take advantage of future business opportunities.
- The Company has a history of operating losses and an accumulated deficit and may never become profitable. The Company does not anticipate generating revenue from sales for the foreseeable future. It has incurred significant losses since its inception in 2006. There can be no assurance that the Company will earn revenues or achieve profitability, which could impair the Company's ability to sustain operations or obtain any required additional funding. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods.

#### Other risks relating to the Company's Business

Early stage of development

The absence of similar products on the market generates a number of unknown factors.

#### Pre-clinical programs

- Failure to successfully identify, develop and commercialise additional products or product candidates could impair the Company's ability to grow.
- Dependence on lead product candidates.

#### Authorisation and certification

- The Company is subject to inspection and will be subject to market surveillance by the EMA,
   FDA and other Competent Authorities for compliance with regulations
- Maintenance of high standards of manufacturing in accordance with Good Manufacturing Practices and other manufacturing regulations and scale-up of manufacturing.

#### Reimbursement, commercialisation and market risk factors

- The price setting, the availability and level of adequate reimbursement by third parties, such as insurance companies, governmental and other healthcare payers is uncertain and may impede the Company's ability to generate sufficient operating margins to offset operating expenses.
- The Company has no experience in sales, marketing and distribution.
- The Company might not find suitable industrial partners to pursue the development, the commercialisation or the distribution of its products candidates.

#### Operational risk factors

- The terms of certain grants and subsidies may hamper the Company in the organisation of its activities and its efforts to partner part or all of its products.
- Manufacturing of the Company's products requires human or derived raw materials to be obtained from third parties.
- The Company may not have or be able to obtain adequate insurance cover in particular in connection with product liability risk.
- If any product liability claims are successfully brought against the Company or its collaborators, the Company may incur substantial liabilities and may be required to limit the commercialisation of it product candidates.
- The Company's employees, principal investigators, consultants and collaborative partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards. The Company's manufacturing and research and development activities may involve the use and disposal of potentially harmful biological materials, hazardous materials and chemicals which create the risk of contamination or injury from these materials, chemicals or agents.
- The Company may face significant competition and technological change which could limit or eliminate the market opportunity for its product candidates.
- Recently the composition of the Company's board of directors has changed considerably.

#### Intellectual property

- The Company's patents and other intellectual property rights portfolio is relatively young and
  may not adequately protect its research programmes and other product candidates, which may
  impede the Company's ability to compete effectively.
- The Company may infringe on the patents or intellectual property rights of others and may face
  patent litigation, which may be costly and time consuming and could result in the Company
  having to pay substantial damages or limit the Company's ability to commercialise its product
  candidates.
- Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other similar requirements imposed by governmental patent agencies, and the Company's or its licensor's patent protection could be reduced or eliminated for non-compliance with these requirements.
- If the Company is not able to prevent disclosure of its trade secrets, know-how, or other proprietary information, the value of its technology and product candidates could be significantly diminished.

#### Financial risk factors

- Fluctuation in interest rates could affect the Group's results and financial position.

# Key Risk Factors related to the Offered Shares and the Offering There may not be a very active public market for the Company's shares, which may cause the shares to trade at a discount to the Offer Price and make it difficult to sell the shares, which may limit the number of shares available for sale or which can negatively impact the market price of the shares when a substantial numbers of shares is sold.

- The market price of the shares may fluctuate widely in response to various factors.
- The minimum amount for the Offering set at € 17.5 million, the amount below which the Offering will not be realized.
- Any future issuances of shares or warrants may affect the market price of the shares and could dilute the interests of existing shareholders.
- The holders of shares outside Belgium and France may not be able to exercise pre-emption rights.
- There are limited shares available for sale in the market.
- The market price of the shares could be negatively impacted by sales of substantial numbers of shares in the public markets.
- The Company does not intend to pay dividends for the foreseeable future.
- Certain significant shareholders of the Company after the Offering may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes.
- Any sale, purchase or exchange of the shares may become subject to the Financial Transaction Tax.

#### Section E - Offering

Element	Disclosure requirement
E.1	Net proceeds and expenses of the Offering
	Assuming a full placement of the Offered Shares and that the Offer Price is at the mid-point of the price range, the gross proceeds of the Offering (assuming exercise of the Increase Option) will be $\in$ 31.2 million. If the Global Coordinator exercises the Over-allotment Option in full, the gross proceeds, at the mid-range of the Offer Price Range shall be further increased to $\in$ 35.9 million. The net proceeds of the Offering, after deduction of fees and expenses relating to the Offering are expected to be approximately $\in$ 28.2 million (assuming exercise of the Increase Option), respectively $\in$ 32.6 million (assuming exercise of the Over-allotment Option in full).
E.2	Use of proceeds
	This Offering has as main purpose to support and accelerate the development of the Company and facilitate the future financing by establishing a public market for the shares of the Company and providing it with access to capital markets.
	The Company intends to use the net proceeds from the Offering (net of fees and expenses to be paid by the Company) for the following purposes (in order of importance):
	<ul> <li>Proceed with its two pivotal Phase III (including the acceleration of patient enrolment) and three Phase I/II clinical trials ongoing in Europe;</li> </ul>
	Optimize production in order to reduce costs of goods sold and to increase production capacity;
	Finance general corporate purposes;
	Launch clinical trials in the US.

#### E.3 Terms and conditions of the Offering

The Offering is comprised of (i) a public offering in Belgium and in France to retail investors and (ii) private placements outside the United States in offshore transactions in accordance with Regulation S under the Securities Act to qualified investors, and, with respect to the EEA, pursuant to an exemption under the Prospectus Directive where implemented by the Relevant Member State.

The Offer Price will be determined by the Company on the basis of a book-building procedure conducted during the Offering Period, in which only Institutional Investors can participate.

The Offer Price will be determined as soon as possible after the end of the Offering Period on the Allocation Date, which is expected to take place on 3 February 2015 and will be published on the website of the Company and by press release on the first publishing day following its determination, which is expected to be 4 February 2015. Both dates are subject to the acceleration or suspension of the Offering Period.

The Offer Price is expected to range between € 14.5 and € 16.5 per Offered Share.

The Offering Period will begin on 22 January 2015 and is expected to close at 5:00 p.m. Brussels time on 2 February 2015, unless it is closed or suspended earlier, provided that the Offering Period will in any event be open for at least six Business Days as from the availability of this Prospectus. Any acceleration or suspension of the Offering Period will be announced on the website of the Company and by press release, and the dates for pricing, allocation, publication of the Offer Price and results of the Offering, listing and trading and completion of the Offering will be adjusted accordingly.

In accordance with Belgian and French regulations, no less than 10% of the Offered Shares will be reserved for Retail Investors. However, the proportion of Offered Shares allocated to retail investors may be higher or lower than 10% of the Offered Shares (possibly substantially), if Retail Investors have applied in aggregate for more or less, respectively, than this percentage.

The Company has the right to proceed with a capital increase for a reduced number of shares. The actual number of Offered Shares subscribed for or sold in the Offering will be confirmed on the website of the Company and by press release together with the Offer Price. The minimum amount set for the Offering is  $\in$  17.5 million, below which the Offering will not be completed.

The Global Coordinator has been granted an Over-allotment Option, exercisable for a period of 30 calendar days from the Listing Date, to subscribe for new shares at the final Offer Price for the sole purpose of allowing the Global Coordinator to cover over-allotments of Additional Shares, if any.

All Offered Shares will be delivered against payment in dematerialized form, through Euroclear Belgium, the Belgian central securities depository.

#### E.4 Material interests to the Offering

Save for (i) the fees payable to the Joint Bookrunners (upon entering into the Underwriting Agreement with the Company, which is expected to occur prior to completion of the Offering, and subject to the terms and conditions thereof), (ii) the conversion of the Bonds upon completion of the Offering and (iii) a bonus payment (at the occasion of the completion of the Offering) to and the vesting or exercisability of certain warrants held by members of the Management Team, so far as the Company is aware, no person involved in the Offering has an interest that could be material to the Offering.

#### E.5 Entity offering the Offered Shares and Lock-ups

The Offered Shares are new shares offered by the Company.

Certain shareholders of the Company have agreed not to transfer any shares held prior to the Offering during a period of 365 days from the Closing Date, except for a limited number of shares (maximum 5,000 shares per shareholder) which may be freely transferred following a shortened lock-up period of 90 days following the Closing Date. The shares covered by the 365 days lock-up agreement represent in total 94.83% of the Company's shares on the Date of this Prospectus.

The holders of Bonds have also agreed not to transfer any shares issued upon conversion of the Bonds (i.e. on completion of the Offering) during a period of 365 days from the Closing Date, except for a limited number of shares (maximum 5,000 shares per shareholder) which may be freely

	transferred following a shortened lock-up period of 90 days.
	Certain exceptions apply.
	In addition thereto, the above mentioned shareholders and bond holders are expected to enter into a soft lock-up undertaking vis-à-vis the Joint Bookrunners, whereby they undertake not to transfer the above mentioned shares for a period of 180 days following the above-mentioned 365 days lock-up period without prior approval by the Joint Bookrunners.
E.6	Dilution resulting from the Offering
	The dilution resulting from the completion of the Offering will depend on the size of the Offering and the amount of the Offer Price. Assuming a full placement of the Offered Shares, the average dilution of the current shareholders would amount to 40.10%. Also, the conversion of the Bonds upon completion of the Offering will further dilute the current shareholders. The number of Shares to be issued upon conversion of the Bonds will depend on the Offer Price. If the Offer Price is set at the lower end of the Offer Price Range, 1,188,465 Shares will be issued upon conversion of the Bonds. If the Offer Price is set at the higher end of the Offer Price Range, 1,044,409 Shares will be issued upon conversion of the Bonds.
E.7	Estimated expenses to be charged to the investor by the Company
	Not applicable. No fees or expenses in connection with the Offering will be charged to investors by the Company.

#### 1 Risk Factors

#### 1.1 Risk factors related to the Company's business

#### 1.1.1 Early stage of development

1.1.1.1 The Company is at an early stage of its development and has not yet commercialised any of its products.

Clinical development - In Europe, the Company has gained certain clinical experience with respect to autologous (cells originating from the patients - PREOB®) cell products, but has only limited clinical experience in allogeneic (cells originating from healthy donors - ALLOB®) cell products. In particular, the product candidates related to the ALLOB® platform are at an early stage of clinical development, namely in Phase I/IIA. Even though the Company's lead product candidates are in Phase III (PREOB® in non-union fractures and in osteonecrosis), this is no guarantee for its success. In the USA, the Company has no clinical and only limited regulatory experience. The Company's product candidates\_may not lead to successful products, as the success of the Company's cell products will be subject to risks and failures inherent to the development of products based on new technologies. These risks include but are not limited to, the inherent difficulty in avoiding unwanted side effects as well as the unanticipated problems relating to product development, testing, regulatory compliance and additional costs and expenses that may exceed current estimates.

Commercial development - Approved products resulting from the Company's research may not become commercially available for many years, if at all. The Company has not yet commercialised any of its products as its product candidates are still subject to clinical trials and may not be successful in their commercial development. Successful products require significant development and investment, including testing to demonstrate their safety, their efficacy and their (cost-) effectiveness prior to commercialisation. Furthermore, problems encountered in connection with the development and utilisation of new technologies and the competitive environment in which the Company operates, might limit the Company's ability to develop commercially successful products. In addition, the Company does not anticipate to generate revenue from sales of commercially successful products for the foreseeable future.

1.1.1.2 The Company's limited operating history may make it difficult for a prospective investor to evaluate the success of the Company's business to date and to assess its future viability.

The Company was founded in 2006 and therefore has a limited operating history. To date, the Company's activities have been limited to raising financing, business planning, developing its technology, identifying potential product candidates and undertaking preclinical studies and clinical studies. The Company has not yet demonstrated its ability to obtain marketing approvals or to conduct sales and marketing activities which are necessary for successful product commercialisation. Also, given its limited operating history, the Company may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. If the Company was to be successful at completing the approval process for one of its product candidates, the Company may consider a transition from the Company's current research and development focus to include a more commercial focus. The Company may not be successful in this transition or may incur greater costs than expected, which would adversely affect the Company's business, prospects, financial condition and results of operation.

#### 1.1.1.3 The absence of similar products on the market generates a number of unknown factors.

The existing treatments (for which the Company aims to develop an alternative through cell-technology based product(s) candidates) are often old techniques, which are painful and invasive. Cell therapy however, is an emerging medical technology, in which few products have yet been proven beneficial, safe and efficient and have obtained marketing authorisation. In general, the early stage of the technology, and consequently the lack of established practices and benchmarks, create uncertainty about prospects and come with inherent risk of unanticipated problems in every stage of the product life, including development, regulations, approvals, reimbursement, market acceptance and operations.

Especially in the orthopaedic field, the Company's innovative cell products would, if and when authorised for marketing, constitute a novel treatment paradigm. To its knowledge, the Company is the only clinical stage company that develops cell products using differentiated bone cells for the treatment of orthopaedic conditions. To date, there are no similar products authorised on the market for commercialisation. The lack of similar

products causes uncertainty about the registration, the reimbursement and revenues of the product candidates related to both the PREOB® and ALLOB® platforms and their acceptance by the regulators, third party payers, doctors and patients. The Company cannot give any assurance that it will be able to deal with these unknown factors which may have an adverse effect on the business, the results, the financial situation and the development of the Company.

#### 1.1.2 Pre-clinical and clinical programs

1.1.2.1 Research programmes and product candidates of the Company must undergo rigorous preclinical tests and clinical trials, of which the start, timing of completion, number and results are uncertain and could substantially delay or prevent the products from reaching the market.

The research programmes and product candidates of the Company must undergo rigorous pre-clinical and clinical trials, of which the start, the timing of completion, the number and the results are uncertain. Such trials could delay or prevent the product candidates from reaching the market. Clinical trials may be delayed for a variety of reasons, including, but not limited to, delays in obtaining regulatory approval to commence a trial, in reaching agreement on acceptable terms with prospective research organisations, manufacturing organisations and clinical trial sites, in obtaining approval of the Competent Authority, in recruiting suitable patients to participate in a trial, in having patients complete a trial or return for follow-up, in obtaining sufficient supplies of clinical trial materials, clinical sites dropping out of a trial and in the availability to the Company of appropriate clinical trial insurances. In particular, the clinical trials related to orthopaedics require longer follow-up periods of up to 24 months. Many factors affect patient enrolment, including, but not limited to, the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, competing clinical trials, clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new products that may be approved for the indications that the Company is investigating and whether the clinical trial design involves comparison to placebo or standard of care. If the Company experiences lower than expected enrolment in the trials, the trials may not be completed as envisaged or may become more expensive to complete which may have an adverse effect on the Company's business, prospects, financial condition and results of operations.

#### 1.1.2.2 Uncertain outcome of clinical trials

The Company's cell products are highly innovative and are based on the differentiation *ex vivo* of human bone marrow cells with a view to producing osteoblastic cells. Although the Phase II clinical results for the use of these differentiated cells in the treatment of osteonecrosis and non-union fractures showed statistically and clinically relevant benefits and demonstrated satisfying safety and efficacy, the success cannot be guaranteed and may not lead to successful therapy products.

If serious adverse side effects are identified for any product candidate, the Company may need to abandon or limit its development of that product candidate, which may delay, limit or prevent marketing approval, or, if approval is received for the product candidate, require it to be taken off the market, require it to include safety warnings or otherwise limit its sales.

Even if the Company's PREOB® and ALLOB® platform therapy product candidates are in clinical programs, not all adverse side effects of the product candidates are known or can be foreseen. Important unpredicted side effects from any of the Company's product candidates could arise either during clinical development or, if approved by the Competent Authorities, after the approved product has been commercialised. While the Company's clinical studies for its product candidates to date have demonstrated an acceptable safety profile, the results from future trials may not support this conclusion. Adverse side effects could prevent the Company or any potential future partner from achieving or maintaining market access and market acceptance of the affected product or could substantially increase commercialisation costs and expenses, which would have an adverse effect on the Company's business, prospects, financial condition and results of operations.

1.1.2.3 The Company's business environment is characterised by rapid technological change and complexity which could limit or eliminate the market opportunity for its product candidates.

The changing competitive landscape is a main issue facing the health care industry. The Company competes with other companies based on technology, product offering, therapeutic area, intellectual property, geographic area and time to market or other factors. The Company's success depends on, *inter alia*, the ability to establish a competitive position with respect to all of these factors. The Company believes that its main competitive advantages are its expertise and know-how in cell therapy in general and in cell therapy for bone diseases in particular, the quality (i.e., efficacy and safety) of its product candidates, its efficient and robust manufacturing

process, the minimal invasive technique through which its products are administrated and the choice of the indications (i.e., unmet medical needs in the fields of bone diseases and orthopaedics). However, the Company's competitors may have greater financial, human and other resources than the Company does.

Although cell therapy is only an emerging medical technology and to date, there are no competitors of the Company offering similar products on its relevant markets, markets for treatments are in general highly competitive and the fields in which the Company operates are characterised by an increase in innovation. No assurance can be given that competitors of the Company are not currently developing, or will not in the future, develop technologies and products that are equally or more effective, safe and/or economical as the current or future offering of the Company.

1.1.2.4 Failure to successfully identify, develop and commercialise additional products or product candidates could impair the Company's ability to grow.

The Company's main focus is to continue its clinical trials and ultimately to obtain approval of its product candidates for the treatment of osteonecrosis, non-union fractures and resistant osteoporosis (PREOB®) and delayed-union fractures and lumbar fusion for degenerative disease of the spine (ALLOB®). The Company also runs preclinical research programs and develops new product candidates. The Company intends to leverage its preclinical research, clinical expertise and manufacturing ability to expand its pipeline to indications for which it believes its products have therapeutic potential. The accumulated data is expected to reduce the time and costs associated with early-stage clinical trials for additional diseases and disorders. However, the identification, selection and development of additional promising products or product candidates require additional resources, whether or not any product or product candidate is ultimately identified. Furthermore, the lack of existing benchmarks in the field of regenerative medicines in general and cellular therapy in particular prevents the Company from relying on existing precedents with respect to such identification, selection and development. The success of the Company's strategy depends partly on the Company's ability to identify, select and develop such products.

#### 1.1.2.5 Dependence on lead product candidate.

PREOB®, with its Phase III clinical trials in Europe for the treatment of non-union fractures and osteonecrosis, is currently the Company's most advanced product candidate. Although Bone Therapeutics' products are different and are developed for different indications, failure to successfully develop the Company's products which are currently most advanced in their clinical process may adversely affect the development of its other products.

#### 1.1.3 Authorisation and certification

1.1.3.1 Nearly all aspects of the Company's activities are subject to substantial regulation.

Regulatory risk for current clinical development activities

The Company's product candidates PREOB® and ALLOB® are advanced therapy medicinal products (ATMPs) which have been developed in compliance with the European legislation and are classified as tissue engineered products within the European regulatory framework governing advanced therapy in Europe (Regulation 1394/2007). In the US, PREOB® and ALLOB® will fall under the Biological Licence Application regulation. In Japan, PREOB® and ALLOB® will fall under the recently approved legislation for regenerative medicine which allows for conditional marketing approval after Phase II clinical trials. The testing, storage, and distribution of human tissues and cells (intended for human use) and of manufactured products derived from human tissues and cells (intended for human use) is specifically regulated in Europe by Directive 2004/23/EC transposed in national laws.

The Company is registered as a "Tissue Establishment" (according to the Belgian Royal Decree of 28 September 2009 on the determination of general conditions with which banks for human body materials, intermediary structures and the production units must comply to be recognized (Arrêté Royale fixant les conditions générales auxquelles les banques de matériel corporel humain, les structures intermédiaires et les établissements de productions doivent satisfaire pour être agréés) and the Belgian Act of 19 December 2008 on the obtaining and the use of human body materials for human medical application or for scientific research (Loi relative à l'obtention et à l'utilisation de matériel corporel humain destiné à des applications médicales humaines ou à fin de recherche scientifique), transposing the Directive). In addition, the Company's manufacturing site has been inspected by the regional competent authorities (Federal Agency for Medicines and Health Products, Belgium) and is registered as a "Pharmaceutical Establishment" and accredited as a "GMP" facility.

The Company has received approval from Regulatory Agencies and Ethic Committees of several European countries for its clinical trials concerning PREOB® and ALLOB® (see Section 6.14 "Regulatory framework"). However, those approvals are exclusively approvals for clinical trials. The Company has not received approvals for commercialisation yet.

Regulatory risks for future regulatory activities

The international biopharmaceutical industry is highly regulated by governmental bodies ("Competent Authorities") imposing substantial requirements on almost all aspects of the Company's activities, notably on research and development, manufacturing, preclinical trials, clinical trials, labelling, marketing, sales, handling, transport and storage of human material, record keeping, promotion and pricing of its research programs and product candidates. In each country where the Company, or any of its partners or licensees, operates, it has to comply with the standards and regulations imposed by the local Competent Authorities. The Competent Authorities include the European Medicines Agency ("EMA") in the European Union and the national Competent Authorities, and Food and Drug Administration ("FDA") in the United States.

The Company has to constantly comply with the standards imposed by the Competent Authorities, which are subject to regular reviews and may possibly result in changes in the applicable regulations.

The standards imposed by a Competent Authority and the approval procedure for clinical trials and/or marketing authorisation may vary from country to country (except in Europe where the marketing authorisation is a centralized procedure), inter alia in timing, detailed costs and efforts necessary to complete those procedures e.g., different reporting procedures. Moreover, the various reasons for which the Competent Authority's approval of clinical trials may be refused, delayed, suspended or withdrawn are not predictable by the Company. If the Company does not comply with one or more of the standards of the Competent Authorities, in a timely manner or at all, it could experience significant delays in development or commercialisation, additional costs, refusals, suspension, withdrawals of approvals resulting in an adverse effect on the Company's business, prospects, financial condition and results of operations.

Although the basic regulatory frameworks for cell-based medicinal products are in place in Europe and in the USA, regulatory experience for these types of products is limited, and consequently the interpretation of these frameworks may sometimes be difficult to anticipate and the regulatory frameworks themselves will continue to evolve. The EMA and FDA are issuing new guidelines on a regular basis.

Assessing the efficacy of products imposes in general longer clinical trial periods and therefore, the development process is generally longer and more expensive than the development of drugs in the other sectors and of medical devices in orthopaedics.

1.1.3.2 If the Company obtains regulatory approval for a product candidate, the product will remain subject to on-going regulatory obligations.

Once commercialised, products may be subject to post-authorisation safety studies or other pharmacovigilance or biovigilance activities, may be subject to limitations on their uses or may be withdrawn from the market for various reasons, including if they are shown to be unsafe or ineffective, or when used in a larger population that may be different from the trial population studied prior to introducing the product on the market. Regulatory approval guidelines may change during the course of the product development and review process, making the chosen development strategy suboptimal. This is even more the case in view of the early stage nature and the absence of benchmarks in the area in which the Company conducts its activities, which may still undergo important regulatory changes. These factors may result in significant delays, increased trial costs, significant changes to commercial assumptions or failure of the products to obtain marketing authorisation.

Even if the Company obtains regulatory approval of a Competent Authority in a specific region or country, such approval could include significant restrictions on the indicated uses or marketing of the product. In addition, the Competent Authority may impose on-going requirements for potentially costly post-approval studies or post-market surveillance.

1.1.3.3 The Company will be subject to market surveillance by the EMA, FDA and other Competent Authorities for compliance with regulations that prohibit the promotion of the Company's products for a purpose or indication other than those for which approval has been granted.

Post-approval, the Company's products may demonstrate different safety and efficacy profiles to those demonstrated in the data on which the approval to test or market such products was based. Such circumstances could lead to the withdrawal or suspension of approval, which could have an adverse effect on the Company's business, financial condition, operating results or cash flows.

1.1.3.4 Maintenance of high standards of manufacturing in accordance with Good Manufacturing Practices and other manufacturing regulations and scale-up of manufacturing.

The Company has its own Good Manufacturing Practices agreement and has obtained three manufacturing and intra-EU distribution authorisations from the Competent Authorities in Belgium, where its current manufacturing facility is located. However, the Company is not relieved from continuously complying with the relevant standards. The Company, and key third party suppliers on which it relies currently or in the future, must continuously comply with Good Manufacturing Practices and the corresponding manufacturing regulations of the Competent Authorities. In complying with these regulations, the Company and its third-party suppliers must expend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against the Company, including the seizure of products and shutting down of production. Any of thethird-party suppliers and the Company also may be subject to inspections by the Competent Authorities. If any of the Company's third-party suppliers or the Company itself fails to comply with Good Manufacturing Practices or other applicable manufacturing regulations, the Company's ability to develop and commercialise the products could suffer significant interruptions.

The Company's manufacturing process involves the handling, transport and storage of human materials and the transformation of human body tissue into a treatment product. The Company has obtained a license as a tissue bank for handling autologous human biological materials and a license as a tissue bank for handling allogeneic human biological materials in collaboration with hospital tissue banks. In order to maintain such license, the Company needs to comply with applicable regulations in this respect. Furthermore, the applicable legislation with respect to the handling and transport of human body tissue varies amongst the different jurisdictions in which the Company could envisage operations, potentially impairing relocation and export opportunities.

Moreover, the Company intends to expand, in collaboration with its affiliate SCTS, its manufacturing capacity to meet anticipated demand for products, when authorised for commercialisation, by building a new manufacturing facility. The Company plans to open this new manufacturing facility in the SCTS building at the BioPark of Gosselies (south of Brussels) mid-2016 after obtaining GMP accreditation. The Company may not be able to expand the manufacturing capacity within the anticipated timeframe or budget or may not be able to obtain the requisite regulatory approvals for the increase in manufacturing capacity in time, or at all. If the Company does not obtain the necessary approvals for this contemplated expansion in a timely manner, its ability to meet demand for its products would be adversely affected. The Company may have difficulties in finding suitable locations or commercially acceptable terms for the leasing of such facilities. Finally, the Company may have difficulties to ensure sufficient supply of human biological materials.

#### 1.1.4 Reimbursement, commercialisation and market risk factors

1.1.4.1 The future commercial success of the Company's product candidates will depend on the degree of market acceptance of its products among third party payers, doctors, patients and the medical community in general.

To date, the Company has no product authorised for commercialisation, and has not undertaken any steps for registration and/or authorisation. The Company's current product candidates are in different phases of clinical trials and the Company may never have a product that is commercially successful. Even the product candidates in Phase III clinical programs require further clinical trials, regulatory review, marketing authorisations, significant marketing efforts and substantial investment before they may provide revenue to the Company.

Clinical data are often susceptible to varying interpretations and analyses, so that a product that performed to satisfaction during clinical trials may nonetheless fail to obtain regulatory approval for marketing. Due to the inherent risk in the development of biopharmaceutical products, there is a risk that not all or none of the product candidates of the Company will be successfully developed and commercialised.

In addition, once introduced to the market, the Company's products may not achieve the desired level of acceptance of the products and perception of the advantages of the products by third party payers, doctors and patients and the medical community in general.

The limited number of scientific publications regarding cell-based technology used to develop the Company's products could adversely affect the benefits, efficacy or safety perception of the Company's products. Efforts to educate the medical community and third party payers on the benefits of the Company's products may require significant resources and may never be successful, which would prevent the Company from generating significant revenues, or becoming profitable.

In particular with respect to allogeneic cells, the safety concerns associated with human materials may affect the ability to generate revenues from the Company's products. Future medical events or studies that would raise or substantiate concerns about the safety of the raw materials used by the Company or other similar raw materials could negatively impact public perception of all human products and of their procurement process. Further, any failure in screening, whether by the Company or by other manufacturers of these human materials, could adversely affect its reputation, the support it receives from the medical community and overall demand for the Company's products.

1.1.4.2 The price setting, the availability and level of adequate reimbursement by third parties, such as insurance companies, governmental and other healthcare payers is uncertain and may impede the Company's ability to generate sufficient operating margins to offset operating expenses.

The commercial success of the Company's products depends in part on the conditions for setting the sales price of its products and the conditions of their reimbursement by the health agencies, insurance companies or other healthcare payers in the countries where the Company intends to commercialise its products. Considering the innovative nature of the Company's product candidates and the lack of similar products, the possible reimbursement levels are difficult to predict. The Company's ability to adapt an adequate pricing strategy is uncertain. Moreover, there is pressure on healthcare spending, on reimbursement and price levels in most countries, due to *inter alia* the current context of healthcare cost control, the economic and financial crisis and the increase in healthcare budgets caused by an aging population.

Moreover, the Company's products may not fit within the existing health technology assessment and reimbursement processes applied throughout the different jurisdictions in which the Company envisages to operate, and may be subject to different reimbursement facilities depending on the jurisdiction in which the Company's products are being offered.

1.1.4.3 The Company has no experience in sales, marketing and distribution.

The Company will have to hire, train, incentivise and retain a techno-commercial sales force or enter into a partnership with an industrial partner, gain the support of key opinion leaders, establish referral networks and introduce a new standard of care in orthopaedic treatment, to successfully commercialise its products once they have been approved for commercialisation. The Company has no experience in sales, marketing and distribution. The Company may be or perceived to be EU centred and may encounter difficulties gaining access to the USA or other markets. There is a risk that the Company will not be able to successfully manage its sales, marketing and distribution when its products come on the market, which will have an adverse effect on the Company's business, prospects, financial condition and results of operations.

Furthermore, market conditions may change resulting in the emergence of new competitors or new treatment guidelines, which may require alterations in the marketing and sales strategy or even of its development strategy.

1.1.4.4 The Company might not find suitable industrial partners to pursue the development, the commercialisation or the distribution of its products candidates.

Depending on the region and depending on the product candidate, the Company's strategy (see Section 6.2, "Company mission and strategy") may include out-licensing and co-developing its products candidates or partnering for the distribution of products developed and/or commercialised on a stand-alone basis. However, in order to conduct this strategy, the Company may need to find a partner, which has sufficient capacity for conducting research, on an international level or which is capable of distributing and commercialising the products. Therefore, the future international success of the Company may depend on its ability to conclude partnerships and on the ability of its partner(s) to meet the aforementioned characteristics.

#### 1.1.5 Operational risk factors

1.1.5.1 The Company has obtained significant grants and subsidies. The terms of certain of these agreements may hamper the Company in its flexibility to choose a convenient location for its activities.

As described in Section 6.11 "Grants and subsidies", the Company has entered into several funding agreements with the Region and to a lesser extent with the European Commission, to partially finance its research and development programmes (the "Research Grants" and "Research Subsidies") and its patent applications (the "Patent Subsidies").

Most of the Patent Subsidies provide that the Company must ensure a valorisation of the relevant patent or patent application in a certain area (in most cases in the Region), unless the prior written consent of the Region is obtained. Although the Region may not refuse such consent if the Company proves that its valorising activities outside of the Region's territory are carried out in the framework of a cooperation with an overall positive effect (in terms of technological or economic development) on the Region's territory, this provision restricts the Company in its choice of geographical location to carry out or further develop its activities. Also, if the Region would refuse to provide its consent, the Company may only valorise the relevant patent (application) outside the Region's territory provided that it informs the Region thereof in writing and refunds the entire subsidy related to the relevant patent (application) to the Region.

In addition, the Research Grants provide that the Company must carry out its exploitation activities (the production and commercialisation of products and the realisation of certain services) in relation to the research domain funded in accordance with the relevant Research Grants on the Member States' territory until the end of the exploitation phase as defined in the respective Research Grants. Some of the Research Subsidies also provide that the experimental development activities carried out by the Company in the framework of the exploitation of the research results obtained in the framework of the relevant Research Subsidy must be carried out on the Member States' territory. These provisions affect the Company's ability to relocate its activities. Furthermore, the Company's ability to relocate its activities is limited by the provisions of the SME Agreement, pursuant to which the Company, in order to keep the funding granted to it, must employ a specific number of employees at its (future) site at the BioPark of Gosselies (south of Brussels).

# 1.1.5.2 The terms of certain grants and subsidies may hamper the Company in the organisation of its activities and its efforts to partner part or all of its products.

The Research Grants, dedicated to support specific research and development programmes of the Company, provide a rigorous timetable for the research and development in relation to, and approval and exploitation of, such programmes. If the Company is unable at any stage to meet the deadlines applicable to the Research Grants, it will need to obtain formal approval from the Region to extend these deadlines. Also, the Research Grants may limit the Company's ability to conduct research with third parties in the field of research covered by the Research Grants and prohibit the granting of any other rights relating to the Company's findings in these fields of research to third parties without the consent of the Region. Furthermore, at the end of the research and development programmes partially financed by the Region through Research Grants, the Company must start reimbursing this funding. The Company may not be able to reimburse this funding under the terms of the agreements governing the Research Grants. In addition, if the Company decides not to enter into an exploitation phase and elects not to reimburse the funding received under any Research Grants, it must transfer all rights in rem relating to the findings of the research to the Region. It is also prohibited from conducting any research for any third party relating to the field of research covered by the Research Grants for a period of 36 or 72 months (as the case may be) following the Company's decision not to enter into the exploitation phase.

Both the Research Subsidies and the Patent Subsidies may prohibit the granting, by way of license, transfer or otherwise, any right to use the results, respectively the patents without the prior consent of the Region. In addition, the Patent Subsidies provide that the Company will lose all or part of its right to any further funding under these Patent Subsidies in the event that the Company ceases to qualify as a "small or medium-sized enterprise".

Also, the subsidies granted to the Company in accordance with the SME Agreement may be recovered by the Region if the Company fails to employ a specific number of employees at its (future) site at the BioPark of Gosselies (south of Brussels).

#### 1.1.5.3 Collaboration with and dependence on SCTS

The Company has a strong collaborative relationship with SCTS, a service provider for cell product manufacturing, in particular in the bone repair field, and which collaborates with the Company on production, quality control and assurance and storage and distribution of cell products, through a Group of Economic Interest (*Groupement d'Interêt Economique*). The Company holds 49.9% of SCTS' share capital and has undertaken in the shareholders' agreement to use the services provided by SCTS as soon as they are operational, and pursuant to which the Company has guarantueed a minimum dividend payment of 6.5% to the other shareholders in SCTS.

Such other shareholders are also, whether directly or indirectly, shareholders of the Company, including Sofipôle SA (23.48%) and Sambrinvest SA (12.72%). As of 1 January 2020, the Company may be held to acquire all the shares in SCTS held by the other shareholders pursuant to a put option, at the net asset value (fonds propres), with a minimum of 90% of the subscription price (in aggregate, epsilon 1,150,000). The exercise of

the put option could lead to a significant cash-out at the level of the Company and could trigger an early repayment obligation under the certain financing agreements entered into by SCTS. Also, the exercise of the put option by the other shareholders could result in the Company losing its qualification as small enterprise, which in turn may impact its entitlement to further funding in accordance with the Patent Subsidies, certain Research Grants and the SME Agreement.

The Company relies on SCTS' services, in particular for its collaboration on manufacturing optimisation and at a later stage, for the manufacturing of PREOB®. In addition, the Company is investing in new facilities at the BioPark of Gosselies (south of Brussels) through SCTS.

Although the Company is by far the largest shareholder of SCTS and has a call option to acquire 100% of the shares until 31 December 2019, the Company has no legal control over SCTS. Although the contractual framework of SCTS is quite restrictive, focussing only on services to be provided to the Company, it cannot be excluded that the corporate interests of SCTS and the Company could diverge. If the Company fails to maintain this collaborative relationship with SCTS, whether on reasonable terms or at all, the research relating to the optimization of the manufacturing process could be delayed and the costs of development and manufacturing could increase. Furthermore, the advanced intertwining of the Company's activities with the development of SCTS may limit future partnering opportunities with other partners.

1.1.5.4 Manufacturing of the Company's products requires human or derived raw materials to be obtained from third parties.

For the development of its research and the conduct of pre-clinical and clinical trials, the Company needs, in particular, human biological materials from diseased or healthy donors. The sourcing of these materials is regulated extensively by the Competent Authorities. The failure to comply with these regulations could cause the Company to be liable or could adversely affect its ability to source these materials. The public perception about the safety of human-derived materials, including bone cells, could adversely affect the market. The inability of the Company to ensure adequate supply and quality of human or derived raw materials may have an adverse effect on the business, the results, the financial situation and the development of the Company.

1.1.5.5 The manufacturing of the Company's products may be more costly than expected.

The Company will have to establish a scalable production platform with supply centres in the relevant regions to manufacture its products. To be able to supply the products at acceptable prices, the Company will have to control its costs and work continuously on the optimization of the manufacturing processes to prolong shelf-life, increase product stability and reduce processing time to increase the span over which the Company can transport the product. The inability of the Company to produce the products at reasonable costs could prevent it from achieving its overall objectives and could thus have an adverse effect on its business, prospects, financial condition and results of operations.

1.1.5.6 The Company may not have or be able to obtain adequate insurance cover in particular in connection with product liability risk.

To date, the Company has liability insurance for its on-going clinical trials. Nevertheless, additional product liability insurance will be necessary in the future (*i.e.* when its products are commercialised), which the Company will only install if it is economically viable, taking into account the level of premiums and the risk and magnitude of potential liability. In such cases, the Company might have to deal with liability claims that may not be covered by its insurance, which may harm the Company's business, prospects, financial condition and results of operations.

1.1.5.7 If any product liability claims are successfully brought against the Company or its collaborators, the Company may incur substantial liabilities and may be required to limit the commercialisation of it product candidates.

Product liability claims due to (unpredicted) adverse side effects of the product candidates may be brought against the Company or its collaborators by participants enrolled in clinical trials, practitioners, researchers, other health/research professionals or others using administering or selling any of the Company's future approved products. The Company may incur substantial liabilities if it cannot successfully defend itself against such claims. From the adverse events reported with the Company's products in clinical trials to date, none have been qualified as severe. To date, no such claims or legal actions have been filed against the Company.

1.1.5.8 The Company's employees, principal investigators, consultants and collaborative partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards.

Fraud or other misconduct by the Company's employees, principal investigators, consultants and collaborative partners could include intentional failures (i) to comply with EMA, FDA or other relevant Competent Authorities' regulations, to provide accurate information to the EMA, FDA and or other relevant Competent Authorities, (ii) to comply with manufacturing standards the Company has established or (iii) to comply with other regulations. If any such actions are alleged and the Company is unable to successfully defend itself or assert its rights, such actions could have a significant impact the Company's business and reputation.

1.1.5.9 The Company's manufacturing and research and development activities may involve the use and disposal of potentially harmful biological materials, hazardous materials and chemicals which create the risk of contamination or injury from these materials, chemicals or agents.

Even if the Company believes that its activities comply with the safety standards under the relevant regulations, the risk of contamination or injury from potentially harmful biological material, hazardous materials and chemicals cannot be eliminated entirely. Further, the cost of continued compliance with such new or current standards could negatively affect the Company's profitability and its business.

1.1.5.10 The Company is subject to competition for its skilled personnel and challenges in identifying and retaining key personnel could impair the Company's ability to conduct and grow its operations effectively.

The services of the Company's management team are critical to the successful implementation of its business, research, product development and regulatory strategies. Members of the Company's management team may terminate their employment or services with the Company at any time with relatively short notice. Two key members of the Company's management team, i.e., the Company's chief executive officer, Mr Enrico Bastianelli, and the Company's chief medical officer, Pr. Valérie Gangji, are married. In general, conflicts between key managers may result in the Company losing the services of a manager or otherwise affect the cohesion within the management team. Upon the departure of certain clinical and scientific personnel or members of its management team, the Company's research and development efforts may be seriously and adversely affected.

Certain key managers do not work for the Company on a full time basis. The Chief Clinical and Regulatory Officer, Mr Guy Heynen, works for the Company on a part-time basis (3 days per week). The Chief Medical Officer, Pr. Valérie Gangji is an active practitioner and provides services to the Company on a regular basis.

The Company's ability to compete in the highly competitive health care sector depends on its ability to attract and retain highly qualified management, scientific and medical personnel. Many of the other biotechnology and pharmaceutical companies and academic institutions that it competes against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than the Company does. Therefore, the Company might not be able to attract or retain these key persons on conditions that are economically acceptable. Furthermore, the Company will need to recruit new managers and qualified scientific personnel to develop its business if the Company expands into fields that will require additional skills. The inability of the Company to attract and retain these key persons could prevent it from achieving its overall objectives and could thus have an adverse effect on its business, prospects, financial condition and results of operations.

#### 1.1.5.11 Recently the composition of the Company's board of directors has changed considerably

Following the latest financing round and in view of the listing of the Company's shares, the Company's board composition changed substantially. Out of the eleven board members, five have been appointed only recently, including three out of the four independent directors. It is yet uncertain whether the Company's board of directors, in its new composition, will be able to perform its role optimally, to interact effectively with the management team, to find an efficient and collegial decision making dynamic and to determine and to agree upon the best strategy for the Company.

#### 1.1.6 Intellectual property

1.1.6.1 The Company's patents and other intellectual property rights portfolio is relatively young and may not adequately protect its research programmes and other product candidates, which may impede the Company's ability to compete effectively.

The Company's success will depend in part on the ability of the Company to obtain, maintain and enforce its patents and other intellectual property rights. The Company's research programs and product candidates are covered by several patent application families, which are either licensed to the Company or owned by the Company. There is one key PREOB® product patent currently granted in the United States, Japan and Singapore, and one key product ALLOB® patent granted in Singapore Japan and Australia. The Company cannot guarantee that the current prosecution of its or its licensors' patent applications will result in granted patents in other territories, including in Europe. The Company cannot guarantee that it will be in a position in the future to develop new patentable inventions or that the Company or its licensors will be able to obtain or maintain these patent rights against patent offices and other third-party challenges to their validity, scope and/or enforceability. The Company cannot guarantee that it is or has been the first to conceive an invention and to file a patent or a patent application, notably given the fact that patent applications are not published in most countries before an 18-month period has expired after the date of the filing. There can also be no guarantee that the Company will successfully commercialise a product before a specific patents 'expiration date'. Moreover, the Company may have no or limited control over the effectiveness of its licensors in preventing the misappropriation of their patents and intellectual property. Because patent law in the biopharmaceutical industry is highly uncertain, there can be no assurance that the technologies used in the Company's research programs and product candidates are patentable, that patents will be granted to the Company or its licensors under pending or future applications, or that patents will be of sufficient breadth to provide adequate and commercially meaningful protection against competitors with similar technologies or products, or that patents granted to the Company or its licensors will not be successfully challenged, circumvented, invalidated or rendered unenforceable by third parties, hence enabling competitors to circumvent or use them and depriving the Company of the protection it may expect against competitors. Also, taking into account its current patent portfolio and the broad nature of the ULB-028 patent claim, the Company may find it increasingly difficult or impossible to obtain additional or adequate patent protection for improvements and future developments in the same area. If the Company or its licensors do not obtain patents in respect of their products or if the patents of the Company or its licensors are invalidated (for example, as a result of the discovery of prior art), third parties may use the technologies without payment to the Company. A third party's ability to use unpatented technologies is enhanced by the fact that the published patent application contains a detailed description of the relevant technology. The Company cannot guarantee that third parties, contract parties or employees will not claim ownership rights over the patents or other intellectual property rights owned or held by the Company.

1.1.6.2 The Company may not be able to protect and/or enforce its intellectual property rights in all key countries or territories.

Filing, prosecuting and defending patents on all of the Company's product candidates throughout the world would be prohibitively expensive for the Company and its licensors. Competitors may use the Company's technologies in jurisdictions where the Company or its licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where the Company has patent protection but where enforcement is not as well developed as in the United States or the European Union. These products may compete with the Company's products in jurisdictions where the Company or its licensors do not have any issued patents and the Company's patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Moreover, it cannot be excluded that the debate on the patentability of elements of the human body could lead to a situation whereby the technology developed by or licensed to the Company can no longer be protected by patents or that such patents cannot be enforced against third parties. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favour the enforcement of patents and other intellectual property rights, particularly those relating to biopharmaceuticals, which could make it difficult for the Company to stop the infringement of its patents or marketing of competing products in contravention of its proprietary rights generally. The inability of the Company to protect and/or enforce its intellectual property rights worldwide could have an adverse effect on its business, prospects, financial condition and results of operations.

1.1.6.3 The Company may infringe on the patents or intellectual property rights of others and may face patent litigation, which may be costly and time consuming and could result in the Company having to pay substantial damages or limit the Company's ability to commercialise its product candidates.

The Company's success will depend in part on its ability to operate without infringing on or misappropriating the intellectual property rights of others. The Company cannot guarantee that its activities, or those of its licensors, will not infringe on the patents or other intellectual property rights owned by others. The Company may expend significant time and efforts and may incur substantial costs in litigation if it is required to defend

patent or other intellectual property right claims brought against the Company or its licensors regardless of whether the claims have any merit. Additionally, the Company cannot predict whether it or its licensors will be successful in any litigation. If the Company or its licensors are found to have infringed the patents or other intellectual property rights of others, it may be subject to substantial claims for damages, which could materially impact the Company's cash flow and financial position. The Company may also be required to cease development, use or sale of the relevant research programme, product candidate or process or it may be required to obtain a license for the disputed rights, which may not be available on commercially reasonable terms, if at all. The Company may be unable to develop or commercialise a product, product candidate or research programme, or may cease some of its operations, which may have an adverse effect on the Company's business, prospects, financial condition and results of operations. To date, no patent infringement claim has been made against the Company.

1.1.6.4 Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other similar requirements imposed by governmental patent agencies, and the Company's or its licensor's patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid by the Company and/or its licensors to the relevant patent agencies in several stages over the lifetime of the licensed patents and/or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse may be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance may result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, the Company's competitors might be able to use its technologies and those technologies licensed to the Company and this circumstance would have an adverse effect on the Company's business, prospects, financial condition and results of operations.

1.1.6.5 If the Company is not able to prevent disclosure of its trade secrets, know-how, or other proprietary information, the value of its technology and product candidates could be significantly diminished.

The Company relies on trade secret protection to protect its interests in its know-how or other proprietary information and processes for which patents are difficult to obtain or enforce, all of which constitute confidential information. The Company may not be able to protect its confidential information adequately. The Company has a policy of requiring its consultants, contract personnel, advisers and third-party partners to enter into confidentiality agreements. However, no assurance can be given that the Company has entered into the appropriate agreements with all of its consultants, contract personnel, advisers, third-party partners or other parties that have had access to its confidential information. There is also no assurance that such agreements will provide for the meaningful protection of confidential information in the event of any unauthorised use or disclosure of information. Furthermore, the Company cannot provide any assurance that any of its employees, consultants, contract personnel or third-party partners, either accidentally or through wilful misconduct, will not cause serious damage to its programs and/or its strategy, by, for example, disclosing confidential information to its competitors. It is also possible that confidential information could be obtained by third parties as a result of breaches of physical or electronic security systems of the Company, its consultants, advisers, third-party partners or other parties that have had access to its confidential information. Any disclosure of confidential data into the public domain or to third parties could allow the Company's competitors to learn confidential information and use it in competition against the Company. In addition, others may independently discover the Company's confidential information. Any action to enforce the Company's rights against any misappropriation or unauthorised use and/or disclosure of confidential information is likely to be time-consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable.

1.1.6.6 If the Company fails to comply with its obligations under the agreement pursuant to which it licenses intellectual property rights from third parties, or otherwise experiences disruptions to its business relationships with its licensors, the Company could lose the rights to intellectual property that is important to its business.

The Company's activities are dependent - at least in part - on the use of intellectual property rights which are for some projects not owned by it, but have been granted to it pursuant to license agreements and which are important to the business (see Section 6.8 "Material agreements").

In particular, for its clinical programs, the Company has entered into license agreements with third parties regarding the ULB-028 patent family and sub-license agreements with SCTS regarding the EP member of the ULB-028 patent family, whereby the Company is granted a back-license. For its preclinical programs, the Company has entered into license agreements with third parties regarding the ULB-061 patent families. Also in preclinical, the Company has been granted exclusive worldwide rights from its chief executive officer, Enrico Bastianelli SPRL, to develop, manufacture and sell regarding the JTA technology for which it has entered into a sub-license manufacturing agreement with its affiliate SCTS whereby the Company is granted a back-license.

The conditions under which Company may maintain the rights granted to it include, but are not limited to, the payment of (i) fees upon achievement of certain milestones, (ii) royalties on the (net) sales of relevant licensed products, (iii) a percentage of revenues incurred from sub-licensees, as well as the performance of other obligations, such as compliance with research and development obligations and with marketing and distribution arrangements. Furthermore, delays or interruptions in the development or exploitation of the relevant technology may be sanctioned under the terms and conditions of the license agreements. If the Company fails to comply with its obligations under the respective license agreements, the licensor may reduce the scope of the license or terminate the license, resulting in the loss of the use of the related intellectual property rights. Should the Company lose any of its licenses, or if it would be unable to obtain new rights on reasonable terms similar to those which it holds under such license, it might be unable to develop, manufacture or sell its products. This could have an adverse effect on the Company's business, prospects, financial condition and operational results. The termination of certain license agreements could substantially impair the Company's ability to generate revenues

In particular, the provisions of the license agreement pursuant to which the Company (and its affiliates) has been granted a non-transferable, exclusive and worldwide license over the technology claimed by the ULB-028 patent family (the ULB-028 License) (see Section 6.12.1 "Patents and patent applications owned or licensed by the Company") could generate an additional cash-out, as the royalties to be paid by the Company to the ULB on revenues received by the Company from sub-licenses under the agreement are based on estimations, and can be adjusted upwards in function of the actual figures. In addition, if the Company fails to meet the agreed objectives under the ULB-028 License, the Licensor may require the Company to produce a written report summarizing its efforts during the previous year and the milestones to be achieved in the next year, and if the licensor demonstrate that such report is reasonably not satisfactory. An independent expert can be called to evaluate the Licensee's report and the Licensor's objections. ULB has the right to reduce the scope of the license, make it non-exclusive or to terminate it. The ULB also has the right to terminate the ULB-028 License if the exploitation of the bone cell therapy by the Company was to be delayed for a period of 2 years or if such exploitation was to be interrupted for a period of 6 months. Any limitation in scope, loss of exclusivity or termination of the ULB-028 License could materially affect the Company's ability to generate revenues. Furthermore, in the event the Company develops an improvement to the BONE-028 patent family and related know-how, the ULB has been granted a right of first refusal to negotiate commercial license rights on such improvement outside the field of scope (skeletal and dental diseases and applications) at fair market conditions to be determined on a good faith basis between the parties, which could affect future partnering opportunities of the Company.

Also, the Company , together with the Region, entered into two agreements with SCTS regarding the recoverable funding by the Region of a research programme, and the exploitation of its results, conducted by SCTS within the scope of (i) the EP member of the ULB-028 patent family, for the optimisation of the manufacturing process of PREOB and (ii) the BPBONE-001 and BPBONE-002 patent families, for the optimisation of the manufacturing process of JTA products for the treatment of osteoarthritis (see Section 6.8, "Material agreements" and Section 6.11, "Grants and subsidies"). Pursuant to these agreements, SCTS owns the results of these research programmes and has the right to decide, together with the Company, to exploit these results. The Company acts as a guarantor for SCTS under these agreements.

#### 1.1.7 Financial risk factors

1.1.7.1 The Company has a history of operating losses and an accumulated deficit and may never become profitable.

The Company is still in early stages of developing its product candidates and has not completed development of any product. The Company does not anticipate generating revenue from sales for the foreseeable future. It has incurred significant losses since its incorporation in 2006. Under IFRS, net loss for the period ended 31 December 2013 was  $\[mathebox{\ensuremath{\ensuremath{\mathbb{C}}} 15,860,000.}$  On 30 September 2014, the Company had an accumulated deficit of  $\[mathebox{\ensuremath{\ensuremath{\mathbb{C}}} 19,757,000.}$  These losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of its product candidates as well as costs incurred for research programs and from

general and administrative expenses, and may result in the Company incurring further significant losses for several years. These losses, among other things, will continue to cause the Company's working capital and the shareholders' equity to decrease. There can be no assurance that the Company will earn revenues or achieve profitability, which could impair the Company's ability to sustain operations or obtain any required additional funding. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. It is likely that the Company may experience fluctuating revenues, operating results and cash flows. As a result, period to period comparisons of financial results are not necessarily meaningful and results of operations in prior periods should not be relied upon as an indication of future performance. For several years, the accumulated consolidated losses of the Company will increase due to the significant cost of Phase III trials (see Section 8.3.1 "Other operating income"). This will result in an increase in the additional resources necessary for its activities.

1.1.7.2 The Company may need substantial additional funding which may not be available on acceptable terms when needed, if at all.

The Company may require additional funding in the future to sufficiently finance its operations and to take advantage of new business opportunities.

The Company's future financing needs will depend on many factors, including the progress, costs and timing of its research and development activities, the clinical trials, the costs and timing of obtaining regulatory approval, the costs of obtaining, maintaining and enforcing its patents and other intellectual property rights, the costs and timing of maintaining or obtaining manufacturing for its products and product candidates, the costs and timing of establishing sales and marketing capabilities and the terms and timing of establishing collaborations, licence agreements and other partnerships. The Company does not expect its existing capital resources and the net proceeds from this Offering to be sufficient to enable the Company to fund the completion of all its current clinical trials through commercialisation. Accordingly, the Company expects it will need to raise additional funds.

The Company's ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which it may have no or limited control, and the Company cannot guarantee that additional funds will be available to it when necessary on commercially acceptable terms, if at all. In addition to non-dilutive financing and grants from the Walloon Region, the Company currently relies on equity financing for additional funding. Changes in regional financing and grant policies, a shift in regional investment priorities or challenges by the European instances may reduce or jeopardise the Company's ability to obtain or retain non-dilutive financing, grants and/or other benefits. For instance, the European Commission has opened a state aid investigation to determine whether the Belgian exemption to pay professional withholding tax on part of the remuneration paid to scientific personnel qualifies as unlawful state aid. The Company has benefitted from this exemption since its introduction. If the European Commission decides that the exemption constitutes unlawful state aid, the Company may be requested to repay all unlawfully received benefits (plus interests) to the Belgian State. Also, future growth of the Company, whether or not including geographical expansion, could limit the Company's eligibility to obtain similar non-dilutive financing or grants.

If the necessary funds are not available, the Company may need to seek funds through collaborations and licensing arrangements, which may require it to reduce or relinquish significant rights to its research programmes and product candidates, to grant licences on its technologies to partners or third parties or enter into new collaboration agreements, the terms could be less favourable to the Company than those it might have obtained in a different context. If adequate funds are not available on commercially acceptable terms when needed, the Company may be forced to delay, reduce or terminate the development or commercialisation of all or part of its product candidates or it may be unable to take advantage of future business opportunities.

#### 1.1.7.3 Fluctuation in interest rates could affect the Group's results and financial position

The Company, in particular its affiliate SCTS, is exposed to interest rate risk. Although interest rate risk arising from the EURIBOR-linked interest rate under SCTS's long term loans may be hedged through the use of financial risk management instruments, fluctuations in interest rate may nonetheless significantly affect its interest expenses.

#### 1.2 Risk Factors related to the Offered Shares and the Offering

1.2.1 There may not be a very active public market for the Company's shares, which may cause the shares to trade at a discount to the Offer Price, which may limit the number of shares available for sale or

## which can negatively impact the market price of the shares when a substantial numbers of shares is sold

Prior to the Offering, there has been no public market for the Company's shares in Belgium, France or elsewhere and an active public market may not develop or be sustained after the Offering. The Offer Price will be determined on the basis of a book building procedure in which only Institutional Investors can participate. 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 the Company's actual financial performance. Although the Company has requested admission of its shares to trading on the regulated markets of Euronext Brussels and Euronext Paris, it is not possible to guarantee the existence of a liquid market for its shares or that such a market, if it is developed, will last. If a liquid market for Company shares does not develop or does not last, the market price of its shares could be affected.

#### 1.2.2 The market price of the shares may fluctuate widely in response to various factors

A number of factors may significantly affect the market price of the shares including changes in the operating results of the Company and its competitors, divergence in financial results from stock market expectations, changes in earnings estimates by analysts, changes in estimates in relation to the duration or success of the Company's clinical trials, changes in the general conditions in the pharmaceutical industry and general economic, financial market and business conditions in the countries in which the Company operates.

In addition, stock markets have from time to time experienced extreme price and volume volatility which, in addition to general economic, financial and political conditions, could affect the market price for the shares regardless of the operating results or financial condition of the Company.

#### 1.2.3 Minimum amount for the Offering set at € 17.5 million

The Company has a right to proceed with a capital increase in a reduced amount. The minimum amount set for the Offering is  $\in$  17.5 million, below which the Offering will not proceed. The actual number of Offered Shares subscribed for or sold will be confirmed on the Company's website and by press release together with the Offer Price. Therefore, (a) only a reduced number of Offered Shares could be available for trading on the market which could limit the liquidity of the Company's shares, and (b) the Company's financial means in view of the uses of proceeds as described in Section 3 "Use of proceeds" might be reduced. The Company might therefore reduce its level of investment or look for further external funding.

# 1.2.4 Future issuances of shares or warrants may affect the market price of the shares and could dilute the interests of existing shareholders

It is expected that the proceeds of the Offering will not be sufficient to finalise the current Phase III clinical trials of the Company for the treatment of osteonecrosis and non-union fractures.

Therefore, the Company may decide to raise capital in the future through public or private offering of equity securities, convertible debt or rights to acquire these securities. The Company may decide to exclude or limit the preferential subscription rights pertaining attached to the then outstanding securities in accordance with applicable law. If the Company raises significant amounts of capital by these or other means, it could cause dilution for the holders of its securities and could have a negative impact on the share price, earnings per share and net asset value per share.

Also, the dilution resulting from issue and exercise of new warrants could adversely affect the price of shares.

#### 1.2.5 Holders of the shares outside Belgium and France may not be able to exercise pre-emption rights

In the event of an increase in the share capital of the Company in cash, holders of shares and other voting securities are generally entitled to preferential subscription rights (unless these rights are excluded or limited by either a resolution of the shareholders' meeting or a resolution by the meeting of Board of Directors). Certain holders of shares outside Belgium or France may not be able to exercise pre-emption rights unless local securities laws have been complied with. In particular, US holders of the shares may not be able to exercise preferential subscription rights unless a registration statement under the Securities Act is declared effective with respect to the shares issuable upon exercise of such rights or an exemption form the registration requirements is available. The Company does not intend to obtain a registration statement in the USA or to fulfil any requirement in other jurisdictions (other than in Belgium and France) in order to allow shareholders in such jurisdictions to exercise their preferential subscription rights (to the extent not excluded or limited).

#### 1.2.6 Limited shares available for sale in the market

As set out in Section 15.10.1 "Lock-up arrangements", the number of shares that are available for sale in the public market following the admission to listing of the Company's shares will be limited by several arrangements further described in the aforementioned Section of this Prospectus. Pending such arrangements, the liquidity of the shares trading on the regulated markets of Euronext Brussels and Euronext Paris may be limited and this may cause the Company's share price to be volatile.

# 1.2.7 The market price of the shares could be negatively impacted by sales of substantial numbers of shares in the public markets

Upon termination of such arrangements, sales of shares that were previously subject to transfer restrictions could cause to decrease the Company's share price. The current restrictions on transfers of shares by shareholders and the Company as described in Section 15.10.1 "Lock-up arrangements" allow to limit sudden, unorganised sales of large numbers of the Company's shares by existing shareholders during a term following the start of the Company's Offering. However, no guarantee can be given that there are no such large, unorganised sales by other shareholders prior to the end of such term, or that there are such large, unorganised sales by existing significant shareholders after such term. Any such large, unorganised sale of shares could have an adverse effect on the Company's share price.

#### 1.2.8 The Company does not intend to pay dividends for the foreseeable future

The Company does not anticipate paying dividends for the foreseeable future. Payment of future dividends to shareholders will be subject to a decision by the shareholders' meeting or the Board of Directors of the Company and subject to legal restrictions pursuant to Belgian corporate law. Furthermore, financial restrictions and other limitations may be included in current or future credit and subsidy agreements.

# 1.2.9 Certain significant shareholders of the Company after the Offering may have different interests from the Company and may be able to control the Company, including the outcome of shareholder votes

Following the completion of the Offering and listing of its shares, the Company will have a number of significant shareholders. For an overview of the Company's current significant shareholders reference is made to Section 5 "Dilution".

Currently, the Company is not aware that any of its current shareholders have entered or will enter into a shareholders' agreement with respect to the exercise of their voting rights in the Company after the completion of the Offering. Nevertheless, they could, alone or together, have the ability to elect or dismiss directors, and, depending on how broadly the Company's other shares are held, take certain other shareholders' decisions that require, or require more than, 50%, 75% or 80% of the votes of the shareholders that are present or represented at 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, or require more than, 50%, 75% or 80% of the votes of the shareholders that are present or represented at shareholders' meetings were such decisions are submitted to voting by the shareholders. Any such voting by the shareholders may not be in accordance with the interests of the Company or the other shareholders of the Company.

#### 1.2.10 Any sale, purchase or exchange of the shares may become subject to the Financial Transaction Tax

On 14 February 2014, the EU Commission adopted a proposal for a Council Directive (the "**Draft Directive**") on a common financial transaction tax (the "**FTT**"). The intention is for the FTT to be implemented through an enhanced cooperation procedure in 11 member states (Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Spain, Slovakia and Slovenia, together the "**Participating Member States**").

Pursuant to the Draft Directive, the FTT will be payable on financial transactions, provided (a) at least one party to the financial transaction is established or deemed established in a Participating Member State, and (b) there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transactions, or is acting in the name of a party to the transaction. The FTT will however not apply to (*inter alia*) primary market transactions referred to in Article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue.

The rates of the FTT will be fixed by each Participating Member State, but will amount to at least 0.1% of the taxable amount for transactions involving financial instruments other than derivatives. The taxable amount for such transactions will in general be determined by reference to the consideration paid or owed in return for the

transfer. The FTT will be payable by each financial institution established or deemed established in a Participating Member State which is either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction has been carried out on its account. When the FTT due was not paid within the applicable time limits, each party to a financial transaction, including persons other than financial institutions, will become jointly and severally liable for the payment of the FTT due.

Investors should therefore in particular note that, following implementation, any sale, purchase or exchange of shares will be subject to the FTT at a minimum rate of 0.1%, provided that the abovementioned criteria are met. The investor may be liable to pay this charge or reimburse a financial institution for the charge, and/or the charge may affect the value of the shares. The issuance of new shares should not be subject to the FTT.

A statement made by the Participating Member States (other than Slovenia) indicated that a progressive implementation of the FTT is being considered and that the FTT may initially only apply to transactions involving shares and certain derivatives, with implementation occurring by 1 January 2016. Full details are however not available.

The Draft Directive remains subject to negotiations between the Participating Member States and may therefore be changed at any time. Moreover, once the Draft Directive has been adopted (the "FTT Directive"), it will need to be implemented into the respective domestic laws of the Participating Member States, whereby the domestic provisions implementing the FTT Directive could deviate from the FTT Directive itself.

Investors should consult their own tax advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of shares in the Company.

### 2 Important information

#### 2.1 General and responsibility statement

#### 2.1.1 Proportionate disclosure

This Prospectus relates to a public offering and an application for the admission to trading on a regulated market of shares by an issuer which qualifies as SME and, as a result, the level of disclosure of this Prospectus is proportionate to this type of transaction in accordance with Annex XXV of the Prospectus Regulation.

#### 2.1.2 Responsibility for the content of the Prospectus

In accordance with Article 61, §1 and 2 of the Belgian Act of June 16, 2006 on the public offering of securities and the admission of securities to trading on a regulated market (*Loi relative aux offres publiques d'instruments de placement à la négociation sur des marchés réglementés*) (the "**Prospectus Act**"), the Company, with registered office at rue Adrienne Bolland 8, 6041 Gosselies (Charleroi), Belgium, represented by its Board of Directors, assumes responsibility for the completeness and accuracy of the content of the Prospectus. The Company declares that, having taken all reasonable care to ensure that such is the case, the information contained in this Prospectus is, to its knowledge, in accordance with the facts and contains no omission which would affect its import.

Neither the Joint Bookrunners, nor their affiliates nor any person acting on their behalf is responsible for, nor is any of them making any representation or warranty, express or implied, concerning the Company, its past or future performance or the completeness or accuracy of this Prospectus and any supplement thereto.

#### 2.1.3 Decision to invest

In making an investment decision, investors must rely on their own examination of the Company and the terms of the Offering, including the merits and risks involved as described in this Prospectus. Investors should rely only on the information included in this Prospectus. Neither the Company nor the Joint Bookrunners have authorised any other person to provide investors with different information. If anyone provides different or inconsistent information, it should not be relied upon. The information contained in this Prospectus is provided as of the date shown on the front cover of this Prospectus only. The Company's business, financial condition, results of operations and the information set forth in this Prospectus may have changed since that date.

In accordance with Belgian law, every significant new factor, material mistake or inaccuracy relating to the information included in this Prospectus which is capable of affecting the assessment of the Offered Shares and which arises or is noted between the time when this Prospectus is approved and the completion of the Offering, or as the case may be, the time when trading of the Offered Shares on the relevant market begins, whichever occurs later, will be mentioned in a supplement to this Prospectus. Investors who have already agreed to subscribe to 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 acceptances, provided that the new factor, mistake or inaccuracy referred to above arose before the completion of the Offering and the delivery of the Offered Shares. The supplement is subject to approval by the Belgian Financial Services and Markets Authority (*Autorité des services et marchés financiers*, the "FSMA") and will, following such approval, be notified to the French Financial Markets Authority (*Autorité des Marchés Financiers*, the "AMF") in accordance with the European passport system provided by the Prospectus Directive, in the same manner as this Prospectus and must be made public in the same manner as this Prospectus.

The Joint Bookrunners and their affiliates are acting exclusively for the Company and no one else in connection with the Offering, and will not be responsible to any other person for providing the protections afforded to their client or for providing any advice in relation to the Offering.

None of the information in this Prospectus should be considered investment, legal or tax advice. Investors should consult their own counsel, accountant, expert and other advisors for legal, tax, business, financial and related advice regarding purchasing the Offered Shares. Neither the Company nor the Joint Bookrunners make any representation to any offeree or purchaser regarding the legality of an investment in the Offered Shares by such offeree or purchaser under applicable investment or similar laws or regulations.

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 in the Offering. It contains selected and summarised information, does not express any commitment or acknowledgement of waiver and does not create

any right expressed or implied toward anyone other than a potential investor. It cannot be used except in connection with the Offering. The content of this Prospectus is not to be construed as an interpretation of the rights and obligations of the Company, of the market practices or of agreements entered into by the Company.

#### 2.2 Approval of the Prospectus

The FSMA approved the English version of this Prospectus on 20 January 2015 in accordance with Article 23 of the Prospectus Act. The FSMA's approval does not imply any judgment on the merits or quality of the Offering, the Offered Shares or the Company.

On 20 January 2015, the FSMA notified this Prospectus to the AMF in accordance with the European passport mechanism provided for in the Prospectus Directive. The AMF has passported this Prospectus on or around 21 January 2015. This passport does not imply any judgement by the AMF on the merits or quality of the Offering, the Offered Shares or the Company.

This Prospectus has been prepared and approved in English language and has been translated in French language. The summary has been prepared and approved in English language and has been translated in French language and in Dutch language. The Company is responsible for verifying the consistency between the language versions of the Prospectus and the summary. The English version of this Prospectus is legally binding.

The Offering and this Prospectus have not been submitted for approval to any supervisory body or governmental authority outside Belgium and France.

#### 2.3 Notice to investors

#### 2.3.1 Notice to investors in the United States

The Offered Shares may not be offered or sold in the United States unless pursuant to registration under the Securities Act or an applicable exemption from such registration. The Offered Shares have not been and will not be registered under the Securities Act, or with any securities regulatory authority of any state or other jurisdiction in the United States, and may not be offered, sold, pledged or otherwise transferred except pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and in compliance with any applicable state securities laws.

The Offered Shares have not been approved or disapproved by the U.S. Securities and Exchange Commission, any state securities commission in the United States or any other United States regulatory authority, nor have any of the foregoing authorities passed upon or endorsed the merits of the Offering or the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offence in the United States.

#### 2.3.2 Notice to investors in France

For the purpose of the offer to the public in France, the Company notified this Prospectus to the AMF in accordance with the European passport mechanism provided for by the Prospectus Directive. The notification to the AMF does not imply any judgement by the AMF on the merits or quality of the Offering, the Offered Shares or the Company.

#### 2.3.3 Notice to investors in the EEA

This Prospectus has been prepared on the basis that all offers of Offered Shares (other than offers contemplated in this Prospectus in Belgium and France once this Prospectus has been approved by the FSMA, passported in France and published in accordance with the Prospectus Directive (2003/71/EC)) will be made pursuant to an exemption under the Prospectus Directive, as implemented in members states of the European Economic Area ("EEA"), from the requirement to produce a prospectus for offers of securities.

Accordingly, any person making or intending to make any offer within the EEA of Offered Shares (outside Belgium and France) should only do so in circumstances in which no obligation arises for the Company or the Joint Bookrunners to produce a prospectus for such offer. None of the Company or the Joint Bookrunners has authorised or do authorise the making of any offer of the Offered Shares through any financial intermediary, other than offers made through the Joint Bookrunners which constitute the final placement of Offered Shares contemplated herein.

In relation to each Member State of the EEA which has implemented the Prospectus Directive (each, a "**Relevant Member State**") an offer to the public of Offered Shares contemplated by this Prospectus may not be made in that Relevant Member State unless this Prospectus has been approved by the competent authority in

such Relevant Member State and published in accordance with the Prospectus Directive as implemented in such Relevant Member State (which approval is only obtained and performed in relation to the Offering in Belgium and in France), unless such offer in such Relevant Member State of any Offered Shares is made under the following exemptions under the Prospectus Directive, if and to the extent such exemptions have been implemented in that Relevant Member State:

- to qualified investors within the meaning of the law in that Relevant Member State implementing the Prospectus Directive;
- to fewer than 100 or, if the Relevant Member State has implemented the Directive 2010/73/EU amending the Prospectus Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the Joint Bookrunners for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of Offered Shares shall result in a requirement for the publication by the Company or the Joint Bookrunners of a prospectus pursuant to Article 3 of the Prospectus Directive. For the purposes of this representation, the expression an "offer to the public" in relation to any Offered Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the Offering and any Offered Shares to be offered so as to enable an investor to decide to purchase the Offered Shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression "Prospectus Directive" means Directive 2003/71/EC (and any amendments thereto, including the Directive 2010/73/EU amending the Prospectus Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State.

### 2.3.4 Notice to investors in the United Kingdom

This Prospectus is for distribution only to persons who (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the "Financial Promotion Order"), (ii) are persons falling within Article 49(2)(a) to (d) ("high net worth bodies corporate, unincorporated associations etc") of the Financial Promotion Order, (iii) are outside the United Kingdom, or (iv) persons to whom an invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as "Relevant Persons").

Any invitation, offer or agreement related to the purchase of Offered Shares may only be proposed or entered into with Relevant Persons. The Offered Shares may not be offered or issued in favour of persons located in the United Kingdom, with the exception of Relevant Persons. Any person other than a Relevant Person may not use or rely on this Prospectus or any information therein. The individuals responsible for the distribution of this Prospectus must comply with the legal terms applicable to the distribution of this Prospectus.

#### 2.3.5 Notice to investors in Switzerland

The Offered 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. This Prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under Article 652a of the Swiss Code of Obligations or Article 116+ of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under Art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. It is the responsibility of any person residing in Switzerland who wishes to take part in this Offering to ascertain that the legislation and formalities applicable in Switzerland are complied with.

#### 2.3.6 Notice to investors in Japan

None of the Offered Shares have been, and will not be, registered under the Financial Instruments and Exchange Law, as amended (the "**FIEL**"). This Prospectus is not an offer of securities for sale or subscription, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or entity organized under the laws of Japan) or to others for reoffer or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements under the FIEL and otherwise in compliance with such law and any other applicable laws, regulations and ministerial guidelines of Japan.

#### 2.3.7 Notice to prospective investors in Australia, Canada or South Africa

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

#### 2.4 Available information

#### 2.4.1 Prospectus

This Prospectus is available in English language and in French language and a summary in Dutch language. This Prospectus will be made available to investors, free of any charge, at the registered office of the Company, at rue Adrienne Bolland 8, 6041 Gosselies and can be obtained upon request by phone at +32 2 529 59 90. This Prospectus will also be made available to investors, free of any charge, at the branches of Banque Degroof. Subject to certain conditions (i.e. the acceptance of a disclaimer), this Prospectus is also available on the Company's website, <a href="www.bonetherapeutics.com">www.bonetherapeutics.com</a>. Subject to certain conditions, this Prospectus is also available on the internet at the following website: <a href="www.degroof.be">www.degroof.be</a>.

Posting this Prospectus and the summary on the internet does not constitute an offer to sell or a solicitation of an offer to purchase, and there will not be a sale of any of the Offered Shares in the United States or in any other jurisdiction in which such offer, solicitation or sale would be unlawful prior to its registration or qualification under the laws of such jurisdiction or to or for the benefit of any person to whom it is unlawful to make such offer, solicitation or sale. The electronic version may not be copied, made available or printed for distribution. Other information on the website of the Company or on any other website does not form part of this Prospectus.

#### 2.4.2 Company documents and other information

The Company must file its coordinated articles of association and all other deeds that are to be published in the Belgian Official Gazette with the clerk's office of the commercial court of Charleroi (Belgium), where they are available to the public. A copy of the most recently coordinated articles of association and of the Company's corporate governance charter is also available on the Company's website (<a href="www.bonetherapeutics.com">www.bonetherapeutics.com</a>) as from the Closing Date.

In accordance with Belgian law, the Company must annually prepare audited statutory financial statements. The statutory financial statements and the reports of the Board of Directors and of the statutory auditor relating thereto are filed with the National Bank of Belgium, where they are available to the public.

Furthermore, as a listed company, the Company must publish its statutory financial statements and semi-annual interim financial statements (in the form as provided by the Belgian Royal Decree of 14 November 2007 relating to the obligations of issuers of financial instruments admitted to trading on a Belgian regulated market (as amended from time to time) ("Arrêté royal relatif aux obligations des émetteurs d'instruments financiers admis à la négociation sur un marché réglementé"). Copies will be available on the Company's website (www.bonetherapeutics.eu).

The Company will also have to disclose price sensitive information, information about its shareholders' structure and certain other information to the public. In accordance with the Belgian Royal Decree of 14 November 2007, such information and documentation will be made available through press releases, the Company's website, the communication channels of Euronext Brussels and Euronext Paris or a combination of these media.

### 2.4.3 Presentation of financial and other information

The Prospectus includes extracts of the audited consolidated financial statements of the Company for the financial years ended on 31 December 2012 and 31 December 2013 prepared in accordance with IFRS as adopted by the European Union. The aforementioned consolidated financial statements (as prepared under IFRS) were audited by the statutory auditor of the Company. The statutory auditor have rendered an unqualified auditor's report on the aforementioned consolidated financial statements and have given, and not withdrawn, their written consent to the inclusion of their auditor's reports in relation thereto and the references to themselves herein in the form and context in which they are included.

The interim condensed consolidated financial statements for the 9-month period ended 30 September 2014 in accordance with IFRS as adopted by the European Union included herein have been reviewed by the statutory auditor as described in his review report included in this Prospectus. The statutory auditor of the Company has

reviewed the comparative financial numbers for the 9-month period ended 30 September 2013 as included in the IFRS interim condensed financial statements. The statutory auditor of the Company has rendered an unqualified limited review opinion report on the aforementioned interim condensed consolidated financial statements for the 9-month period ended 30 September 2014 and for the 9-month period ended 30 September 2013 and has given, and not withdrawn, their written consent to the inclusion of their auditor's reports in relation thereto and the references to themselves herein in the form and context in which they are included.

The reports referred to in this paragraph are set out under Annex C.

In this Prospectus, references to "€" are to the currency of the Member States participating in the European Monetary Union. Some numerical figures included in this Prospectus have been subject to rounding adjustments. Accordingly, numerical figures shown as totals in certain tables may not be an exact arithmetic aggregation of the figures that precede them.

### 2.5 Market and industry information and information derived from third parties

Information relating to markets and other industry data pertaining to the Company's business included in this Prospectus has been obtained from internal surveys, scientific publications and publicly available information. The main sources for industry information were peer-reviewed publications, sector association studies and government statistics. The Company accepts responsibility for having correctly reproduced information obtained from publications or public sources, and, in so far as the Company is aware and has been able to ascertain from information published by those industry publications or public sources, no facts have been omitted which would render the reproduced information inaccurate or misleading. However, the Company has not independently verified information obtained from industry and public sources. Certain other information in this Prospectus regarding the industry reflects the Company's best estimates based upon information obtained from industry and public sources. Information from the Company's internal estimates and surveys has not been verified by any independent sources.

### 2.6 Forward looking statements

Certain statements in this Prospectus are not historical facts and are forward-looking statements. From time to time, the Company may make written or oral forward-looking statements in reports to shareholders and in other communications. Forward-looking statements include statements concerning the Company's plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditure, research and development, financing needs, plans or intentions relating to partnership or acquisitions, competitive strengths and weaknesses, business strategy and the trends which the Company anticipates in the industries and the political, economic, financial, social and legal environment in which it operates and other information that is not historical information.

Words such as "believe", "anticipate", "estimate", "expect", "intend", "predict", "project", "could", "may", "will", "plan" and similar expressions are intended to identify forward-looking statements, but are not the exclusive means of identifying such statements.

By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, and risks exist that the predictions, forecasts, projections and other forward-looking statements will not be achieved. These risks, uncertainties and other factors include, amongst other things, those listed under Section 1 "Risk Factors".

# 3 Use of proceeds

In case of full subscription of the Offering at the mid-range of the Offer Price Range, the gross proceeds from the issuance of New shares will amount to  $\in$  27.1 million. If the Increase Option is exercised, the gross proceeds, at the mid-range of the Offer Price Range, will amount to  $\in$  31.2 million. If the Global Coordinator exercises the Over-allotment Option in full, the gross proceeds, at the mid-range of the Offer Price Range, shall be further increased to  $\in$  35.9 million. An estimate of the costs and expenses of the Offering is listed in Section 15.6 "Costs and remuneration of intermediaries".

Save for (i) the fees payable to the Joint Bookrunners (upon entering into the Underwriting Agreement with the Company, which is expected to occur prior to completion of the Offering, and subject to the terms and conditions thereof (see Section 15.6 "Costs and remuneration of intermediaries", (ii) the conversion of the Bonds upon completion of the Offering (See Section 9.4.3 "Automatically convertible bonds") and (iii) a bonus payment to and the vesting or exercisability of certain warrants held by members of the Management Team (see Section 10.9.2 "Securities held by members of the Management Team"), so far as the Company is aware, no person involved in the Offering has an interest that could be material to the Offering.

The minimum amount of the Offering is set at € 17.5 million.

This Offering has the main purpose to support and accelerate the development of the Company and facilitate future financing by establishing a public market for the shares of the Company and by providing an access to capital markets.

The Company intends to use the net proceeds from the Offering (net of fees and expenses to be paid by the Company) over a time horizon from 2015 to 2017 for the following purposes:

- To proceed on on-going European clinical trials with 2 pivotal Phase III (including the acceleration of patient enrolment) and 3 Phase I/II trials (approximately 65% of net proceeds).
  - Two Phase III
    - Further patient enrolment of the Phase III osteonecrosis trial (PREOB®) with completion of the interim analysis (estimated, on the basis of currently available information, during the second half of 2016) and including an acceleration of the patient enrolment program
    - Completion, or near completion, of patient enrolment of the Phase III non-union trial (PREOB®) including an acceleration of the patient enrolment program (estimated, on the basis of currently available information, by the end of 2017)
  - Three Phase I/II
    - Completion of the Phase IIA osteoporosis trial (PREOB®) (estimated, on the basis of currently available information, by the end of 2017)
    - Completion of the Phase I/IIA delayed union trial (ALLOB®) (estimated, on the basis of currently available information, during the first half of 2017) and preparation of the Phase IIB or Phase III trial
    - Completion of the spine fusion Phase IIA trial (ALLOB®) (estimated, on the basis of currently available information, during the first half of 2017) and preparation of the Phase IIB or Phase III trial.
- To launch clinical trials in the US (approximately 15% of net proceeds):
  - the Phase III for osteonecrosis (estimated, on the basis of currently available information, around the second half of 2016)
  - the Phase III for non-union (estimated, on the basis of currently available information, around the second half of 2016)
- To finance general corporate purposes (approximately 15% of net proceeds).
- To optimize production in order to reduce cost of goods sold and to allow an increase in production capacity at the existing site (approximately 5% of net proceeds).

The net requirement in cash is expected to amount to approximately  $\in$  9.0 million in 2015. The annual expenditure is further expected to increase in the following years, amongst others due to setting up and

conducting clinical trials in the US for which the approach has yet to be defined and for which a partner has to be identified. The Company has in its projections not taken into consideration yet any income from partnering activities which could positively impact the cash burn in the future

At the date of this Prospectus, the Company cannot predict with certainty all of the particular uses of the net proceeds of the Offering, or the amounts that will effectively be allocated to the above projects.

In the event the gross proceeds do not reach the targeted amount, the Company will allocate the net proceeds in priority to ongoing European clinical trials as described above.

The Board of Directors and Management of the Company have the discretion to set the amounts and timing of expenditures, which will be based on many factors, including all conditions that may be imposed by regulatory authorities to the Company, the progress of its clinical trials, the research of potential partnerships, strategic collaborations and all resulting funding, such as the existence of candidates for the licensing or acquisition, the net proceeds of the Offering, all received grants or subsidies, and the costs and operating expenses of the Company. Consequently, the management of the Company will have flexibility in allocating the net proceeds of the Offering.

Depending on the use to be made of the actual proceeds of the Offering, as described before, or elsewhere, the Company intends to invest the net proceeds in risk-free short-term securities and interest-bearing investment grade and other money market instruments.

# 4 Capitalisation, indebtedness and working capital

### 4.1 Capitalisation and indebtedness

The following table sets forth the capitalization and indebtedness of the Company as of 30 September 2014. The non-audited figures for capitalization and indebtedness have been extracted, without material adjustment, from the Company's reviewed interim condensed consolidated financial statements prepared in accordance with IFRS, as of and for the nine months period ended 30 September 2014. In order to update the indebtedness position presented for the period ending 30 September 2014, the Company has added information on all significant movements related to the fourth quarter of 2014 to present an estimated updated situation at 31 December 2014. The information on significant changes is unaudited numbers. As the Company does not have set-up the consolidated financial statements for the period ending 31 December 2014, the Result for the period as shown for the period ending 30 September 2014, has not been further updated. As the other elements included in the Capitalization position have not been subject to any change, the position presented for the period ending 30 September 2014 has not been modified.

This information presented as of 30 September 2014 should be read in conjunction with the reviewed interim condensed consolidated financial statements as of and for the nine months period ended 30 September 2014 and the related notes thereto.

(€'000) - Capitalization	As of 30 September 2014	significant movements during Q4*	reference	updated situation as per 31 December 2014 **
Shareholder's Equity - Capitalization	-1,811			PM
Share capital	10,466			10,466
Share premium	7,480			7,480
Share-based payments	0			0
Retained earnings	-15,860			-15,860
Result of the period	-3,897	PM		PM

Indebtedness	As of 30 September 2014	significant movements during Q4*	reference	updated situation as per 31 December 2014 **
Total Current financial receivables	6,660	445		7,105
receivables related to forgivable loans and grants	3,752	445	(1)	4,197
receivable related to GIE	2,908	0		2,908
Total Current financial debt	3,340	9,530		12,870
Secured	2,898	0		2,898
bank loans	2,858	0	(2)	2,858
finance lease liabilities	40	0		40
Unsecured	442	0		442
government loans	314	0		314
loans from related parties	128	0		128
convertible bonds held < 1Yr	0	9,530	(3)	9,530

Total Non-Current financial debt	6,570	767		7,337
Secured	97	0		97
finance lease liabilities	97	0		97
Unsecured	6,473	767		7,240
government loans	3,537	767	(4)	4,304
loans from related parties	1,448	0		1,448
put on non-controlling interest	1,488	0		1,488
Cash and Cash Equivalent	1,735	9,779	(5)	11,514
Net Current Financial Indebtedness	-5,055	-694		-5,749
Net Non Current financial indebtedness	6,570	767		7,337
Net Financial Indebtedness (Cash)	1,515	73		1,588

During the fourth quarter of 2014, the following significant transactions (\*) took place impacting the situation as set forth in the above mentioned table resulting in an updated (unaudited) situation as per 31 December 2014 (\*\*).

- Current financial receivables and in particular government loans were impacted with a net amount of  $\in 0.45$  million. The Company obtained new forgivable loans ("avances récupérables") from the Walloon Region for an amount of  $\in 2.56$  million ( $\in 1.88$  million through Bone Therapeutics and  $\in 0.68$  million through SCTS). In addition the Company obtained  $\in 0.68$  million related to new subsidies granted by the Walloon Region. In respect of those new subsidies and forgivable loans, the Company received in cash an amount of  $\in 1.60$  million on account of Bone Therapeutics and  $\in 0.41$  million on account of SCTS as upfront payments. Furthermore the Company received also an amount of  $\in 0.79$  million in relation to existing forgivable loans. In total this resulted in a reduction of the outstanding amount receivable during the second quarter of  $\in 2.79$  million.
- (2) For the caption current financial debt bank loans, on a net basis, no significant change took place, and therefore the balance as per 31 December 2014 remains unchanged compared to the position as per 30 September 2014. Note however that significant movements are to be reported. The Company withdrew an additional amount of € 1,00 million from the straight loan facility provided by BNP Paribas Fortis SA during the fourth quarter of 2014 before repaying the entire amount from the straight loan facility, being € 1,500,000 at 31 December 2014. Besides, the straight loan facilities provided by BNP Paribas Fortis SA/NV and ING Belgique SA/NV to SCTS were fully used by the end of December 2014. SCTS drew an additional amount of € 500,000 after September 2014 on this facility. As such, the net impact on the current financial debt bank loans, as per 31 December 2014, remains unchanged.
- (3) On 18 December 2014, the Company issued automatically convertible bonds for an amount of € 10.0 million at the occasion of the extraordinary shareholder's meeting. The bond issue was fully subscribed and paid. The bonds will be converted upon completion of the Offering or at a later point in time (30 September 2015) in case no IPO takes place before this date. As such, these bonds are to be presented under current financial debt. Taking into consideration the cost of the operation, which amounted to € 0.47 million, the net debt to be reported amounts to € 9.53 million.
- (4) Non-current government loans have increased with € 0.77 million representing the 30% non-turnover depending refundable part of the amount granted as new "avances récupérables" during the period representing a total of € 2.56 million.
- Finally, the consolidated cash position of the Company increased from  $\in$  1.74 million at 30 September 2014 to  $\in$  11.51 million at 31 December 2014. This increase is mainly a result of the above mentioned transactions being, on one hand, the gross proceeds linked to the issue of convertible bonds for an amount of  $\in$  10.00 million, the receipt of payments related to forgivable loans and subsidies for a total amount of  $\in$  2.79 million and on the other hand, the use of cash for an amount of  $\in$  1.28 million related to the operational cash burn and other working capital movements.

# 4.2 Working capital statement

On the date of this Prospectus, the Company is of the opinion that, taking into account its available cash and cash equivalents on 30 September 2014 and the proceeds of the issue of bonds of 18 December 2014 and 8 January 2015 (in aggregate €10.35 million), it has sufficient working capital to cover the working capital needs for a period of at least 12 months as of the date of this Prospectus.

### 5 Dilution

### 5.1 Shareholders prior to the completion of the Offering

The table below provides an overview of the significant shareholders representing more than 5% of the Company's share capital prior to the completion of the Offering.

The Company has issued Bonds which convert automatically into shares upon completion of the Offering. The exact number of shares to be issued upon conversion of the Bonds is unknown at the date of this Prospectus as it will depend on the Offer Price. The number of Shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 166.5% of the nominal value of the Bonds, and the denominator is equal to the Offer Price (see Section 9.4.3 "Automatically convertible bonds"). The Bonds were subscribed by certain existing shareholders of the Company and by certain new investors. It is expected that two of these new investors will hold more than 5% of the shares following conversion of the Bonds, i.e. SFPI SA and Sofipôle SA, which have each subscribed to 2,500 Bonds.

The overview must be read together with the notes referred to below.

Share- / Warrant- / Bondholder	Number of shares	%	Warrants in number of shares	%	Total number of shares and warrants (in number of shares)	%	Number of convertible bonds <sup>(1)</sup>
Jacques Reymann	538,382	15.57	-	-	538,382	14.31	50
Theodorus II SA	401,610	11.61	-	-	401,610	10.67	-
S.R.I.W. SA	349,531	10.11	-	-	349,531	9.29	-
Christian Boon Falleur	218,834	6.33	-	-	218,834	5.82	100
Enrico Bastianelli	110,820	3.20	100,000	2.66	210,820	5.60	
Sambrinvest Spin- off/Spin-out SA	191,260	5.53	-	-	191,260	5.08	-
JJ Verdickt & Consorts	175,107	5.06	-	-	175,107	4.65	50
Other shareholders	1,472,696	42.59	204,760(2)	5.44	1,677,456	44.58	975
SFPI SA	-	-	-	-	-	-	2,500
Sofipôle SA	-	-	-	-	-	-	2,500
Other bondholders	-	-	-	-	-	-	4,175
Total	3,458,240	100	304,760(3)	100	3,763,000	100	10,350

Notes:

An overview of the shares, warrants and convertible bonds held by the directors, respectively the Management Team, is provided in Section 10.9.1, "Securities held by directors", respectively Section 10.9.2, "Securities held by members of the Management Team".

<sup>(1)</sup> Each convertible bond has been issued with an anti-dilutive warrant attached to it. These anti-dilutive warrants expire lapse upon completion of the Offering and become void. In the event the Offering is not completed, the anti-dilution warrant continue to have effect to protect the holders thereof against a possible down round private placement of the Company.

<sup>(2) 59,800</sup> of the 204,760 Warrants issued have been granted to executive directors of the Company (Wim Goemaere and Guy Heynen), who are at present not a shareholder of the Company.

<sup>(3)</sup> Total amount of Warrants issued by the Company.

## 5.2 Dilution following the completion of the Offering and listing of the Shares

The dilution resulting from the completion of the Offering will depend on the size of the Offering and the amount of the Offer Price.

Assuming a full placement of the Offered Shares, the average dilution of the current shareholders would amount to 40.10%.

Also, the conversion of the Bonds upon completion of the Offering (see Section 9.4.3 "Automatically convertible bonds") will further dilute the current shareholders. The number of Shares to be issued upon conversion of the Bonds will depend on the Offer Price.

- If the Offer Price is set at the lower end of the Offer Price Range, 1,188,465 Shares will be issued upon conversion of the Bonds.
- If the Offer Price is set at the higher end of the Offer Price Range, 1,044,409 Shares will be issued upon conversion of the Bonds.

# 6 Business description

### 6.1 Introduction

#### 6.1.1 Brief description

The Company is a biotechnology company with an advanced clinical pipeline of cell products for bone fracture repair and fracture prevention (two Phase III and three Phase II). These areas are characterized by high unmet medical needs due to the lack of efficacious and safe, non-invasive, treatments and by limited competition<sup>2</sup>, despite large markets (see Section 6.3 "The high unmet medical needs for bone disorders"). Indeed, the current standard-of-care involves heavy surgery and long recovery periods. The Company is creating a new and unique treatment approach using differentiated bone-forming cells (i.e., osteoblasts) administered via a minimally invasive percutaneous procedure, expected to offer significant benefits over the current standard-of-care.

Solid preclinical foundations and clinical results support its research and development programs. The Company has extensive knowledge of bone physiology and pathophysiology and collaborates closely with prestigious academic and medical institutions. The Company has worldwide exclusive rights for a series of patents and technologies related to bone cell products, production methods and their applications (see Section 6.12, "Intellectual property").

Until 30 September 2014, the Company has raised  $\in$  19.3 million in equity, through (i) a direct investment of  $\in$  18 million in Bone Therapeutics SA (see the condensed consolidated statement of the financial position at 30 September 2014 – Annex C – Financial information) and (ii) an investment of  $\in$  1.3 million in invested cash through the non-controlling interest held by third parties in its affiliate SCTS SA (shown as other non-current liabilities, as explained in Annex C – note 5.10 – notes relating to the consolidated financial statements for the year ending 31 December 2013). Furthermore, after the reporting period ended 30 September 2014, the Company raised an amount of  $\in$  10.3 million in convertible bonds, to be converted in Shares upon the completion of the Offering (see note 9 – notes to the condensed consolidated statement of financial position at 30 September 2014 – Annex C – Financial information). In addition the Company secured an amount of  $\in$  20.4 million in non-dilutive funding, mainly through recoverable cash advances provided by the Walloon Region and to lesser extent through regular grants. In total,  $\in$  18.6 million was granted to Bone Therapeutics SA (of which  $\in$  6 million was still outstanding as per 30 September 2014 - see Section 6.11.1.1 "Recoverable cash advances" and Section 6.11.1.2 "Subsidies") and  $\in$  1.8 million was granted to SCTS SA (of which  $\in$  1.1 million was still outstanding as per 30 September 2014 - see Section 6.11.2.1 "Recoverable cash advances" and Section 6.11.2.2 "Subsidies").

#### 6.1.2 High unmet medical needs in bone fracture repair and fracture prevention

Bone is a naturally regenerative organ that, like skin, has the capacity to repair itself in healthy individuals. Bone comprises bone-forming cells (osteoblasts) and bone-resorbing cells (osteoclasts) ensuring a balance between bone formation and resorption. However, there are situations (traumatic or non-traumatic) in which bone loses its regenerative capacity. In some traumatic (i.e., severe bone fractures) or non-traumatic (i.e., degenerative bone diseases) situations, the regenerative capacity of bone is exceeded, leading to bone-related disorders. The bone field is characterized by a wide range of pathologies, from orthopaedic conditions such as severe fractures to inflammatory rheumatic diseases such as rheumatoid arthritis.

In the context of bone regenerative system failure, the Company has identified two segments with high unmet medical needs (i.e., a medical need that is not addressed adequately by an existing therapy<sup>3</sup>): fracture repair (post-fracture stage) and fracture prevention (pre-fracture stage). The relevant fracture repair and fracture prevention markets (including the osteoporosis market) represent a global market of around USD 34 billion and 42 million patients. The Company's products target about a third of these markets representing approximately 12 million patients in Europe, the USA and Japan, with limited competition<sup>4</sup> (See Section 6.3, "The high unmet medical needs for bone disorders").

<sup>-</sup>

<sup>&</sup>lt;sup>2</sup> Competition can be can be considered as limited if there are only a few (less than 5) competing clinical programs (as from phase I) with other products in the same indication; products at an early (preclinical) stage of development are not considered due to the very long development time of these products.

<sup>&</sup>lt;sup>3</sup> FDA Guidance for Industry – Available Therapy, July 2004.

<sup>&</sup>lt;sup>4</sup> Orthoworld, The Orthopaedic Industry Annual Report for 2013 (relating to fracture repair procedures and spine procedures) – Transparancy Market Research, Osteoporosis Drugs Market – Global Industry Analysis, Pipeline Analysis, Size, Share, Growth, Trends & Forecast, 2014-2020 (relating to treatment of osteoporosis patients).

These unmet medical needs exist (i) because most existing treatments are painful invasive surgical procedures, some of which, such as bone graft surgery in fracture repair or core decompression for osteonecrosis, dating back from the beginning of the 20th century and (ii) because as innovation has been lacking, there are only rare treatments in clinical development, whatever the types of treatment class (small molecules, biologicals or cell products).

Despite such high unmet needs, the Company faces limited competition from pharmaceutical, biopharmaceutical (including regenerative and cell therapy companies) and/or medical devices companies, as well as from research institutions.

	Indications CURRENT TREATMENT: LIMITATIONS AND LACK OF INNOVATION		CLINICAL PROGRAMS IN CELL THERAPY
	Non-Unions	Surgery; bone auto- or allograft	PREOB® Xcel-Mt- <u>Osteo</u> -Alpha ( <u>Xcelia,</u> Ph I/II)
REPAIR	Delayed-Unions	Wait & see situation	ALLOB®
	Spine Fusion	Surgery; bone auto- or allograft  InFuse® (Medtronic)	ALLOB®  Neofuse® (Mesoblast, Ph II)  Xcel-Mt-Osteo-Alpha (Xcelia, Ph I/II)
PREVENTION	Osteonecrosis	Surgery: core decompression THA*	PREOB®
PREVE	Osteoporosis	(No last-line)	PREOB®

Figure 1: The above diagram shows the existing treatments in the fields targeted by the Company, and the bone cell products in development by the Company which aim to introduce an alternative for the respective existing treatments.

In all its target indications besides spine fusion, the Company is the only clinical stage company developing bone cell products using differentiated bone cells for the treatment of orthopaedic conditions. In its target indications, the Company competes with the standard-of-care, introducing with its cell products breakthrough therapeutic alternative.

Competitors can be companies developing undifferentiated cell products in such fields targeted by the Company. In the field of non-union and delayed-union fractures, Wright Medical Technology (the US) and Novadip Biosciences (BE) are potential future competitors (their products are in clinical development) (See Section 6.3.1.1, "Non-Union and Delayed-Union").

In the spinal fusion market, Mesoblast, with its undifferentiated stem cell product combined with synthetic bone substitutes, is the main competitor. The other competitors known by the Company such as Theracell, Xcelia or Novadip Biosciences, all developing undifferentiated cell products, are preclinical or early clinical phase companies (See Section 6.3.1.2, "Spinal fusion and rescue spinal fusion").

Finally, in the field of osteonecrosis, the Academic EU project, REBORNE, has been initiated to develop a cell product to treat osteonecrosis (See Section 6.3.2.1, "Osteonecrosis of the hip").

#### 6.1.3 A breakthrough technology

The Company is bringing a unique value proposition by developing a range of innovative cell products administrable via a minimally invasive procedure.

The Company aims to improve:

- Efficacy: by developing innovative cell products both autologous (originating from patients) and allogeneic (originating from a universal donor) - composed of differentiated bone-forming cells (also called osteoblastic cells).
- Safety: by offering a minimally invasive approach involving implanting the cells with a needle (e.g., trephine) directly at the bone defect site through the skin, replacing the need for invasive surgery.

Regarding efficacy, the Company's differentiated cells have already acquired the capacity to form bone and are therefore more likely to have beneficial effects in bone diseases than other types of cells (including undifferentiated cells). Increased safety is also explained by this differentiation. Acquired function is expected to minimise the toxicity risk due to unwanted biological activities as well as uncontrolled proliferation.

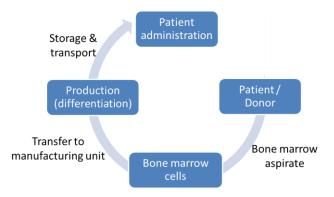


Figure 2: The above diagram shows the manufacturing cycle of the Company's products starting with bone marrow harvesting from the patient (PREOB®) or a healthy donor (ALLOB®) to obtain the stem cells that are expanded and differentiated into bone-forming cells and implanted at the bone defect site.

#### 6.1.4 The fracture repair and prevention field offers large market opportunities

#### 6.1.4.1 The Fracture Repair Market

Non-union (absence of healing after 6-9 months) and delayed-union (slowed healing) fractures (see Section 6.3.1, "The Fracture Repair Market" for more details) and degenerative spine disorders are indications in which bone has lost its regenerative capacity. These indications have been identified by the Company as requiring innovative treatments.

Each year, close to 10 million fractures occur and more than 3 million fracture repair procedures are performed in Europe, the US and Japan. Global sales of fracture repair fixation materials reached \$6.5 billion in 2013<sup>5</sup>, with an estimated growth rate of 7.2% (from 2014 through 2020).<sup>6</sup> Out of the 3 million fracture repair procedures, a significant proportion will suffer from impaired fracture healing in which the healing process is slowed down (delayed-union) or is completely interrupted (non-union).

The Company estimates that delayed-union fractures affect nearly 1 million patients per year in Europe, the US and Japan and non-union fractures nearly 300,000 patients.<sup>7</sup>

Standard treatment options for non-union fractures typically involve highly invasive surgery (i.e., autologous/allogeneic bone graft), which is painful, requires months of rehabilitation and has a considerable risk of serious complications. Due to the risks of current treatments, orthopaedic surgeons often take a "wait and see" approach for delayed-union fractures, sometimes for several months, which delays the patient's return to normal life and places a significant financial burden on society.

As part of its fracture repair segment, the Company also targets degenerative disorders of the spine with high unmet medical needs.

Degenerative disorders of the spine, including degenerative disc disease, scoliosis and stenosis, are treated by spinal fusion surgery in which two or more vertebrae are bridged to fuse an unstable portion of the spine or immobilize a painful vertebral motion segment. Traditionally, a bone graft is used in spinal fusion, but this approach does not always yield the desired results, and in 5% to 35% of cases leads to non-union or persistent

<sup>6</sup> Orthopedic Trauma Fixation Devices Market – Global Forecast, Market Share, Size, Growth and Industry Analysis 2014 – 2020.

 $<sup>^{\</sup>rm 5}$  Orthoworld. The orthopaedic industry annual report for year ending December 31, 2013.

<sup>&</sup>lt;sup>7</sup> Company estimates based on: Singer et al. Epidemiology of fractures in 15,000 adults: the influence of age and gender. *J Bone Joint Surg Br.* 1998(80)243-248; US governmental data: CDC Health data for the year 2010: Hospital discharges by diagnosis; Crowley et al. Femoral diaphyseal aseptic non-unions: Is there an ideal method of treatment? *Injury* 2007 (38)S55-63; Tressler et al. Bone Morphogenetic Protein-2 Compared to Autologous Iliac Crest Bone Graft in the Treatment of Long Bone Nonunion. *Orthopedics* 2011(12)e877-84; Phieffer et al. Delayed unions of the tibia. *J Bone Joint Surg Am.* 2006(1)206-216.

pain.<sup>8</sup> The Company estimates that in Europe, the US and Japan, each year, approximately over 1 million spinal fusion surgeries are performed.9

#### 6.1.4.2 The Fracture Prevention Market

In the fracture prevention market, the Company focuses on indications such as osteonecrosis of the hip and severe (or treatment-resistant) osteoporosis that are in high need of innovative treatments.

Osteonecrosis is a painful and disabling condition in which the hip joint progressively degenerates, ultimately leading to the collapse of the hip, requiring total hip replacement. The Company estimates that approximately 170,400 new patients are affected by osteonecrosis each year in Europe, the US and Japan. 10 Pre-fractural osteonecrosis is generally treated by core decompression, the results of which have been highly controversial. Other treatment options, such as total hip replacement, which require highly invasive surgery, are not recommended for young patients (80% of patients are under the age of 50<sup>11</sup>), due to the limited lifespan of prosthetics<sup>12</sup>.

Severe osteoporosis is expected to create the largest bone degeneration market targeted by the Company; over 30 million people in Europe, the US and Japan are affected by the disease<sup>13</sup> and up to a third of these patients are estimated to not respond to current treatments and will therefore still lose bone mass and ultimately experience fractures.14

#### A broad and late-stage pipeline 6.1.5

The Company has developed 2 first-in-class products, PREOB® and ALLOB®, which target 5 indications and offer the potential for additional product extensions.

PREOB®, the Company's autologous osteoblastic cell product, is derived from ex vivo cultured bone marrow cells of patients. Phase II clinical results have already demonstrated excellent safety and efficacy results, with statistically and clinically relevant benefits, giving the Company a strong clinical rationale to continue clinical development. PREOB® is currently in 2 pivotal Phase IIB/III trials in Europe for osteonecrosis and non-union fractures and in a Phase IIA trial for severe osteoporosis.

ALLOB®, the Company' allogeneic osteoblastic cell product, is derived from ex vivo cultured bone marrow cells of healthy adult volunteer donors. ALLOB® is currently in two Phase I/IIA proof-of-concept trials for treatment of delayed-union fractures and spinal fusion procedures.

In addition, the Company is conducting preclinical research on next generation products such as combined cellmatrix products for large bone defects and maxillofacial applications ("MXB") or enhanced viscosupplementation for osteoarthritis ("JTA").

All of the Company's products are manufactured to the highest GMP standards and all trials are designed in close consultation with the regulatory authorities. PREOB® and ALLOB® are classified as Advanced-Therapy medicinal Products in Europe, which is renowned to have some of the strictest guidelines for the production of cell products.

<sup>14</sup> Confavreux et al. Defining treatment failure in severe osteoporosis. *Joint Bone Spine* 2010(77)128-132.

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<sup>&</sup>lt;sup>8</sup> Aghion et al. Failed back syndrome. *Medicine & Health / Rhode Island* 2012(95)391-393.

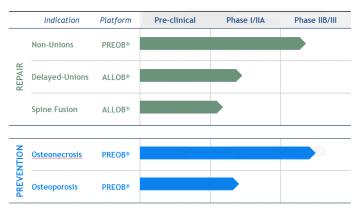
Company estimates based on: Hospital discharge data from the Agency for Healthcare Research & Quality for the US: Statistics by the Bundesamt Wiesbaden (Germany); Medtech European Markets for Spinal Fusion Products, March 2006.

<sup>&</sup>lt;sup>10</sup> Company estimates based on: OECD Health Data 2011; Lieberman et al. Osteonecrosis of the hip: management in the twenty-first century. J Bone Joint Surg Am 2003(84)834-853; Mankin et al. Nontraumatic necrosis of bone. NEJM 1992(326)1473-1479; Vail et al. The incidence of osteonecrosis. Osteonecrosis – etiology, diagnosis and treatment 1997 p.43-49.

Mont MA, Hungerford DS. Non-traumatic avascular necrosis of the femoral head. J Bone Joint Surg Am. 1995 (77)459-474.

<sup>&</sup>lt;sup>12</sup> Amanatullah et al. Current Management Options for Osteonecrosis of the Femoral Head: Part II, Operative Management, *The American* Journal of Orthopedics 2011(40)216-225.

13 Orthoworld. The orthopaedic industry annual report for year ending December 31, 2012.



 $\textbf{\it Figure 3: Clinical Pipeline with PREOB} {}^{\otimes}\text{: autologous approach; ALLOB} {}^{\otimes}\text{: allogeneic approach.}$ 

### 6.1.6 Historical key steps for the Company

2006 • Founded as a spin-off from the Université Libre de Bruxelles (Brussels, Belgium)  2007 • € 0.9 million raised in seed financing • Initiation of operations • PREOB® classified as Pharmaceutical Product by the European Medicines Agency • PREOB® for osteonecrosis granted ODD status in Europe  2008 • € 4.5 million raised in an equity financing round • PREOB® for osteonecrosis granted ODD status in the US  2009 • Initiation of the allogeneic osteoblastic program ALLOB®  2010 • Certificate of GMP Compliance granted  2011 • € 6.6 million raised in an equity financing round • ALLOB® classified as Tissue Engineered Product (non-combined) under ATMP classification 1394/2007EMA • Tissue Production Establishment license for PREOB®  2012 • IRD patent granted in Europe • Approval of PREOB® Phase III osteonecrosis trial in Europe and treatment of first patients • Clearance to start PREOB® Phase IIB/III trial for the treatment of non-union fractures		Histori	cal key steps for the Company
2007 • € 0.9 million raised in seed financing Initiation of operations PREOB® classified as Pharmaceutical Product by the European Medicines Agency PREOB® for osteonecrosis granted ODD status in Europe  2008 • € 4.5 million raised in an equity financing round PREOB® for osteonecrosis granted ODD status in the US  2009 • Initiation of the allogeneic osteoblastic program ALLOB®  2010 • Certificate of GMP Compliance granted  2011 • € 6.6 million raised in an equity financing round ALLOB® classified as Tissue Engineered Product (non-combined) under ATMP classification 1394/2007EMA Tissue Production Establishment license for PREOB®  2012 • IRD patent granted in Europe • Approval of PREOB® Phase III osteonecrosis trial in Europe and treatment of first patients • Clearance to start PREOB® Phase III osteonecrosis trial in Europe and treatment of first patients • Clearance to start PREOB® Phase III osteonecrosis trial in Europe and treatment of celliproducts • Establishment of the Walloon Cell Therapy Platform: infrastructure for clinical trials and commercial production of cell products • 6 for million raised in an equity financing round • ALLOB® Tissue bank/Intermediary Structure license & manufacturing authorization for Europe PREOB® patent granted in JP & US • Start of Phase IIA osteoporosis trial for PREOB® • ALLOB® granted ODD status for osteonecrosis in Europe • Approval of ALLOB® Phase III trial in delayed-union fractures • € 3.8 million Marie Curie research grant awarded to the Company and partners  Wim Goemacre appointed as Chief Financial Officer of the Company  2014 • IRD patent granted in JP & AU • ALLOB® granted ODD status for osteonecrosis in the US • Clearance to start ALLOB® Phase III trial for in spinal fusion procedures for degenerative lumbar disc disease • Renewal of Certificate of GMP Compliance  The Company and partners awarded prestigious M-ERA.net research funding • Bone Therapeutics and Kasios collaborate on novel product for spinal fusion • Guy Heynen appointed as Chief Clinical and Regulatory	Year		Key Milestones
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***************************************		•	€ 10 million raised in convertible bonds
<ul> <li>Bone Therapeutics expands products portfolio with new research into innovative combined cell-matrix product</li> </ul>	2015	•	€ 350,000 raised in convertible bonds
		•	Bone Therapeutics expands products portfolio with new research into innovative combined cell-matrix product

### 6.2 Company mission and strategy

The Company aims to be a leading regenerative company providing innovative cell products for high unmet medical needs (defined as a medical need that is not addressed adequately by an existing therapy <sup>15</sup>) in the fields of bone fracture repair and prevention. To achieve this objective, the Company is pursuing the following strategies:

#### Finalize Phase III trials and advance towards market authorization

The Company intends to complete the development of PREOB®, currently in the last clinical phase for the treatment of osteonecrosis and non-union fractures. For both studies, the Company aims to include an acceleration of the patient recruitment program. Subject to a positive outcome, the Company will apply for marketing authorisation with the EMA in Europe and the FDA in the US. To increase its chances of success in obtaining market approval, the Phase III trials were designed according to the recommendations of the EMA, after receiving their scientific advice. In addition, the Company obtained advice from the FDA in the US in the context of their pre-Investigational New Drug Application ("pre-IND") consulting program to design the osteonecrosis trial.

To allow the Company to seek marketing approval for the US market, it intends to launch a Phase III clinical trial in the US for osteonecrosis as well as non-union fractures. The preparation of these bridging studies will be initiated by setting up a pre-IND meeting with the FDA (following their previous positive opinions). The US trial is expected to be a controlled, randomized, blinded trial.

#### Accelerate promising Phase I/II trials

It is the Company's goal to perform the on-going Phase I/II clinical trials as rapidly and efficiently as possible. As with all trials the Company conducts, the trials are designed in close consultation with the regulatory authorities and are designed to meet the requirements of the EMA. This should allow for a smoother transition to Phase III, after establishment of safety and efficacy in the current trials, and subject to a positive outcome, to subsequent marketing applications. Efforts are being made to accelerate the Company's clinical projects by expanding the trials to several countries.

#### Leverage the cell differentiation platform and advance the preclinical pipeline

The Company intends to leverage its preclinical research, clinical data and manufacturing capabilities to efficiently expand its pipeline to indications for which it believes its products have therapeutic potential. The accumulated data should reduce the time and costs associated with early-stage clinical trials for additional diseases and disorders.

In vitro and in vivo experiments with the injectable combined cell-matrix product, MXB, have already yielded promising results. The Company intends to continue to investigate the products' safety profile and capacity to induce new bone formation, after which it plans to start trials for patients suffering from large bone defects. An extension to the joint field is being made by the development of JTA, an enhanced viscosupplement for the treatment of knee osteoarthritis.

#### Scale-up of manufacturing capabilities

The Company plans to open a new manufacturing facility at the BioPark of Gosselies (south of Brussels) mid-2016 after obtaining GMP accreditation. The modular design of the facility will allow for a progressive – on-demand - increase in commercial production capacity with up to 5,000 batches for PREOB<sup>®</sup> and 12,000 batches for ALLOB<sup>®</sup>.

The Company plans to establish a scalable production platform with supply centres in Europe, the US and the Asia-Pacific region. To reduce the costs of the product, the Company is continuously working on the optimization of the manufacturing processes.

Additionally, the optimization efforts cover the reduction of processing time and the increase of product stability in order to prolong the products' shelf-life and increase the timespan over which the Company can supply the products.

### **Build development and commercial partnerships**

The Company's strategy for selecting partners for osteonecrosis, non-union and delayed-union will be dependent on the region and indication. In Europe, except for osteoporosis, the Company currently envisages pursuing a stand-alone approach for the development and commercialization of its products but may consider a

<sup>&</sup>lt;sup>15</sup> FDA Guidance for Industry – Available Therapy, July 2004.

partner for distribution in some countries. In other regions including the US and Japan, the Company may consider co-development and licensing opportunities for its products and indications.

The Company intends to look for a partner to further develop the application of PREOB® in severe osteoporosis after completion of the Phase IIA trial.

The Company considers partnerships with major medtech or pharma players as a serious option for its future development. By way of example, Osiris has recently announced that it has entered into an exclusive worldwide partnership with Stryker Corporation.

### 6.3 The high unmet medical needs for bone disorders

The bone-related disorder industry, in which the Company operates, encompasses various pathologies, from orthopaedic conditions such as severe fractures and bone fracture risk diseases to inflammatory rheumatic diseases such as rheumatoid arthritis. Depending on the indication, competition could come from pharmaceutical, biopharmaceutical (including regenerative and cell therapy companies) and/or medical devices companies, as well as from research institutions.

The relevant fracture repair and fracture prevention markets (including the osteoporosis market) represent a global market of around USD 34 billion and 42 million patients. The Company's products target about a third of these markets representing approximately 12 million patients in Europe, the USA and Japan, with limited competition <sup>16</sup>. The market addressed by the Company is characterized by high unmet medical needs (defined as a medical need that is not addressed adequately by an existing therapy <sup>17</sup>). Indeed, most current treatments are either minimally effective or require invasive surgery at significant risk of major complications. In addition, most treatments are associated with long hospitalization and recovery time after surgery with a persisting risk for re-intervention. Despite this, the field of fracture repair and prevention has so far remained relatively clear of new treatments and there are almost no reported clinical trials. In bone cell therapy clinical development programs are still limited to a small number of indications (e.g., spinal fusion) and companies (e.g., Mesoblast), although there is a growing interest at the level of academic research.

#### 6.3.1 The Fracture Repair Market

Bone is a naturally regenerative organ, and fractures are currently well-managed in the majority of patients. However, there are traumatic situations in which bone fails to regenerate itself leading either to a totally interrupted regeneration process (non-union) or a slowed down regeneration process (delayed-union).

#### 6.3.1.1 Non-Union and Delayed-Union

### **Description**

Non-union fractures are characterised by a failure to achieve bone union within 6-9 months as, all reparative processes have ceased, hence requiring additional surgical intervention. The development of a non-union is mostly related to the type and degree of injury. Prompt and appropriate treatment of a fracture is of great importance to avoid impaired healing, since injury of soft tissue or inadequate immobilization can lead to the development of a non-union. Additional predisposing factors are, among others, smoking and the use of certain types of medication. Non-union fractures can be classified according to their radiographic appearance (i.e., Weber-Cech classification) into hypertrophic non-unions (although bone is formed, union has not occurred) and hypotrophic non-unions (characterized by low biological activity and the absence of new bone formation). Hypertrophic non-unions are the result of a mechanical problem, such as inadequate mobilization of the fracture. Given correct stabilization, they will heal without further stimulus. Hypotrophic non-unions, on the other hand, do not have sufficient healing potential and will require an additional stimulus. Research showed that non-union may be related to an altered viability and function of the mesenchymal and bone cells. These observations provide the rationale to implant differentiated bone-forming cells at the site of non-union and in this way kick-start the healing process.

A delayed-union fracture is defined as a fracture that has not united within a period of time that would be considered adequate for bone healing. Inadequate reduction of a fracture leading to instability or poor immobilization may be a reason for delay in fracture union. Other factors such as age, smoking, alcohol consumption or a medical condition can increase the risk of a delayed-union. Currently a "wait and see"

<sup>&</sup>lt;sup>16</sup> Orthoworld, The Orthopaedic Industry Annual Report for 2013 (relating to fracture repair procedures and spine procedures) – Transparancy Market Research, Osteoporosis Drugs Market – Global Industry Analysis, Pipeline Analysis, Size, Share, Growth, Trends & Forecast, 2014-2020 (relating to treatment of osteoporosis patients).

<sup>&</sup>lt;sup>17</sup> FDA Guidance for Industry – Available Therapy, July 2004.

approach is mostly adopted in the treatment of delayed-union fractures, sometimes for several months, which delays the patient's return to a normal life and places a significant financial burden on society.

#### Market Size

In the US, long bone fractures account for approximately 10% of all non-fatal injuries. <sup>18</sup> Close to 10 million fractures occur every year and over 3 million fracture repair surgeries are performed in Europe, the US and Japan. This led to revenues of more than \$6.5 billion in the global fracture repair market in 2013, an increase of 6.6% compared to the year before. Major driving factors for the fracture repair devices market are the increase in the elderly population, growing healthcare costs, and the increase in prevention measures for various orthopaedic-related problems. The leading causes of orthopaedic fracture cases are the ageing population, increasing participation in sports and rising number of road accidents. This market is expected to continue to grow steadily over the coming years.<sup>19</sup>

The Company has estimated the incidence of non-union and delayed-union fracture on (i) the number of osteosynthesis (orthopaedic external or internal fixation devices) annually performed and (ii) the reported rates of fractures evolving to non-union or delayed-union. Studies on osteosynthesis indicate a rate of 44/10,000 in Europe (Scotland),<sup>20</sup> and of 35/10,000 in the US.<sup>21</sup> An average rate of 40/10,000 was consequently adopted for all regions. Reported rates of fractures evolving to delayed or non-unions being variable, the estimates are provided as base, best and worst case<sup>22</sup> scenario. These estimates take into account the fact that access to the treatment may differ from 100% (i.e., not all patients requiring a treatment are actually having access to appropriate treatment). In the base case scenario, the annual number of addressable patients in Europe, the US and Japan is estimated to be 214,500 for non-union and 715,000 for delayed-union.

	Non-unions	Delayed-unions
Population (EU, US & JP)	993m	993m
Osteosynthesis rate (/10,000)	40	40
Osteosynthesis patients (/year)	3,972,000	3,972,000
Incidence NU&DU (/10,000)	2.4 (1-4)	8 (6-10)
NU&DU patients ('000)	238.4 (99.3-397.2)	794.4 (595.8-993)
Access to healthcare	90%	90%
Addressable population ('000) (NU&DU patients x health care access)	214.5 (89.4-357.5)	715 (536.9-893.7)

Indicated numbers are base (worst-best) case scenarios. DU: delayed-union; NU: non-union. Company estimates based on references in text.

#### Competition

The use of osteosynthesis material and bone grafts is a well-established practice for the repair of fractures.

In the case of a non-union, numerous techniques have been developed ranging from non-invasive procedures (ultrasound and electromagnetic stimulation) to surgical re-interventions using bone auto or allograft (synthetic bone substitutes or cadaver bone: DBM from Biomet, Synthes, etc.). To date, bone autograft remains the gold standard treatment for this condition as it presents 75-85% efficacy and advantageously avoids risks of disease transmission.<sup>23</sup> Yet, associated side-effects are considerable, with complications (pain at harvest site, infection...) reported in 20% of patients (for iliac crest harvest procedures in particular).

Apart from bone grafting, Osigraft<sup>TM</sup> (the (ortho-) biological product (i.e., protein) *rhBMP-7*; Olympus Biotech) was, to the Company's knowledge, the only pharmaceutical therapy approved (in a restricted indication) but has now been withdrawn from the market, leaving it open to new players in the field. Studies have revealed poor

<sup>&</sup>lt;sup>18</sup> Kanakaris et al., The health economics of the treatment of long-bone non-unions. *Injury* 2007(38S)S77-S84.

<sup>&</sup>lt;sup>19</sup> Orthoworld. The orthopaedic industry annual report for year ending December 31, 2013.
<sup>20</sup> Singer et al. Epidemiology of fractures in 15,000 adults: the influence of age and gender. *J Bone Joint Surg Br.* 1998(80)243-248.

<sup>&</sup>lt;sup>21</sup> US governmental data: CDC Health data for the year 2010: Hospital discharges by diagnosis.

<sup>&</sup>lt;sup>22</sup> Crowley et al. Femoral diaphyseal aseptic non-unions: Is there an ideal method of treatment? Injury 2007 (38)S55-63; Tressler et al. Bone Morphogenetic Protein-2 Compared to Autologous Iliac Crest Bone Graft in the Treatment of Long Bone Nonunion. Orthopedics 2011

<sup>(12)</sup>e877-84; Phieffer et al. Delayed unions of the tibia. J Bone Joint Surg Am. 2006(1)206-216.

<sup>23</sup>Friedlaender G, et al. Osteogenic protein-1 (BMP-7) in the treatment of tibial non-unions: a prospective, randomised clinical trial

comparing Rhop-1 with fresh autograft. *J Bone Joint Surg Am*. 2001(83)151-158.

<sup>24</sup> Friedlaender G, et al. Osteogenic protein-1 (BMP-7) in the treatment of tibial non-unions: a prospective, randomised clinical trial comparing Rhop-1 with fresh autograft. J Bone Joint Surg Am. 2001(83)151-158.

results for other "orthobiologics" (PDGF from BioMimetic Therapeutics, PTH from Lilly or Kuros and more recently *Romosozumab* from Amgen/UCB<sup>25</sup>), forcing them to stop their clinical development.

To its knowledge, the Company is the only clinical stage company that develops bone cell products using differentiated bone cells for the treatment of non-union and delayed-union fractures.

Excluding the bone void filler products in support of bone graft surgeries, Wright Medical Technology (the US) has developed an injectable bone void filler product for delayed/non-unions of non-weight-bearing bones smaller than 3mm to be mixed with blood or marrow and Novadip Biosciences (BE) has a preclinical stage autologous undifferentiated cell product mixed with cadaver bone.

Overview of cell therapy companies active in non-union and delayed-union.<sup>26</sup>

Companies	Location	Product(s)	Source	Product type	Indication	Status
Wright Medical Technology	US	Ignite <sup>®</sup>	Autologous	Injectable scaffold – medical device	Non-union or Delayed-union of <3mm of non- weight-bearing bones	N/A
Xcelia	Spain	Xcel-Mt-Osteo- Alpha	Autologous	Bone marrow-derived MSC	Non-union	Ph I/IIA ongoing
Novadip Biosciences	Belgium	Creost <sup>®</sup>	Autologous	Adipose-derived MSC (3D structure)	Non-union	Preclinical (some clinical data under hospital exemption)
Stopped clinical	l programs:					
Vericel Corporation	US	Ixmyelocel-T	Autologous	MSC/HSC/EP + scaffold	Non-union	PhI/II completed in 2007

EP: endothelial progenitor cell; HSC: hematopoietic stem cell; MSC: mesenchymal stem cells. Vericel Corporation was formerly Aastrom Biosciences.

Today, there is no therapeutic option - both safe and efficacious<sup>27</sup> - for the management of non-union fractures. In this context, the Company intends to position its cell therapy-based products as a first-line treatment for this indication. The Company expects its products to be as efficacious as the standard-of-care (bone autograft), and superior in terms of patient safety (i.e., the minimally-invasive cell implantation would avoid open surgery and a long hospital stay and allow for a faster recovery).

Similarly, Bone Therapeutics' bone cell products are being considered for the treatment of delayed-union fractures. As this indication is rarely treated by physicians, the Company will first have to introduce this new approach in the management of these fractures. Instead of waiting (for the confirmation of a non-union diagnosis), surgeons will be provided with an early non-invasive therapeutic option, offering reduced healing time and yielding substantial cost savings. The Company believes that it can play a significant role in creating this new market, given the fact that the Company benefits from being an early actor in the field.

#### 6.3.1.2 Spinal fusion and rescue spinal fusion

### **Description**

Spinal fusion is considered as the gold standard surgery for treating a broad spectrum of degenerative spine disorders, including degenerative disc disease, spondylolisthesis, scoliosis and stenosis, to relieve pain and improve function. Spinal fusion consists of bridging two or more vertebrae with the use of a cage and graft material, traditionally autologous bone graft, – placed into the intervertebral space - for fusing an unstable portion of the spine or immobilizing a painful vertebral motion segment. Despite the fact that spinal fusion surgery is routine, non-union and failure to relieve lower back pain are unfortunately still frequent as on average 30% of spinal fusion patients are not completely satisfied with their surgery.<sup>29</sup>

### **Market Size**

Over 1 million spinal fusions are performed each year in Europe and the US, the majority of which are to address degenerative lumbar disc disease. The Company's estimates regarding market size are based on hospital discharge data from the Agency for Healthcare Research & Quality for the US, statistics by the

<sup>&</sup>lt;sup>25</sup> UCB Prospectus dated 6 March 2013.

<sup>&</sup>lt;sup>26</sup> Company websites and clinicaltrials.gov.

<sup>&</sup>lt;sup>27</sup> Bone autograft has a high efficacy, but is associated with high complication rates.

<sup>&</sup>lt;sup>28</sup> Heckman et al. The economics of treating tibia fractures. The cost of delayed unions. Bull Hosp Jt Dis. 1997(56)63-72.

<sup>&</sup>lt;sup>29</sup> Rajaee et al. National trends in revision spinal fusion in the USA: Patient characteristics and complications. *The bone and joint journal* 2014(96)807-816.

Bundesamt Wiesbaden (Germany) and market reports (Medtech). On that basis, the number of spinal fusion procedures per 10,000 people was calculated at 14.4 for the US and 9 for Europe. Epidemiological studies showed that half of spinal fusion procedures concern lumbar spinal fusions. Access to healthcare was set at 100%, since the calculations are based on performed surgeries. Using these data, the Company estimates that each year 542,000 patients in Europe, the US and Japan undergo lumbar spinal fusion surgery.

	Lumbar spinal fusion
Population (EU, US & JP)	993m
Spinal fusion rate (/10,000)	9 (EU&JP) – 14.4 (US)
Spinal fusion patients	1,084,000
Lumbar spinal fusion rate (/10,000) (50% x spinal fusion rate)	4.5 (EU&JP) – 7.2 (US)
Lumbar spinal fusion patients	542,000
Access to healthcare	100%
Addressable population (patients x health care access)	542,000

Company estimates based on references in text.

One of the most common complications encountered in spinal fusion surgery is failed fusion (complete or partial), reported in approximately 5% to 35% of procedures, which could lead to debilitating pain, deformities, and subsequent revision surgery. Its management is one of the most challenging problems in this field. Procedures to salvage failed lumbar fusions focus on achieving a solid fusion, and consequently relieving and controlling pain and symptoms, minimizing disability, and improving the quality of life. Management of failed lumbar fusion begins with a careful analysis of its cause before considering a revision. In rescue surgery, surgeons may fix any technical errors of the first procedure, place new graft material in the best possible biological environment and correct the biomechanical environment to yield the best chance of fusion. However, revision surgeries are associated with higher procedure-related complication rates, technical difficulties, and longer operative times.<sup>30</sup> Moreover, success rates are poor and not always reliable for both fusion and clinical

Through review of scientific literature and interviews with spine surgeons, the Company has estimated that the average proportion of failed spinal fusions is close to 25% (range from 5% to 35% 31). When comparing this rate of failure with the reported rate of revision surgery it appears that only 25% of patients with failed spinal fusion have the revision procedure they need.<sup>32</sup> Reasons for this are the high complication rate and the difficulty of surgery, as mentioned above. Access to healthcare has therefore been set to 25%. The Company consequently estimates the addressable population for rescue lumbar spinal fusion to be 33,875 in Europe, the US and Japan.

	Rescue lumbar spinal fusion
Population (EU, US & JP)	993m
Spinal fusion patients	542,000
Spinal fusion failure	25%
Rescue spinal fusion patients	135,500
Access to healthcare	25%
Addressable population (incidence x health care access)	33,875

Company estimates based on references in text.

In recent years, the spinal fusion market has grown considerably; spinal fusions increased by 77% in the US from 2002 to 2011.<sup>33</sup> According to a GlobalData report, this growth is largely the results of the increase in indications for which spinal surgery can be performed. GlobalData estimates that the market will continue to grow, albeit at a smaller annual rate of 5%. On the one hand, the ageing population supports expansion; on the other hand, changing reimbursement policies may start putting pressure on the market. The Company believes that through the development of new minimally invasive treatments, more patients suffering from failed spinal fusion will be eligible for a revision surgery.

The spinal fusion market is segmented in two product classes, i.e., hardware devices (plates, screws and cages) and bone grafts. These two classes are inter-related as the hardware is needed to stabilise the vertebrae and the

<sup>&</sup>lt;sup>30</sup> Ma et al. Comparative In-Hospital Morbidity and Mortality after Revision versus Primary Thoracic and Lumbar Spine Fusion Spine J. 2010 (10)881-889.

Aghion et al. Failed back syndrome. Medicine & Health / Rhode Island 2012(95)391-393.

<sup>&</sup>lt;sup>32</sup> Awe et al. Impact of total disc arthroplasty on the surgical management of lumbar degenerative disc disease: Analysis of the Nationwide Inpatient Sample from 2000 to 2008. Surgical Neurology International 2011(2)139-143.

33 Size of spinal fusion market to suffer amid scrutiny. GlobalData, Joseph Gregory, May 6, 2014.

grafts needed to promote fusion. Bone autograft is still perceived as the gold-standard for spinal fusion procedures, despite high safety concerns (in particular donor site pain). As a wide array of alternatives is now on the market, a gradual shift is observed from bone autograft towards bone substitutes. This overcrowded product class - with over 200 different products available for the surgeons - is currently dominated by major medical device manufacturers. The bone substitutes on the market are (i) allografts, mostly cadaver bone (*DBM* from Biomet, Zimmer, Synthes, etc.) and (ii) ceramics (Stryker, Baxter, etc.). The market for bone substitutes is characterized by rapid technological change, frequent introduction of new products and evolving surgical practices toward minimally invasive procedures. Experts estimate that this market will be driven mostly by innovation and by the companies' novel positioning as part of a broad therapy system. In such a therapeutic setting, the synergic combination of hardware devices, bone substitutes and adapted surgeries would ensure better therapeutic outcomes.

By contrast, the regenerative segment of the spinal fusion market has little or no competition with only one approved orthobiologic therapy (*recombinant growth factors* such as Medtronic's Infuse<sup>®</sup>).

Recently, the negative media coverage surrounding Medtronic's Infuse<sup>®</sup> (along with FDA investigations, lawsuits and decreased sales) has opened the market to alternative therapies.<sup>35</sup> In this changing landscape, the Company believes that its cell products, used as an add-on therapy to synthetic bone substitutes in standard fusion procedures, could offer a better treatment option - and will be cost-effective by achieving a faster and solid fusion. A cell therapy approach for spinal fusion has already been investigated by Mesoblast with its undifferentiated stem cells. Following completion of Phase II in 2012, Phase III has remained on hold due to a change in Mesoblast's priorities.<sup>36</sup>

Overview of cell therapy companies active in lumbar spinal fusion.<sup>37</sup>

Companies	Location	Product(s)	Source	Product type	Status
Theracell	UK	Chondroseal	Autologous	Adipose-derived stem cells + injectable scaffold	NA
Mesoblast	Australia	Neofuse®	Allogeneic	Bone-marrow-derived MPC + scaffold	Ph II completed On hold
Xcelia	Spain	Xcel-Mt-Osteo-Alpha	Autologous	Bone marrow-derived MSC	Ph I/IIA ongoing
Novadip Biosciences	Belgium	Creost <sup>®</sup>	Autologous	Adipose-derived MSC (3D structure)	Preclinical (some clinical data under hospital exemption)
Stopped clinical prog	grams:				
Vericel Corporation	US	NA	Autologous	MSC/HSC/EP + scaffold	PhI/IIA completed

EP: endothelial progenitor cell; HSC: hematopoietic stem cell; MSC: mesenchymal stem cells. Vericel Corporation was formerly Aastrom Biosciences.

In parallel, the Company is also considering its cell products as last-line treatment for failed spinal fusion procedures. In this setting, the products would be implanted by a minimally-invasive percutaneous injection into the failed fusion to trigger bone formation. The Company expects these products to compete advantageously with standard medical practises (i.e., open re-interventions) with regard to enhanced safety and efficacy.

### 6.3.2 The Fracture Prevention market

There are non-traumatic situations in which bone fails to regenerate naturally. Certain diseases or conditions can indeed alter the bone regeneration system increasing significantly the risk of fracture. This segment has suffered from a dramatic lack of innovation.

#### 6.3.2.1 Osteonecrosis of the hip

### **Description**

Osteonecrosis of the hip is characterized by the death of bone cells and loss of the associated marrow elements. It is a painful condition in which the joint degenerates progressively, ultimately leading to collapse of the femoral head, requiring a total hip replacement. Different stages of osteonecrosis can be distinguished of which stages I & II represent the stages before fracture and stages III & IV the stages after fracture. Early diagnosis

<sup>36</sup> Mesoblast press release dated 26 August 2014.

<sup>&</sup>lt;sup>34</sup> Myeroff C and Archdeacon M. Autogenous Bone Graft: Donor sites and Techniques. The Journal of Bone and Joint Surgery. 2011; 93A (23): 2227-36

<sup>35</sup> http://www.drugwatch.com/infuse/.

<sup>&</sup>lt;sup>37</sup> Company websites and clinicaltrials.gov.

and treatment are important to potentially improve outcome. The exact cause is unknown, but risk factors include corticosteroids, alcohol, trauma and blood abnormalities (e.g., coagulation or sickle cells). This condition typically affects relatively young people (30-50 years old<sup>38</sup>, only 20% of patients are older than 50<sup>39</sup>), where hip replacement is not appropriate due to the limited lifespan of the prosthesis. Unfortunately, due to the lack of alternative treatments, nearly 50% of patients will require a hip replacement before the age of 40. It is estimated that out of the total hip arthroplasties ("THA") performed, which exceed 1.5 million procedures each year in the US and in Europe, about 10% can be attributed to osteonecrosis. 40 The sales related to hip replacement exceeded \$6 billion in the US in 2013. 41 Assuming 10% of the hip prosthesis market in Europe and the US concerns osteonecrosis, the market of hip replacement for osteonecrosis can be estimated to be close to € 1 billion.

#### Market Size

The incidence of osteonecrosis was calculated by the Company as it is the underlying condition of about 10% of total hip arthroplasties. For this procedure, detailed statistics by country are available from the organization for economic co-operation and development (OECD).<sup>42</sup> The number of THA was reported to be 17.9/10,000 for Europe<sup>43</sup> and 17.8/10,000 for the US in 2011. Epidemiology studies were used to determine the share of THA that is linked to osteonecrosis, which was 10% on average. On the basis of these data, the Company estimates that the incidence of osteonecrosis is 1.8/10,000, leading to an annual number of 170,400 patients in Europe, the US and Japan as a base case scenario. Since this calculation was based on the number of performed surgical procedures, access to healthcare was set at 100%.

	Osteonecrosis	
Population (EU, US and JP)	993m	
THA rate (/10,000)	17.8 (US) – 17.9 (EU) – 11.5 (JP)	
ON diagnosis	10% (5%-18%) – 10% (JP)	
ON incidence (/10,000)	1.8 (0.9-3.2) – 1.2 (JP)	
ON patients ('000)	155.7 (77.9-276.8) + 14.7 (JP)	
Access to healthcare	100%	
Addressable population (*000) (ON patients x health care access)	155.7 (77.9-276.8) + 14.7 (JP)	

Indicated numbers are base (worst-best) case scenarios. ON: osteonecrosis. Company estimates based on references in text.

The Company estimates that, today, two thirds of osteonecrosis patients go undiagnosed or are diagnosed too late. Increased awareness, for example through new treatments, can potentially reduce this number in the future.

#### **Competition**

Currently, no treatment has been approved for the management of pre-fractural stage (I & II) osteonecrosis of the femoral head.

Core decompression is the most used therapeutic option for early-stage osteonecrosis: despite the highly variable reported success rates (14-82% 45) and a controversial efficacy, this surgical procedure dating back to the 1940s is still considered as the standard of care. Other available treatments include (i) conservative interventions (e.g., exercise, electrical stimulation) which are usually used upon diagnosis and (ii) surgical approaches, such as osteotomy or bone graft. These surgeries show good results, but their invasiveness limits their application to advanced stage (III) patients. Other therapeutic options more recently developed (e.g., with

<sup>&</sup>lt;sup>38</sup> Lane NE. Therapy Insight: osteoporosis and osteonecrosis in systemic lupus erythema-tosus. Nature Clinical Practice Rheumatology. October 2006; 2(10): 562-569.

Mont MA, Hungerford DS. Non-traumatic avascular necrosis of the femoral head. J Bone Joint Surg Am. 1995; 77: 459-474

<sup>&</sup>lt;sup>40</sup> 5-12%: Lieberman et al. OSteonecrosis of the hip: management in the twenty-first century. J Bone Joint Surg Am 2003(84)834-853; 10%: Mankin et al. Nontraumatic necrosis of bone. NEJM 1992(326)1473-1479; 5-18%: Vail et al. The incidence of osteonecrosis. Osteonecrosis - etiology, diagnosis and treatment 1997 p.43-49.

<sup>&</sup>lt;sup>41</sup> Orthoworld. The orthopaedic industry annual report for year ending December 31, 2013.

<sup>&</sup>lt;sup>42</sup> OECD Health Data 2011.

<sup>&</sup>lt;sup>43</sup> Based on incidence in 13 selected countries (Belgium, France, Germany, Luxembourg, Netherlands, Austria, Denmark, Finland, Italy, Sweden, Spain, Switzerland and Norway) with a total of 386 million inhabitants.

<sup>&</sup>lt;sup>44</sup> 5-12%: Lieberman et al. Osteonecrosis of the hip: management in the twenty-first century. *J Bone Joint Surg Am* 2003(84)834-853; 10%: Mankin et al. Nontraumatic necrosis of bone. NEJM 1992(326)1473-1479; 5-18%: Vail et al. The incidence of osteonecrosis. Osteonecrosis

etiology, diagnosis and treatment 1997 p.43-49.
 <sup>45</sup> Ciombor, Deborah McK, Aaron, Roy K. M.D. Biologically Augmented Core Decompression for the Treatment of Osteonecrosis of the Femoral Head. Techniques in Orthopaedics March 2001; 16(1): pp 32-38.

growth factors, cement, bone marrow graft) are either perceived to have limited effectiveness or excessive complexity. 46

Furthermore, to the best of the Company's knowledge, there are no on-going clinical studies for this condition and no other cell therapy companies active in osteonecrosis using differentiated bone cells.

Overview of cell therapy companies active in osteonecrosis. 47

Companies	Location	Product(s)	Source	Product type	Indication	Status
REBORNE (Academic EU Project)	Europe	REBORNE ORTHO-2	Autologous	Bone marrow–derived MSC	Osteonecrosis	PhI ongoing
Abandoned						
Vericel Corporation	US	NA	Autologous	MSC/HSC/EP	Hip osteonecrosis	PhII completed in 2010

EP: endothelial progenitor cell; HSC: hematopoietic stem cell; MSC: mesenchymal stem cells. Vericel corporation was formerly Aastrom Biosciences.

The Company's products have been designed as an effective add-on therapy to core decompression. It will therefore not compete with, but aim to improve established treatments. While preserving the minimally invasive character of the current standard of care, this approach will address the physiopathogenic mechanisms proposed for the disease, i.e., the implantation of osteoblasts would address cell depletion and dysfunction and local ischemia by secretion of angiogenic factors. In view of the satisfactory efficacy and safety data obtained in the Phase II clinical trial, the Company believes this treatment, if approved, could improve the current standard of care as first-line treatment for early-stage osteonecrosis patients.

#### 6.3.2.2 Severe osteoporosis

#### Description

Osteoporosis is characterized by an excessive loss of bone mass leading to bone fragility and increased risk of fracture.

#### Market Size

The disease affects approximately 75 million people in Europe, the US and Japan, of which 30 million have an established osteoporosis, making it one of the most common and debilitating chronic diseases. The severity of the condition can be best understood by the fact that, in Europe, one osteoporotic fracture occurs every 30 seconds. In 2013, the global osteoporosis drug market generated \$8 billion in revenues<sup>48</sup>, with the market expected to grow at a compound average growth rate of 4-5%<sup>49</sup>.

#### Competition

Several anti-osteoporotic treatments exist of which most prevent bone resorption and do not induce bone formation. Despite the availability of these treatments, osteoporosis remains a significant health problem for patients who do not respond to or fail to comply with their regimens. Up to 30% of osteoporosis patients do not respond adequately to treatment and are still losing bone mass or experiencing fractures.<sup>50</sup>

The market for osteoporosis is segmented on the basis of the drugs' mechanisms of action. Available biologics either inhibit bone resorption (bisphosphonates (*alendronate*; Merck), RANK–L inhibitors (*denosumab*; Amgen, etc.), or promote bone formation (parathyroid hormone (*teriparatide*; Eli Lilly)).<sup>51</sup> Traditionally dominated by bisphosphonates, the market is expected to substantially change over the next decade following the recent genericization of biphosphonates and the emergence of new drug classes as second-line therapies.<sup>52</sup> Despite demonstrated efficacy, most available drugs are not fully satisfying due to safety issues (e.g., osteonecrosis of

<sup>48</sup> PharmaPoint: Osteoporosis - Global Drug Forecast and Market Analysis to 2022.

<sup>&</sup>lt;sup>46</sup> Zalavras et al. Osteonecrosis of the femoral head: evaluation and treatment. J Am Acad Orthop Surg 2014(22)455-464.

<sup>&</sup>lt;sup>47</sup> Company websites and clincialtrials.gov.

<sup>&</sup>lt;sup>49</sup> Global Industry Analysts, Osteoporosis Therapeutics: A Global Strategic Business Report (2012); Infiniti Research Limited (Technavio), Osteoporosis Drugs Market in the APAC Region 2015-2019 (2014); Infiniti Research Limited (Technavio), Global Osteoporosis Drugs Market Report 2014-2018 (2014); Transparency Market Research, Osteoporosis Drugs Market (2013).

<sup>&</sup>lt;sup>50</sup> Confavreux et al. Defining treatment failure in severe osteoporosis. *Joint Bone Spine* 2010(77)128-132.

<sup>&</sup>lt;sup>51</sup> Geusens et al. Drug Insight: choosing a drug treatment strategy for women with osteoporosis – an evidence-based clinical perspective *Nature Clinical Practice Rheumatology* 2008(4)240-248.

<sup>&</sup>lt;sup>52</sup> Visiongain. Osteoporosis Treatment and Prevention: World Drug Market Forecast 2014-2024 & Future Prospects for Leading Companies.

the jaw), intolerance to treatment and regimen inconvenience. Together with the 35% non-responding patients, these concerns motivate physicians to seek novel alternative treatments<sup>53</sup>.

It is a highly competitive field for first-line with multiple major pharmaceutical companies operating in the field. The Company believes there is a significant opportunity for cell therapy-based products, such as the Company's products, as last-line treatment for patients who do not respond to the available biologics or who fail to comply with their regimens. Potential competitors would include *odanacatib* (Merck) and *romosozumab* (Amgen) which are likely to enter the market in the coming years for first-line treatment.

#### 6.3.3 Other indications

The Company is developing preclinical products and is extending its clinical products to other indications, such as the inflammatory diseases osteoarthritis and rheumatoid arthritis. Inflammatory diseases with bone involvement (rheumatoid arthritis and osteoarthritis) represent a market of approximately 175 million patients <sup>54</sup>.

#### 6.3.3.1 Osteoarthritis

Osteoarthritis is a degenerative joint disease, which affects the articular cartilage. It is associated with ageing and will most likely affect the knees, hips, fingers, and lower spine region. Osteoarthritis is the sixth leading cause of disability worldwide. It is estimated globally that 9.6% of men and 18.0% of women aged over 60 years have symptomatic osteoarthritis. The global osteoarthritis therapeutics market was worth \$4.4 billion in 2010 and is estimated to grow at an annual rate of 3.8%, reaching \$5.9 billion by 2018. 56

As far as the Company is aware, there is currently no approved cure or regenerative treatment for osteoarthritis. Treatment focuses on relieving and controlling pain and symptoms, preventing disease progression, minimizing disability, and improving quality of life. In severe cases, when therapies do not work, surgery may be considered as a last resort. Surgical interventions include total joint arthroplasty and joint lavage and debridement.

There are only 10 reported medicines for osteoarthritis, the most common form of arthritis, affecting more than 75 million people in Europe, US and Japan (PhRMA 2014), from which, 4 are cell products.

### 6.3.3.2 Rheumatoid arthritis

Rheumatoid arthritis is a chronic systemic disease that affects the joints, connective tissues, muscle, tendons, and fibrous tissue. It tends to strike during the most productive years of adulthood, between the ages of 20 and 40, and is a chronic disabling condition often causing pain and deformity.

Rheumatoid arthritis prevalence varies between 0.3% and 1% and is more common in women and in developed countries. Within 10 years on onset, at least 50% of patients in developed countries are unable to hold down a full-time job. The rheumatoid arthritis treatment market is expected to grow modestly over the next decade, with sales in the US, France, Germany, Italy, Spain, the UK and Japan increasing from \$11.1 billion in 2011 to \$15.2 billion in 2021. Treatment of rheumatoid arthritis focuses on controlling symptoms and preventing joint damage. Non-steroidal anti-inflammatory drugs (NSAID), corticosteroids or disease-modifying anti-rheumatic drugs (DMARD) are prescribed, but these drugs may cause serious side effects. Several biologics have been approved for rheumatoid arthritis treatment, of which the first-line drug is a TNF-alpha inhibitor. Unfortunately, up to 40% of patients do not respond to this treatment. It is a highly competitive field for first-line therapy with a number of marketed products and 55 products in clinical development (PhRMA 2014). Three products are now well established in the market: *adalimumab* (Abbott/Eisai), *infliximab* (Johnson & Johnson) and *etanercept* (Amgen/Pfizer). However, these drugs are not fully satisfying in terms of safety (infections, allergies, etc.), tolerance and treatment response (~40% of the patients do not respond to treatment or lose responsiveness over time). Interestingly enough, in a recent publication from the NEJM, such antibodies were shown not to be superior to the old anti-rheumatic drugs *azulfidine & hydroxychloroquine*.

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<sup>&</sup>lt;sup>53</sup> Confavreux et al. Defining treatment failure in severe osteoporosis. Joint Bone Spine 2010(77)128-132.

<sup>&</sup>lt;sup>54</sup> Orthoworld. The orthopaedic industry annual report for year ending December 31, 2013.

<sup>&</sup>lt;sup>55</sup> Woolf et al. Burden of major musculoskeletal conditions. Bulletin of the World Health Organization 2003(81)646-656.

<sup>&</sup>lt;sup>56</sup> GlobalData report: Osteoarthritis (OA) Therapeutics – Pipeline Assessment and Market Forecast to 2018.

<sup>&</sup>lt;sup>57</sup> Woolf et al. Burden of major musculoskeletal conditions. Bulletin of the World Health Organization 2003(81)646-656.

<sup>58</sup> Decision Resources: http://decisionresources.com/News-and-Events/Press-Releases/Rheumatoid-Arthritis-091412.

<sup>&</sup>lt;sup>59</sup> Emery et al. Rituximab versus an alternative TNF inhibitor in patients with rheumatoid arthritis who failed to respond to a single previous TNF inhibitor: SWITCH-RA, a global, observational, comparative effectiveness study. *Ann Rheum Dis* 2014(0)1-6.

<sup>&</sup>lt;sup>60</sup> O'Dell et al. Therapies for Active Rheumatoid Arthritis after Methotrexate Failure. *NEJM* 2013(369)307-318.

### 6.4 Technology

In the human body, adult stem cells can be found in all types of tissue. They function as a repair system for the body, since they have the capacity to differentiate into specialized cell types. Most adult stem cells are lineage-restricted, meaning that they are already committed to differentiate into a more limited number of cell types. In this way, mesenchymal stem cells ("MSC") can convert into cell types such as bone cells, cartilage cells, fat cells, etc.

The Company's technology platform is based on a unique approach in which mesenchymal stem cells, derived from bone marrow of patients or donors, are stimulated to differentiate into osteoblasts (i.e., bone-forming cells). There are two important types of cells in the body that are involved in bone homeostasis, namely osteoblasts and osteoclasts, which regulate the dynamic and constant remodelling of the skeleton. Osteoblasts are responsible for bone matrix synthesis and subsequent mineralization, while osteoclasts resorb the bone.

Local implantation of biologically active osteoblastic cells (pre-osteoblasts and osteoblasts) at the bone defect site is intended to mimic the natural process of bone formation and repair.

More specifically, the mode-of-action is dual.

- On the one hand, the osteoblastic cells will replace the defective or missing osteoblasts by new osteoblasts that will form new bone and repair the defective bone.
- On the other hand, the presence of osteoblastic cells will create a healthy bone environment by recruiting haematopoietic and osteoprogenitor cells and secreting matrix proteins.

The implanted cells are expected to adhere onto the existing tissue and matrix, where they will produce new bone matrix that will be calcified. Finally, the cells will differentiate into osteocytes and become imbedded into the calcified new bone matrix.

### **6.4.1** *PREOB*<sup>®</sup>: autologous cell product

PREOB® is a cell-based medicinal product ("**CBMP**") derived from autologous (derived from the patient) bone marrow MSC. A bone marrow aspirate is performed from the iliac crest of the patient under local anaesthesia, after which MSC are isolated, expanded and differentiated. The active part of the product thus comprises human autologous osteoblastic cells – including pre-osteoblasts and osteoblasts. The manufacturing process is performed in strict GMP compliance and follows procedures that ensure aseptic manufacturing, full traceability, and quality control.

PREOB® cells do not express any hematopoietic markers, but rather exhibit the features of osteoblastic cells, including the expression of typical cell surface proteins and the secretion of bone matrix proteins, growth factors and enzymes, which indicates their differentiation away from the MSC towards the osteoblast.

Safety and efficacy of PREOB® administration was confirmed in preclinical studies. Safety parameters, including clinical signs, body weight, blood chemistry and haematology were evaluated. A long-term toxicity study showed that PREOB®, when administered systemically at very high doses, did not cause any excess morbidity or mortality and did not induce any organ toxicity. In addition, tumourigenesis studies showed the absence of tumour development after PREOB® administration in immunodeficient mice (these mice lack the component of the immune system that causes an immune response and consequent rejection of foreign). Importantly, efficacy studies showed that PREOB® induced significant new bone formation.

The distribution of PREOB® in the body was assessed after systemic as well as local administration of the cells in rodents. When administered systemically, the cells circulated in the body and did not accumulate in non-bone organs such as the brain, heart, lungs, kidney, liver or spleen. Locally administered cells were retained at the fracture site.

### 6.4.2 ALLOB®: allogeneic cell product

ALLOB<sup>®</sup> is the Company's allogeneic product that consists of human allogeneic bone-forming cells derived from cultured bone marrow MSC of healthy adult volunteer donors. ALLOB<sup>®</sup> has been classified as Tissue Engineered Product (non-combined) by the EMA under the ATMP classification 1394/2007.

ALLOB® cells express master osteoblast genes, mesenchymal and bone matrix adhesion markers and display bone-forming properties. The cells are able to adhere, synthesize and mineralize new bone matrix. Engraftment of the ALLOB® cells as well as bone-forming and bone repair capacity was demonstrated in mouse model by local administration at the defect site.

Safety studies did not show changes in clinical signs or in laboratory parameters and no anomalies in microscopic or macroscopic observations. Additionally, no ectopic (meaning in an abnormal location) bone formation could be detected when the cells were injected in muscles. Safety was further investigated by intravenous administration of ALLOB® cells at high doses to immunodeficient mice. These high doses did not cause any excess morbidity or mortality during a 24-week observation period and no evidence for ectopic bone formation or other abnormalities was detected. Finally, ALLOB® cells are immune-privileged and do not elicit an immune response.

Biodistribution studies performed after injection of ALLOB® at the fracture site confirmed that the cells remain on site and do not migrate or accumulate in other non-bone organs, such as brain, heart and lungs.

Additional preclinical experiments were designed to investigate the use of ALLOB® in combination with  $\beta$ -tricalcium phosphate (" $\beta$ -TCP") granules for spinal fusion procedures. The  $\beta$ -TCP scaffold is a synthetic bone substitute designed, optimized, and indicated for bone void filling, in particular in spinal fusion procedure. ALLOB® cells were shown to adhere and spread within the pores of the granules. Importantly, ALLOB® cells were shown to migrate out of the granules, adhere and grow in culture.

The efficacy of the ALLOB<sup>®</sup>/ $\beta$ -TCP mix was assessed *in vivo* and compared to the administration of the granules alone as a control. After 28 days, all animals treated with ALLOB<sup>®</sup>/ $\beta$ -TCP showed new bone formation, while none of the control animals did.

### 6.4.3 Administration via a minimally invasive approach

Administration of the cells is achieved via a minimally invasive technique. The cells are administered directly into the bone defect site through a small skin incision using a small-diameter trephine (similar to a large needle – diameter is 5 mm). During the implantation, the position of the trephine into the bone defect site is visualized by fluoroscopy (a standard radiography used by orthopaedic surgeons). The simple procedure is performed under anaesthesia in an operating room, whereby it only takes 20 minutes to administer the injection.

In case of lumbar spinal fusion, ALLOB<sup>®</sup> is mixed with  $\beta$ -TCP granules and administered locally at the spine surgery site. The procedure includes placement of an interbody (i.e., between the vertebrae) cage and is performed under general anaesthesia in accordance with the standard-of-care procedure of the investigating site.

Administration of PREOB® to osteoporosis patients is achieved by intravenous infusion.

### 6.5 Pipeline

Based on its bone cell technology platform, the Company has built a broad pipeline with different preclinical and clinical candidates in different indications.

Overview of completed and ongoing clinical trials and the preclinical program.

Product	Indication	Project alias	Study title	Nb. of patients	Follow-up (month)	Status
Fracture Repair						
PREOB®	Non-union fracture	PREOB®-NU1	Open, non-controlled, proof-of- concept Phase IIA trial	28	12	Completed
		PREOB®-NU3	Randomized, reference- controlled, pivotal Phase IIB/III trial	176	12	Ongoing (initiated in Q3 2012)
ALLOB®	Delayed-union fracture	ALLOB®-DU1	Open non-controlled proof-of- concept Phase I/IIA trial	32	6	Ongoing (initiated in Q4 2013)
ALLOB®	Spinal fusion	ALLOB®-IF1	Open non-controlled pilot proof-of-concept Phase IIA trial	16	12	Ongoing (initiated in Q3 2014)
	Rescue spinal fusion	ALLOB <sup>®</sup> -RIF1	Open, non-controlled proof-of- concept Phase IIA trial	16	12	Approved in Q4 2014 (just started)
Fracture Pr	revention					
PREOB®	Osteonecrosis	PREOB®-ON2	Randomized, reference- controlled Phase IIB trial	63	24	Completed
		PREOB®-ON3	Randomized, double-blind, placebo-controlled pivotal	130	24	Ongoing

Product	Indication	Project alias	Study title	Nb. of patients	Follow-up (month)	Status
			Phase III trial			(initiated Q1 2012)
PREOB®	Severe osteoporosis	PREOB <sup>®</sup> -OP1	Open non-controlled proof-of- concept Phase IIA trial	20	6	Ongoing (initiated in Q2 2013)
Preclinical	programs					
JTA	Osteoarthritis		Preclinical phase	NA	NA	
MXB	Large bone defe maxillofacial de		Preclinical phase	NA	NA	

#### 6.5.1 Pipeline of fracture repair products

In bone fracture repair, the Company's products are currently being evaluated in two clinical trials, one Phase IIB/III trial for non-union fractures and one Phase I/IIA trial for delayed-union fractures. Both clinical trials are based on minimally invasive implantation of autologous (PREOB®) or allogeneic (ALLOB®) osteoblastic cells at the bone defect site. The Company has initiated a Phase IIA trial for spinal fusion and a Phase IIA trial for rescue spinal fusion.

#### 6.5.1.1 Non-union fractures

**Clinical development – Phase IIA**: "Treatment of refractory atrophic non-union fractures by preosteoblastic cells grafting: a pilot study."

This pilot study was designed to assess the safety and efficacy of PREOB® over 12 months after a single percutaneous administration in patients with hypotrophic non-union fractures. Non-unions were diagnosed by CT scan or X-ray and were defined as fractures that had not united within 6 months.

In this trial, 28 hypotrophic non-union patients were treated, of which 13 had at least one or more additional surgeries after the initial osteosynthesis (stabilization of the fracture by mechanical devices) at the beginning of the trial. The mean non-union duration (i.e., time between fracture onset and PREOB® treatment) of this group of patients was 22 months. Primary outcomes of the study were safety, clinical symptoms evolution and radiological healing. Clinical symptoms, i.e., pain and evaluation of health status, were measured using the visual analogue scale (VAS). Radiological scores were measured by CT-scan and X-ray.

85% of patients treated with  $PREOB^{\otimes}$  in this study met the primary clinical criteria; their clinical and radiological scores improved, avoiding the need of a rescue surgery. More specifically, these patients showed improvement in their health status of at least 25% (66%, p<0.001) and an increase in CT scan score of at least 2 points (from 5.9 to 9.2, p < 0.01). In the global disease evaluation (general health status), a 2-stage evolution was observed, with an immediate improvement after 1 month, followed by a gradual improvement up to month 12 (see figure 4).

66% improvement in patient health status (p<0.001)

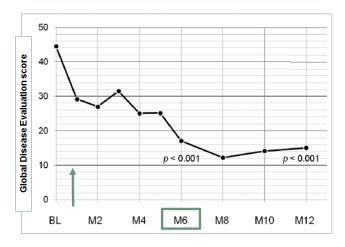


Figure 4: The graph shows the evolution of the Global Disease Evaluation (GDE, measures improvement of health state) score over 12 months (M). P-values indicate the difference with baseline (BL).

From the three treated patients requiring a rescue surgery, 2/3 showed instability of osteosynthesis, which might explain the unsatisfactory results.

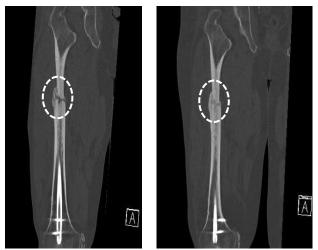


Figure 5: These images show the status of healing of a femoral non-union before (left) and 6 months after (right) a single administration of PREOB®. The non-union site is indicated by a circle.

The study showed no safety concerns. Reported adverse reactions were mainly related to the implantation procedure and remained limited to fever and inflammation. Other reported adverse events were pain at the bone marrow harvest site, nausea, and dizziness.

Building on these positive results, the Company applied for the required clinical trial authorisations to start a Phase IIB/III program.

Clinical development – Phase IIB/III: "A pivotal Phase IIB/III, multicentre, randomized, open, controlled study on the efficacy and safety of autologous osteoblastic cells (PREOB®) implantation in non-infected hypotrophic non-union fractures."

This Phase IIB/III study was designed in compliance with the EMA requirements (Scientific Advice) and based on the design of the Phase IIA study. The program now runs at 10 investigational sites in 3 different countries, Belgium, France and the Netherlands, and efforts are being made to extend the trial to additional sites and to additional countries.

In this ongoing Phase IIB/III study, the safety and efficacy of PREOB® will be evaluated in the treatment of hypotrophic non-union fractures of long bones. 176 patients will be randomized to either receive a single percutaneous administration of PREOB® or bone autograft as reference treatment on a non-inferiority design. This non-inferiority design means that PREOB® does not need to show superiority over the standard-of-care (75 to 85% success) but equivalence (within a certain margin) – PREOB® expected benefit being improved safety thanks to its minimally invasive implantation approach over the very invasive standard-of-care.

The evaluation will be based on the global disease evaluation, pain scales, functional scores and radiological improvement over 12 months. As for the Phase IIA, treatment success will be defined by the following criteria: no need for a rescue surgery, improvement of the global disease evaluation by at least 25% and improvement of the CT scan scores by at least 2 points.

### 6.5.1.2 Delayed-union fractures

Clinical development – Phase I/IIA: "A pilot Phase I/IIA, multicentre, open proof-of-concept study on the efficacy and safety of allogeneic osteoblastic cells (ALLOB®) implantation in non-infected delayed-union fractures."

This first-in-its-kind study was designed in compliance with EMA requirements (Scientific Advice) and was initiated in June 2014. The trial has been approved in three countries, i.e., Belgium, the UK and Germany. The

addition of Germany shows the robustness of the design, since the German Competent Authorities work with very strict regulations on regenerative therapies.<sup>61</sup>

The trial will enrol 32 patients presenting with a delayed-union fracture of a long bone that has not healed after minimum 3 and maximum 7 months. This unique positioning on early fracture treatment is only allowed by the use of an allogeneic product (i.e., ALLOB®) implanted by a minimally invasive approach. It is intended to offer a treatment for patients who are not currently treated.

Safety and efficacy of a single administration of ALLOB® at the bone defect site will be evaluated over 6 months, with an additional post-study follow-up over 24 months. Primary criteria for the study are: no requirement for a rescue surgery, improvement of the global disease evaluation by at least 25% or radiological score improvement of at least 2 points. The study can be prematurely stopped at 16 patients.

Two sub-studies are incorporated in the protocol: one including patients in which the fracture has not shown any signs of healing over 4 previous weeks (no-healing sub-study) and one including fractures that showed slow signs of healing over 4 previous weeks (slow-healing sub-study).

After the treatment of the first cohort of 4 patients, the Safety Monitoring Committee (SMC), consisting of one pharmacist and three medical doctors, reviewed the two weeks post-treatment safety data of these 4 patients. Based on their safety review, the SMC unanimously recommended the continuation of the trial.

The efficacy results of the first 4 treated patients have recently been made available.

During the follow-up period - within the first 6 months after ALLOB administration, 3 out of the 4 delayed-union fractures have completely healed and the last one has shown significant progress to healing, without reaching full healing within the follow-up period. In particular, the delayed-union fractures of the patients at baseline (prior to treatment) showed a very low radiological score (an average of 6, while the lowest score possible is 4) and significantly increased after treatment to an average of 11.7 (while the maximums is  $12^{62}$ ).

The fact that 3 out of the 4 treated delayed-union fractures have fully consolidated in such a short period of time demonstrates the strength of this product.



Figure 6: These images show the progression of healing of a tibial delayed-union fracture from baseline (left) to 6 months after (right) a single administration of ALLOB® of the first patient treated in the proof-of-concept Phase I/IIA trial.

### 6.5.1.3 Spinal fusion

In the spinal fusion studies, the Company combines its  $ALLOB^{\$}$  cells with osteoconductive micro-granules. Therefore, the Company has entered into collaboration with Kasios $^{\$}$ , a European leader in synthetic bone substitutes. The combination of  $ALLOB^{\$}$  and the micro-granules is expected to have the potential to enhance 3D growth and bone growth, bringing advantages in stability and structure. More specifically the use of  $ALLOB^{\$}$  mixed with  $\beta$ -TCP at the fusion site aims to promote the fusion process by (i) providing biologically active osteoblastic cells; (ii) creating a healthy bone environment; and (iii) guiding the growth of bone tissue in three dimensions. This approach presents the three required features, i.e., osteogenic, osteoconductive and

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<sup>&</sup>lt;sup>61</sup> Although all countries have very high standards for cell products, Germany has more than the others given attention to this group of innovative treatments with the Paul-Ehrlich Institut (the biologicals arm of the German Competent Authority) and their presence at the Committee for Advanced Therapies at the European Medicines Agency.

<sup>&</sup>lt;sup>62</sup> The radiological healing is assessed by CT scan using the Tomographic Union Score (TUS). The TUS can range from 4 to 12.

osteoinductive, for bone formation enhancement. Preclinical studies have already shown that osteoblastic cells mixed with  $\beta$ -TCP present the ability to induce formation and mineralization of bone tissue. <sup>63</sup> Based on these findings, the local implantation of ALLOB® mixed with  $\beta$ -TCP should provide an effective therapeutic strategy for lumbar spinal fusion to promote bone formation at the lesion site of affected patients.

**Clinical development – Phase IIA**: "A pilot Phase IIA, Multicentre, Open, Proof-of-concept Study on the Efficacy and Safety of Allogeneic Osteoblastic Cells (ALLOB<sup>®</sup>) in Lumbar Spinal Fusion."

The proof-of-concept study for spinal fusion procedures was initiated in September 2014. It will include 16 patients that suffer from symptomatic degenerative lumbar disc disease who require single level lumbar fusion. Stability will be achieved by the implantation of an interbody cage (PEEK; polyetheretherketone) according to the standard-of-care surgical approach. Local administration of ALLOB® mixed with  $\beta$ -TCP granules is intended to promote bone formation during the lumbar interbody fusion and avoid the need for a revision surgery.

Safety and efficacy will be determined over 12 months, with a 24-month post-study follow-up. Efficacy will be determined by change in the Oswestry Disability Index and change from baseline in main fusion score (radiological evaluation) at month 12.

#### 6.5.1.4 Rescue spinal fusion

The current failure rate for spinal fusion is very high, with rates of 5% to 35% reported in literature. Failed fusion often comes with debilitating pain and deformity, therefore these cases require a revision surgery to place new/better graft material in order to provide a new boost to the fusion process. However, revision procedures are associated with even higher complication rates as well as disappointing clinical and radiological improvement. By providing a minimally invasive alternative to a second surgery, the quality of life of these failed-fusion patients can be enhanced. The Company recently received the approval to start this second spinal fusion study that focuses on these patients in which a first spinal fusion has failed.

**Clinical development – Phase IIA:** "A pilot Phase IIA, single-site, open, proof-of-concept study on the safety and the efficacy of allogeneic osteoblastic cells (ALLOB<sup>®</sup>) implantation in rescue interbody fusion."

In this proof-of-concept trial, 16 patients requiring a revision surgery after failure of an initial lumbar spinal fusion (15 months) will be treated by percutaneous administration of a single dose of ALLOB<sup>®</sup>. Safety and efficacy of this treatment over 12 months will be evaluated by change from baseline in mean fusion score and in ODI 2.1 clinical evaluation. Two populations of patients will be studied, a symptomatic population and an asymptomatic population.

#### 6.5.2 Pipeline for fracture prevention products

The Company's products for fracture prevention are currently in Phase III development for osteonecrosis of the hip and Phase II development for severe osteoporosis.

### 6.5.2.1 Osteonecrosis of the hip

Osteonecrosis of the hip is characterized by the death of bone cells and loss of the associated marrow elements. It is a painful condition in which the joint degenerates progressively, ultimately leading to the collapse of the femoral head requiring a total hip replacement. The cause and pathophysiology of osteonecrosis has not been completely unravelled. It was initially suggested that obstruction of the blood flow was at the basis of the disease, but this hypothesis has never been confirmed. Evidences exist that demonstrate the direct involvement of mesenchymal and osteoblastic cells. More specifically, it has been shown that the activity and number of MSC and osteoblastic cells have decreased in patients affected by osteonecrosis. In line with these observations, studies showed that the grafting of bone marrow cells into the necrotic hip improves clinical and radiological scores. A very important observation was made in these studies; the effectiveness of the bone marrow graft was directly linked to the number of MSC with osteogenic properties present in the bone marrow. The implantation of PREOB®, which is composed of osteoblastic cells, should provide a more effective treatment.

 <sup>&</sup>lt;sup>63</sup> Gan et al., The clinical use of enriched bone marrow stem cells combined with porous beta-tricalcium phosphate in posterior spinal fusion.
 *Biomaterials* 2008(29)3973-3982; Beuvelot et al. *In vitro* assessment of osteoblast and macrophage mobility in presence of β-TCP particles by videomicroscopy. *J Biomed Mater Res A.* 2010 (1)108-115.
 <sup>64</sup> Weinstein et al. Apoptosis of osteocytes in glucocorticoid-induced osteonecrosis of the hip. *J Clin Endocrinol Metab* 2000(85)2907-2912.

Weinstein et al. Apoptosis of osteocytes in glucocorticoid-induced osteonecrosis of the hip. *J Clin Endocrinol Metab* 2000(85)2907-2912.
 Gangji et al. Treatment of osteonecrosis of the femoral head with implantation of autologous bone-marrow cells. A pilot study. *J Bone Joint Surg.* 2004(86)1153-1160.

**Clinical development – Phase IIB**: "Treatment of osteonecrosis of the femoral head by implantation of preosteoblastic cells: a randomized, controlled double blind pilot study."

The Phase IIB study, conducted at the Erasme University Hospital (Brussels) and CHU Sart-Tilman (Liège), enrolled 53 patients with early prefractural stage (I and II) osteonecrosis of the femoral head. From these patients, 63 hips were randomized into two groups: one group (including 32 hips) was treated with PREOB® and the other group (including 31 hips) with an active reference (i.e., bone marrow graft). Both treatments were combined to core decompression, the standard treatment.

Of the 53 patients, 43 were treated at one hip, while 10 were treated at both hips. These bilaterally-treated patients received PREOB® in one hip and reference in the other.

Safety and efficacy were determined over 24 and 36 months. Primary endpoints included clinical (Pain VAS) and radiological (progression to fractural stage) changes at month 24 and 36.

The study showed that a single administration of PREOB® translates into a strong and prolonged improvement of clinical symptoms (pain and function) versus baseline (>40%) and reference levels (>60%). Fracture risk was reduced by 41.9% at 24 months and by 43.5% at 36 months compared to the reference treatment.

According to the literature, the fracture rate at 24 months reaches 66% with Standard of Care<sup>66</sup>. The study showed that with PREOB®, the fracture rate, still at 24 months, decreases to 19%, enabling a decrease in fracture risk of about 71% compared to the Standard of Care.

### 40% p=0.367 p=0.492 20% 64% pain improvement (p=0.008)-20% 0.010p=0.003 -40% p<0.001 -60% M12 ---PRFOR® -0-Ref.

#### Pain Relief Evolution from Baseline

p-values indicate the difference vs. baseline

Figure 7: The graph shows the evolution of the pain score over 36 months (M) in comparison to baseline.

An interesting observation was made in patients where both hips were treated. The reference-treated hip of these patients showed more improvement than that of patients who were only treated at one hip with this reference (0% fracture risk of reference hip in patients treated at both hips vs. 54.5% fracture risks of reference hip in patients treated at this hip alone), suggesting a contralateral effect of PREOB<sup>®</sup>.

No severe adverse effects, related to PREOB® or to the procedure, were reported, except for 2 patients who had a prolonged hospital stay due to fever and inflammatory symptoms. These symptoms quickly resolved.

Altogether, these data strongly supported further development of PREOB® in osteonecrosis, with the initiation of a Phase III study on the efficacy and safety of PREOB® in patients with early-stage osteonecrosis of the femoral head.

**Clinical development – Phase III:** "Phase III, pivotal, multicentre, randomized, double-blind controlled Study to evaluate the Efficacy and Safety of Autologous Osteoblastic Cells (PREOB®) Implantation in Early Stage Non Traumatic Osteonecrosis of the Femoral Head."

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Average of 4 rates in 3 different references: Bozic KJ, Zurakowski D, Thornhill TS. Survivorship analysis of hips treated with core decompression for nontraumatic osteonecrosis of the femoral head. J Bone Joint Surg Am. 1999; 81: 200-209.

Gangji V, Hauzeur JP, Matos C, De Maertelaer V, Toungouz M, Lambermont M. Treatment of osteonecrosis of the femoral head with implantation of autologous bone-marrow cells. A pilot study. J Bone Joint Surg. 2004; 86: 1153-1160.

Koo KH, Kim R, Ko GH, Song HR, Jeong ST, Cho SH. Preventing collapse in early osteonecrosis of the femoral head. A randomised clinical trial of core decompression. J Bone Joint Surg Br. 1995; 77: 870-874.

This pivotal trial was designed according to the EMA/FDA requirements (Scientific Advice/pre-IND). The trial is currently ongoing in 32 sites in Belgium, France, the Netherland, the UK and Germany.

Following a superiority design, the study will enrol 130 patients with early stage (non-fractural) osteonecrosis of the hip of which 65 patients will receive a single percutaneous administration of PREOB®, while the other 65 patients will receive a placebo via the same procedure. Compared to the Phase IIB which had also a superiority design, the use of placebo instead of the active reference of the Phase IIB was required by the double-blinding. Finally, using the same endpoints as for the Phase IIB, pain (WOMAC score) and fracture risk (x-ray) evolution will be evaluated over 24 months.

#### 6.5.2.2 Severe osteoporosis

Clinical development – Phase IIA: "Treatment of Severe Osteoporosis by Intravenous Infusion of Preosteoblastic Cells: An Open Pilot Study."

This study aims to demonstrate the safety and efficacy of PREOB® in the treatment of osteoporotic patients who do not respond to pharmacological treatments. 20 patients will be treated with a single intravenous administration of PREOB®. In this study, the fate and distribution of PREOB® will be determined by SPECT/CT scan after intravenous infusion and the effect on clinical symptoms and on bone markers will be measured over 12 months.

### 6.5.3 Preclinical programs

#### 6.5.3.1 MXB

MXB is an injectable combined osteoblastic cell-matrix product for the treatment of large bone defects by a minimally invasive approach. The combined cell-matrix product is initially liquid polymerises *in situ*. Preclinical research showed that this product is non-immunogenic and highly resorbable. The scaffold structure displays an optimal porosity with micro- and macropores as well as cell adhesion factors. Preliminary results indicate very strong mineralisation capacity of the cells inside the composite scaffold. Two weeks after injection, *in vivo* bone size almost doubled after a single administration of MXB in the calvaria bone formation model.

#### 6.5.3.2 JTA

JTA is an enhanced viscosupplement for intra-articular administration into the osteoarthritic joint. A Phase I/IIB clinical study is in preparation. This prospective, double-blind, reference-controlled study in preparation aims to evaluate the safety and efficacy of JTA-treatment for osteoarthritis. Seventy-five patients suffering from symptomatic osteoarthritis of the knee will be enrolled to receive a single intra-articular injection. The patients will be randomized into three groups, with two groups receiving 2 different doses of JTA and one group receiving reference product (Ostenil<sup>®</sup> Plus). Safety and efficacy will be assessed after 6 months, with an interim analysis at month 3. The primary endpoint will be the mean differences in WOMAC<sup>®</sup> VA3.1 pain subscale scores between baseline and month 6, compared between JTA and the reference group.

### 6.6 Positioning and pricing strategy

### 6.6.1 Positioning and pricing strategy in fracture repair

### 6.6.1.1 Positioning and pricing strategy of PREOB® for non-union and delayed-union fractures

The standard of care treatment for non-union fractures is bone autograft. This is currently perceived to be the only therapy providing all the necessary properties for a successful treatment; more specifically, it combines osteogenic, osteoinductive and osteoconductive properties. However, bone autograft is a highly invasive procedure associated with major complications. Consequently, PREOB® will be positioned as a first-line treatment for this condition. The price of PREOB®, if approved, will be determined based on cost-effectiveness data. Kanakaris  $et\ al$ . estimated the costs related to non-union fractures including medical and non-medical direct costs as well as indirect costs from lost wages and impairment in the UK. They concluded that the average overall cost of a non-union fracture of the femur was nearly  $\[mathebox{\ensuremath{\in}}\]$  21,700 (including investigation, hospitalization, operation, drugs, rehabilitation and indirect costs). The cost of bone autograft in the treatment

<sup>&</sup>lt;sup>67</sup> Kanakaris et al. The health economics of the treatment of long-bone non-unions. *Injury* 2007(38)77-84.

of non-unions is estimated to be € 7,700<sup>68</sup> (this number includes surgery, implant, hospitalization and theatre costs for the UK). Treatment with PREOB® instead of bone autograft can reduce the long-term costs (earlier treatment) as well as surgery, hospitalization and complication costs (decreased need for hospitalization and less side effects).

Currently, most delayed-union fractures are left untreated and a "wait and see" approach is applied. This delays the patient's return to a normal life and places a significant financial burden on society. Reducing healing time could create substantial cost savings by decreasing the need for secondary procedures and the amount of time needed for a patient to return to a normal life.<sup>69</sup> ALLOB<sup>®</sup>, if approved, will thus be positioned as a first line treatment for delayed-unions. The price of ALLOB® will be determined based on cost-effectiveness data, comparing the costs of treatment delay and eventual surgery to early treatment with ALLOB®.

### 6.6.1.2 Positioning and pricing strategy of ALLOB® for spinal fusion procedures

The current gold standard for facilitation of spinal fusion surgery is bone autograft. Since treatment with ALLOB® is an addition to a currently accepted method, limited market education would be necessary. ALLOB® for spinal fusion would, if approved, be positioned as a first line treatment.

#### 6.6.2 Positioning and pricing strategy in fracture prevention

### 6.6.2.1 Positioning and pricing strategy of PREOB® in osteonecrosis treatment

Early-stage osteonecrosis is mostly treated by core decompression. However, this treatment is subject to variable success rates. For late-stage osteonecrosis, currently the only option is total hip replacement. Based on current practice and available treatment options, nearly half of the patients will require total hip replacement before the age of 40, creating a substantial unmet medical need in the osteonecrosis field. PREOB®, if approved, will be positioned as a first-line treatment for early-stage osteonecrosis. The price of PREOB® for osteonecrosis will depend on cost-effectiveness analyses which will be most affected by the delay in disease progression. Core decompression is estimated to have a cost of € 2,400,<sup>70</sup> and total hip replacement a cost of € 9,400<sup>71</sup> in the UK and over \$28,000 in the US. Treatment with PREOB® will decrease costs related to surgery as well as hospitalization.

### 6.6.2.2 Positioning of PREOB® for osteoporosis

PREOB® if approved for the treatment of osteoporosis will be positioned as a last-line treatment in patients not responding to existing treatments. The Company will search for a partner to commercialize the product after finalization of the Phase II study.

#### 6.6.3 Indicative pricing, time to market and peak sales

To date, the Company has no product authorised for commercialisation and the price setting, the availability and level of adequate reimbursement by third parties is highly uncertain.

According to an assessment study commissioned by the Company and to management beliefs, the Company estimates that a price level between € 10,000 and € 15,000 for Europe and between € 15,000 and € 22,000 for the US would be justified – and likely to be reimbursed - if sufficient efficacy is demonstrated.

On the basis of currently available information, the Company estimates that the time to market for its first product would be around 2020. The Company would expect to reach peak sales within 5 to 6 years in line with the standard of the industry (which may however vary for the different products and indications (in function among others of the learning curve required to introduce change in the medical community and of the unmet medical need).

The commercial success of the products will depend in part on the conditions for setting the sales price and the conditions of their reimbursement in the countries where the Company intends to commercialise its products. Considering the innovative nature of the Company's product candidates and the lack of similar products, the possible reimbursement levels are difficult to predict.

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<sup>68</sup> Alt et al. A health economic analysis of the use of rhBMP-2 in Gustilo-Anderson grade III open tibial fractures for the UK, Germany, and France. Injury 2009(40)1269-1275; Dehabreh et al. A cost analysis of treatment of tibial fracture nonunion by bone grafting or bone morphogenetic protein-7. Int Orthop 2009(33)1407-1414.

Heckman et al. The economics of treating tibia fractures. The cost of delayed unions. Bull Hosp Jt Dis. 1997(56)63-72.

WPA Fee Schedule: http://www.wpa.org.uk/medical/medicalfees.aspx?heading\_id=all; NICE TAG Total hip replacement and resurfacing arthroplasty for endstage arthritis of the hip, February 2014

71 NICE TAG Total hip replacement and resurfacing arthroplasty for endstage arthritis of the hip, February 2014.

#### 6.7 **Investments**

The Company is currently investing in new facilities through SCTS, in view of opening a new manufacturing facility in Gosselies (south of Brussels) mid-2016 after obtaining GMP accreditation. The modular design of the facility will allow for a progressive - on-demand - increase in commercial production capacity with up to 5,000 batches for PREOB® and 12,000 batches for ALLOB®.

The new facilities will provide accommodation for both the Company's as well as SCTS's activities in respect of production, research and development (including production process development) and will be the headquarter of the Company.

The total program represents an investment of approximately € 9.50 million. The investment plan has been staged in three phases. A first phase is expected to be completed by the end of March 2015 and includes the entire shell of the building and the completed administration and research and development facilities. By the end of 2015 the second phase, including the first two manufacturing units, is expected to be completed. The third phase is planned for 2017 and comprises the installation of four more production units, to meet the production requirements for clinical trials, pre-commercial and the first commercial activities. Further modules can be added in future to increase capacity in line with demand. These additional modules fall outside the scope of the aforementioned investment budget.

The total facility represents approximately 3,000 m<sup>2</sup> in total of which 1,700 m<sup>2</sup> of administrative facilities and R&D facilities including an animal house and 1,300 m<sup>2</sup> foreseen for production activities. The new animal house will allow pursuing the preclinical animal studies required to support the development of clinical and preclinical candidates. These animal studies encompass efficacy and toxicity studies that are regulatory required.

The investment project is fully financed by four different sources. The direct investment for the Company amounts to € 1.27 million representing the equity investment of the Company into SCTS. In addition to the equity investment by the Company an amount of € 1.28 million in equity has been provided for by other shareholders of SCTS, representing the non-controlling interest. A further amount of € 0.87 million in subordinated loans has been provided for by two regional investment bodies (related parties) and € 2.90 million is provided through an investment grant provided for by the Region under the SME Agreement. Finally, € 3,250,000 is provided in bank loans in equal shares by BNP Paribas Fortis SA and ING Banque SA (see also Section 6.10 "Financing Agreements").

The facility fits in a larger project known as the Walloon Cell Therapy Platform ("PWTC") (Pôle Wallon de la Thérapie Cellulaire) whereby two cell therapy companies<sup>72</sup> have joined forces to build facilities at a joined location on the Industrial Park "Aéropôle" at Gosselies (50 km south of Brussels, near the airport Brussels South) (see also Section 9.3 "Holdings"). PWTC comprises three service companies: SCTS (Skeletal Cell Therapy Support), HCTS (Hepatic Cell Therapy Support) and SISE (Société d'Infrastructure, de Services et d'Energies) (See Section 9.3 "Holdings"). SCTS and HCTS will make a maximum use of shared services provided through SISE SA to establish their industrial project, but on the same time maintaining control of their proprietary production processes and know-how by having their own physically separated building infrastructure. The project allows for both companies to considerably expand their production capacity in future. Besides a service provider, SISE SA is also the landowner on which the infrastructure of SCTS is constructed. There is long term (99 years) lease agreement in place between SISE and SCTS.

The Company invests in equipment to support its research and development and production activities on a regular basis.

Overview of the Company's principal investments for the financial years ended on 31 December 2012 and 31 December 2013.

(in Thousands of €)	2013		2012	Before 2012	Total
	Disposals	New	New	New	
Property under construction	0	1,604	418	0	2,022
Laboratory equipment	-9	133	94	1,548	1,766
Land	0	233	0	0	233
Other	-4	12	20	135	163
Intangible assets	0	61	24	11	96

Property under construction relates to the new facilities constructed by SCTS at the BioPark of Gosselies (south of Brussels). The investment for 2012 is € 418,000 and for 2013 the amount is € 1,604,000. At 31 December 2013 the total amount invested is  $\in$  2.022.000.

<sup>&</sup>lt;sup>72</sup> Bone Therapeutics SA through SCTS SA and Promethera SA through its subsidiary HCTS (Hepathic Cell Therapy Support) SA.

Laboratory equipment includes capital expenditure for € 94,000 in 2012 and € 133,000 in 2013. At 31 December 2013 the total amount invested is € 1,766,000 (included disposals € 9,000 and an amount of € 100,000 is related to assets under finance lease in 2013 and € 81,000 in 2012.

Land represents a long lease right of 99 years on which the new facilities of the Company are being constructed. The amount is  $\in$  233,000.

Others investments include IT material and office furniture. At 31 December 2013, the total amount invested is  $\in$  163,000(included disposals  $\in$  4,000).

Intangible assets consist only of software. At 31 December 2013, the total amount invested is € 96,000.

### 6.8 Material agreements

For information on the Company's material financing agreements see Section 6.10 "Financing Agreements".

For information on the Company's material grants and subsidies agreements see Section 6.11 "Grants and subsidies".

The Company has entered in addition into the following material agreements, including license related agreements:

### 6.8.1 Shareholders' agreement in relation to SCTS

The Company entered into a shareholders' agreement in relation to SCTS dated 30 November 2011 (as amended on 20 February 2013), together with the other shareholders in SCTS (which are, whether directly or indirectly, also shareholders of the Company). This agreement contains a set of provisions governing the rights and obligations of the Company in relation to SCTS. Amongst others, the agreement contains a broad undertaking by the Company to use the services provided by SCTS in accordance with the invoicing policy included in the agreement, which results in undertaking by the Company to guarantuee a preferred minimum dividend payment of 6.5% to the other shareholders of SCTS. Also, under the agreement the other shareholders of SCTS have a put option, pursuant to which the Company will be bound, as of 1 January 2020, to acquire the shares of such shareholders which have exercised their put option at net asset value, with a minimum of 90% of the subscription price (in aggregate, € 1,150,000). In addition, the agreement contains a call option right pursuant to which the Company has the right, until 31 December 2019, to acquire the shares held by such other shareholders, for a price generating an internal rate of return of 8% for these shareholders.

### 6.8.2 License agreement between Université Libre de Bruxelles (ULB) and the Company regarding ULB-028 patent family

The Company entered into a license agreement with the ULB regarding the ULB-028 patent family which is owned by the ULB. This agreement provides the Company and its affiliates with a personal and non-transferable, exclusive, worldwide license over the technology claimed by the ULB-028 patent family. The ULB retains the right to operate this technology for research and educational purposes only. The Company may grant sublicenses, the choice of such sub-licensee(s) being subjected to prior approval by the ULB. In consideration of the rights granted to the Company, the Company must make payments to the ULB upon achievement of certain development and patent related milestones. In addition, the Company must pay to the ULB (i) single digit royalties based on the net sales of licensed products sold by the Company and (ii) a high single digit percentage of all revenues received from sub-licensees for products as of Phase III and low double digit royalties for products in Phase I or II.

The Company has recognized that it must diligently perform research and development obligations and objectives as set out in the company and development plan and must use its best efforts to promote, market and distribute the above technology in a manner consistent with the said plan. In the case of failure to do so, the Licensor may require the Company to produce a written report summarizing its efforts during the previous year and the milestones to be achieved in the next year, and if the licensor demonstrate that such report is reasonably not satisfactory, an independent expert can be called to evaluate the Licensee's report and the Licensor's objections. If the Company does not succeed to reach the new objectives fixed, either on a mutual agreement by the Parties or by the independent expert, Licensor may either reduce the scope of the agreement or make the agreement non-exclusive or terminate it.

In the event that the Company develops an improvement to the technology, it must grant the ULB a free, perpetual, worldwide and non-exclusive license over such improvement for research and educational purposes only. The ULB is also granted a right of first refusal to negotiate license rights over such improvement outside the skeletal and dental diseases and application field for commercial purposes. In the event that the ULB

develops an improvement to the technology, the Company has a right of first refusal to negotiate license rights over such improvement at fair market conditions.

This license agreement will expire on the date of expiry of the last to expire patents in the licensed patent family or ten years after the first commercialization date, whichever is latest. Either party may terminate the agreement if the other party (i) is in breach of its terms and fails or has not taken reasonable steps to remedy the breach within 60 days of receiving written notice to do so, (ii) is declared bankrupt, has its assets placed in the hands of a receiver or makes accommodation for the benefits of creditors or (iii) ceases to do business.

# 6.8.3 Co-ownership agreement between the ULB, the University de Liège-Patrimoine, le Centre Hospitalier de Liège and the Company regarding the ULB-061 patent family

The ULB, the University de Liège-Patrimoine (ULG), le Centre Hospitalier de Liège (CHU) and the Company entered into a co-ownership agreement dated 18 October 2011 regarding the ULB-061 patent family.

According to this agreement, the Company owns 15 % of the claimed invention and related patent rights, the ULB owns 70 % of the invention and rights and the ULG and CHU jointly own the remaining 15 %. None of the granted rights can be exercised by a single party but only jointly. While the day-to-day administration of the patent rights and the economic valorisation of the claimed invention will be taken care of by the ULB, all decisions regarding to the geographic scope of the patent rights or their technical content shall be taken jointly by the parties.

The Company is granted a right of first refusal of an exclusive patent license agreement regarding the considered patent family. Such license agreement was entered into on 17 April 2014 (see under 6.8.4 below).

The costs and benefits generated by the patent prosecutions and the operation of the claimed invention shall be shared by the parties according to their respective part in the ownership of the invention and related patents, after a 10 % deduction attributed to the ULB for covering its costs for the daily administration of the patent rights and the economic valorisation of the claimed invention.

If the claimed invention is operated by the Company according to its above right of first refusal, the cost of the patent prosecution shall be supported by the Company for the duration of the granted patent license and the benefits of this operation shall be shared with the other parties according to their part in the ownership of the invention and related patent rights.

Each party is granted a right of first refusal relating to the stake of the other parties in the ownership of the claimed invention and related patent rights, and no party is authorized to assign its part in this ownership before the other parties have exercised their right of first refusal.

Each party shall remain the sole owner of its improvements to the invention. If such improvements are provided jointly by the parties, they shall negotiate their respective part in the ownership of these improvements according to their respective contribution to the latter. This agreement remains in force until the expiration or withdrawal of the last patent. However, each party is authorized to leave the co-ownership after a 5 year time period has lapsed following the signature date of the agreement.

# 6.8.4 License agreement between the ULB, the University de Liège-Patrimoine, le Centre Hospitalier de Liège and the Company regarding the ULB-061 patent family

The ULB, the University de Liège-Patrimoine (ULG), le Centre Hospitalier de Liège (CHU) and the Company entered into a co-ownership agreement dated 18 October 2011 (see under 6.8.3 above) regarding the ULB-061 patent family, according to which the Company was granted a right of first refusal to obtain a license agreement regarding the said patent family. Implementing this right of first refusal, the parties entered into a license agreement on 17 April 2014. Under this agreement, the Company is granted an exclusive, non-assignable, worldwide license to use the technology claimed by the ULB-061 patent family in the field of bone and joint pathologies.

The licensors however retain the right to operate this technology in the above field for research and educational purposes only. The Company may grant sublicenses, the choice of sub-licensee(s) being subject to prior approval by the licensors. In consideration of the rights granted to the Company, it pays certain moderate lump-sum amounts and single digit royalties to the licensors.

The Company recognizes that it must use its reasonable commercial efforts to develop products under the technology according to a development program (which the Company may reasonably amend) appended as schedule 2 to the license agreement (preclinical development during 2014-2016, exploratory Phase I/IIA study

during 2017-2019, confirmatory Phase IIB/III study during 2020-2024, regulatory approval (CE marking) during 2025, EU product launch from 2026).

The Company must use its best efforts to manufacture and market such products according to a marketing plan to be drafted by the Company not later than 60 months after the date of the license agreement. If it fails to do so, the licensors may require the Company to produce a written report summarizing its efforts during the previous year and the milestones to be achieved in the next year, and if the licensors demonstrate that such report is reasonably not satisfactory, they may terminate the license agreement.

In the event that the Company develops an improvement to the technology, it must grant the licensors a free, perpetual, worldwide non-exclusive license over such improvement for research and educational purposes only. In the event that the ULB develops an improvement to the technology and is willing to license it, the Company has a right of first refusal to negotiate license rights over such improvement in the field of the license.

The license agreement will expire on the expiry of the obligation to pay royalties as determined above. In such case the license is said to become perpetual and fully paid-up. The Company may terminate the license agreement at its discretion by giving 6 months prior written notice to the licensors.

Either party may terminate the agreement if the other party is in breach of its terms and fails or has not taken reasonable steps to remedy the breach within 60 days of receiving a written notice to do so.

The licensors may terminate the agreement if the Company, (i) ceases to carry on its business related to the agreement, (ii) is likely to become insolvent or bankrupt or subjected to liquidation or insolvency proceedings or (iii) commits an act of dishonesty with respect to the licensors or the technology (such as challenging ownership or validity of patents in the patent family).

# 6.8.5 License agreement between Enrico Bastianelli SPRL and the Company regarding the BPBONE-001 and BPBONE-002 patent families

The Company entered into a license agreement with Enrico Bastianelli SPRL regarding the BPBONE-001 and BPBONE-002 patent families (the agreement refers to the priority patent application number claimed for both families, derived from divisional applications of the said priority application) which were owned by Enrico Bastianelli SPRL prior to their transfer to the Company. This agreement provides the Company and its affiliates with a personal and non-transferable, exclusive, worldwide license over the technology claimed by the BPBONE-001 and BPBONE-002 patent families. The Company may grant sublicenses, the choice of sublicensee(s) being subjected to prior approval by Enrico Bastianelli SPRL.

In consideration of the rights granted to the Company, the Company pays certain moderate lump-sum payments and average low single digit royalties on net sales to Enrico Bastianelli SPRL. Sublicense agreements are subject to royalties in line with Section 6.8.2 "License agreement between Université Libre de Bruxelles (ULB) and the Company regarding ULB-028 patent family".

The Company recognizes that it must diligently perform research and development obligations and objectives and must use its best efforts to promote, market and distribute the above technology. In the case of failure to do so, Enrico Bastianelli SPRL may terminate the agreement. If the exploitation of the technology by the Company would be delayed for a period of 15 months in comparison to the objectives except in case of *force majeure*, Enrico Bastianelli SPRL may also terminate the license agreement.

In the event that the Company develops an improvement to the technology, Enrico Bastianelli SPRL is granted a right of first refusal to negotiate license rights over such improvement outside the skeletal diseases and application field for commercial purposes.

The license agreement will expire on the date of expiry of the last to expire patents in the licensed patent family or ten years after the first commercialization date. Either party may terminate the agreement if the other party (i) is in breach of its terms and fails or has not taken reasonable steps to remedy the breach within 60 days of receiving written notice to do so, (ii) is declared bankrupt, has its assets placed in the hands of a receiver or makes accommodation for the benefits of creditors or (iii) ceases to do business. If the development of the technology is not sufficiently supported by public research grants, the Company has also the right to terminate the agreement.

This agreement was succeeded by an agreement entered into on 17 December 2014. This agreement confirms that the assignment of the BPBONE-001 and the BPBONE-002 patent families to the Company has taken place. Reflecting this new reality, the rights granted under both patent families and the related data and know-how are quasi identical as under the previous agreement but within the field of joint diseases and applications.

Other provisions which differ from the previous agreement relate to New Improvements (which can be exploited by the Company subject to payments of 50% of the payments described above), New Patents (which will be owned by the Company and otherwise governed by the same terms and conditions), the Term of the agreement (expiration of the patents) and the consequences of Termination (the ownership of the BPBONE-001 and BPBONE-002 patent families and of any New Patent will automatically be transferred to Enrico Bastianelli SPRL).

# 6.8.6 Agreement between Enrico Bastianelli SPRL and the Company regarding the BONE-011 patent family

The Company entered into an agreement dated December 17, 2014 with Enrico Bastianelli SPRL regarding their jointly owned BONE-011 patent family.

Under this agreement the Company is granted an exclusive and worldwide license in the field of cell therapy for bone diseases (royalty-free) and in the field of joint diseases and applications (on a royalty bearing basis). These royalties to be paid by the Company are identical to the royalties and percentages which are due under the agreement between the same parties regarding the BPBONE-001 and BPBONE-002 patent families (see Section 6.8.5 "License agreement between Enrico Bastianelli SPRL and the Company regarding the BPBONE-001 and BPBONE-002 patent families").

Should this agreement be terminated, both co-owners will be entitled to freely use their co-owned BONE-011 patent in the field of their respective activities: cell therapy for the treatment of bone diseases for the Company and the other applications for Enrico Bastianelli SPRL.

# 6.8.7 Sublicense agreement between SCTS and the Company regarding the EP member of the ULB-028 patent family

This agreement provides SCTS with a personal, non-transferable, royalty-free license over the technology claimed by the ULB-028 patent family (patent rights, data and know how related to the said patent rights) to use, perform research, develop and manufacture products in the name of the Company in the framework of the PROFAB agreement (R&D agreement between SCTS, the Region and the Company) (see Section 6.11.2.1 "Recoverable cash advances". This license applies to the osteoarticular indications and applications field.

The Company is granted a worldwide exclusive back-license over all the results and improvements obtained by SCTS in the above field. In consideration of the said back-license, the Company must pay to SCTS certain determined milestones amounts which correspond to the best estimation of SCTS' R&D expenses, but can be adjusted in order to match the real expenses. In addition, the Company must pay single digit royalties to SCTS on the revenues from the manufacturing by the Company of products developed and optimized by SCTS under the PROFAB agreement and low single digit royalties on the revenues from the manufacturing of such products by SCTS.

SCTS is in charge of the prosecution, maintaining in force and defence of the validity of the members of the licensed patent family. SCTS recognizes that it must diligently perform its research, development and manufacturing obligations and objectives as set out in the PROFAB agreement and in a manner which is consistent with the standards of the Company. The license agreement will expire on the date of expiry of the PROFAB agreement or later if agreed by the parties.

In the case of the exploitation of PROFAB results, the expiry of the PROFAB agreement also makes an end to the reimbursement period of the funding under this agreement. The decision not to exploit PROFAB results in the above field needs to be taken by both SCTS and the Company.

Either party may terminate the agreement if the other party (i) is in breach of its terms and fails or has not taken reasonable steps to remedy the breach within 60 days of receiving written notice to do so, (ii) is declared bankrupt, has its assets placed in the hands of a receiver or makes accommodations for the benefits of creditors or (iii) ceases to do business.

# 6.8.8 Sublicense agreement between the Company and SCTS regarding the BPBONE-001 & 002 patent families

This agreement provides SCTS with a personal, non-transferable, royalty-free license over the technology claimed by the BPBONE-001 and 002 patent families (patent rights, data and know how related to the said patent rights) to use, perform research, develop and manufacture products under this technology in name of the Company in the framework of the JTA PROD agreement (R&D agreement between the Company, SCTS and

the Region) (see Section 6.11.2.1 "Recoverable cash advances"). This license applies to the osteoarthritis indications field.

The Company is granted a worldwide exclusive back-license over all the results and improvements obtained by SCTS in the above field. In consideration of the said back-license, the Company must make payments to SCTS in accordance with an agreement between the parties to be set out in a separate document. It is not clear if such separate document has already been agreed between the parties.

SCTS is in charge of the prosecution, maintaining in force and defence of the validity of the members of the licensed patent family. SCTS recognizes that it must diligently perform its research, development and manufacturing obligations and objectives as set out in the JTA PROD agreement and in a manner which is consistent with the standards of the Company.

The license agreement will expire on the date of expiry of the JTA PROD agreement or later if agreed by the parties. In the case of the exploitation of the JTA PROD results, the expiry of the JTA PROD agreement also makes an end to the reimbursement period of the grant under this agreement. The decision not to exploit the PROFAB results in the above field needs to be taken by both SCTS and the Company.

Either party may terminate the agreement if the other party (i) is in breach of its terms and fails or has not taken reasonable steps to remedy the breach within 60 days of receiving written notice to do so, (ii) is declared bankrupt, has its assets placed in the hands of a receiver or makes accommodations for the benefits of creditors or (iii) ceases to do business.

#### 6.9 Collaborations

#### 6.9.1 Industrial collaborations

The Company has entered into industrial collaborations with:

- Kasios SPRL (Belgium and France), to develop a novel product for spinal fusion procedures. The collaboration combines the Company's allogeneic product ALLOB® with Kasios' synthetic microgranules bone substitute. The project is supported by the Region and will run for two years. Kasios is a France-based company with a Belgian subsidiary (Kasios SPRL) that specializes in synthetic bone substitutes for orthopaedics and dental surgery and has an established expertise in biomaterials.
- Fujifilm Manufacturing Europe B.V. (The Netherlands), to identify the therapeutic advantages of the combined use of recombinant-collagen scaffold and cells for orthopaedic applications. A Marie Curie grant has been awarded (part of the European Commission Seventh Framework Programme for Research and Innovation (FP7)) to support the project. The Dutch manufacturing company is one of the largest Fujifilm production companies outside Japan.
- SIRRIS (Belgium) and Image Analysis Ltd. (United Kingdom), to assess the feasibility of developing 3-D patient-tailored bioresorbable bone tissue engineered products for the reconstruction of bone defects. A European M-ERA.net grant has been awarded to support this research. Image Analysis is a medical imaging company set up to bridge the gap between the best of academic research and routine clinical practice. SIRRIS is the Belgian research centre for the technological industry established in 1949, and is a European leader in additive manufacturing.
- BIO.be (Belgium), to develop and valid new alternative control quality methods. The project is subsidized by the Region. BIO.be is a Belgian SME specialized in pathological and genetic analysis (subsidiary of The Institute of Pathology and Genetics - IPG).

# 6.9.2 Academic / Clinical collaborations

# 6.9.2.1 Collaboration with the Université Libre de Bruxelles

The Company has a core academic, research and license collaboration with the Université Libre de Bruxelles and Erasme University Hospital (Brussels). The Université Libre de Bruxelles, owner of the ULB-028 patent family entitled "A method for cell differentiation and uses thereof" (see Section 6.8.1 "License agreement between Université Libre de Bruxelles (ULB) and the Company regarding ULB-028 patent family") concerning PREOB®, has granted the Company a worldwide, exclusive, personal and non-transferable license to use, modify, perform research, develop, manufacture and commercialize the licensed products.

6.9.2.2 Collaboration with the Université Libre de Bruxelles, Université de Liège-Patrimoine and Centre Hospitalier Universitaire de Liège

The Company has entered into a license agreement with the Université Libre de Bruxelles, Université de Liège-Patrimoine and Centre Hospitalier Universitaire de Liège on 17 April 2014 concerning the invention related to "Markers for impaired fracture healing" (see Section 6.8.4 "License agreement between the ULB, the University de Liège-Patrimoine, le Centre Hospitalier de Liège and the Company regarding the ULB-061 patent family"). The Company has been granted a worldwide, exclusive royalty-bearing license to develop, use, make, have made, offer for sale, sell and import products and to perform licensed processes.

#### 6.9.2.3 Collaboration with CHU Sart Tilman Liège

According to Belgian Law, when human biological material is used for the manufacturing of allogeneic advanced therapy medicinal products, the reception and processing of the human biological material and its distribution to a Pharmaceutical Establishment can be done via an accredited "Intermediary Structure" tissue establishment if the latter has an agreement with an accredited Tissue Bank which remains responsible for the donation, testing, procurement and release of the human biological material. The Company will work in collaboration with the LTCG, the accredited Tissue Bank from the CHU Sart-Tilman based in Liège.

#### 6.9.2.4 Collaboration with the Centre for Microscopy and Molecular Imaging (CMMI)

The Company is cooperating for several of its research projects with the Centre for Microscopy and Molecular Imaging (CMMI) that was created in a joint venture between the Université de Mons and Université Libre de Bruxelles. The CMMI has created a profound expertise in imaging and cellular labelling that gives the Company access to essential information for preclinical characterization and validation of products and allows better evaluation of safety and efficacy of clinical products in development. Currently, two projects, funded by the Region, are ongoing in cooperation with the CMMI: (i) the "CARTIM" project was designed to validate the efficacy of new osteoarthritis treatments in a novel model that allows non-invasive and quantitative measurement of cartilage *in vivo*; (ii) the "OSTEOMOD" project will evaluate and follow the efficacy of fracture repair treatments *in vivo* in small animals through quantitative and qualitative imaging.

6.9.2.5 Collaboration with the Department of Rheumatology and Physical Medicine (Hôpital Erasme, Université Libre de Bruxelles)

Bone Therapeutics is collaborating with the Department of Rheumatology and Physical Medicine (Hôpital Erasme, Université Libre de Bruxelles) on the discovery of new systemic cell therapies to treat bone diseases. The joint project, named "OsCirc" for circulating osteoblasts, is a 2-year public-private partnership (PPP) supported by the Region. OsCirc will seek to further evaluate circulating osteoblasts as a differentiated cell product to be utilized as an innovative systemic treatment for bone diseases. This collaborative project will be another important step in developing intravenous cell therapies to treat bone diseases.

# **6.10** Financing Agreements

The Company has entered into a number of agreements with its bankers ING Belgique SA/NV and BNP Paribas Fortis SA/NV which cover short (<1 year), medium (1-3 years) and long (>3years) term financing requirements. These requirements are entered into by the Company and /or by SCTS SA. In addition, the Company has obtained a number of loan facilities through regional investment offices (considered as related parties) such as Sambrinvest SA, Fond de Capital à Risque SA, Novallia SA and Sofipôle SA.

Bone Therapeutics SA has the following financing agreements in place:

- Under the framework of the European Regional Development Fund 2007-2013 (ERDF/FEDER) the Company has been granted, through a selection progress organized by the Walloon Region through Novallia SA, a long term subordinated loan for a an amount of € 500,000 for a period of 10 years (with a 2 years moratorium in respect of capital reimbursements). The loan serves to finance the development of PREOB® for the treatment of non-union fractures. The loan carries a market-based interest rate and as of the third year fixed quarterly instalments are due to reimburse the capital. The loan was concluded on 25 May 2012 and the final repayment is foreseen on 31 March 2022. The first capital reimbursement of € 15,625 was made on 30 June 2014.
- A long term subordinated loan has been awarded to the Company by Sambrinvest SA for an amount of € 250,000 for a period of 7 years (with a 2 years moratorium in respect of capital reimbursements). The loan serves to finance research activities related to severe fractures. The loan carries a market-based interest rate and as of the start of the third year fixed monthly instalments are due to reimburse the

capital. The contract was concluded on 24 February 2011, the loan was granted on 31 July 2012 and the final payment is foreseen on 30 June 2019. The first capital reimbursement of € 4,166.67 was made on 31 July 2014.

- A straight loan credit facility was provided by BNP Paribas Fortis SA/NV for an amount up to € 1,500,000 entered into 18 August 2014 and running until 30 June 2015. This facility allows to prefinance amounts due by the Walloon Region on recoverable cash advances ("avances récuperables" referred to as forgivable loans under IFRS) and subsidies (see Section 6.11 "Grants and subsidies") granted by the Walloon Region. In respect of this arrangement the Company has pledged the amounts to be received from the Walloon Region during the term of this credit facility as well as granted a business pledge mandate ("mandat de fonds de commerce" in respect of the Company for as long the Company wants to use this credit facility. The Company has drawn the entire amount made available through the facility gradually over the period from mid-September to mid-December 2014. The amount has been repaid in full by the Company on 31 December 2014. The facility bears a EURIBOR-based interest rate that amounted to 2.76% for the last tranche drawn.
- Furthermore, the Company has a number of leasing agreements provided by WBC Incubator to finance research equipment, representing an amount outstanding of € 0.11 million as per 30 September 2014.

### SCTS SA has the following financing agreements in place:

- La SA Fonds de Capital à Risque has provided a subordinated loan to SCTS SA for an amount of € 370,000. This loan fits within the framework of Regional support as referred to under the EFDR/FEDER regulations. The duration of the loan is for 15 years. The loan carries a market-based interest rate payable on a monthly basis. Capital reimbursement is based on fixed monthly instalments but with a two year moratorium during which no capital reimbursements will take place. There are no securities provided by SCTS SA in respect of this loan agreement. The contract was concluded on 27 March 2013. The first capital reimbursement of € 2,371.79 is foreseen for 31 March 2016.
- Under the framework of the European Regional Development Fund 2007-2013 (ERDF/FEDER) SCTS SA has been granted, through a selection process organized by the Walloon Region through Novallia SA, a subordinated loan for a an amount of € 500,000 euro for a period of 10 years (with a 2 years moratorium in respect of capital reimbursements). The loan serves to finance the development work (optimization of production processes) under the "PROFAB" project. The loan carries a market-based interest rate and as of the third year fixed quarterly instalments are due to reimburse the capital. The loan was concluded on June 21, 2013 and the final repayment is foreseen on 30 June 2023. The first capital reimbursement of € 15,625 is foreseen for 30 September 2015.
- The Walloon Region (through a delegated mission for Sofipôle SA) has provided a subordinated loan to SCTS SA for an amount of € 500,000. This loan serves to co-finance the construction project for a platform for cellular therapy in the SCTS building at the BioPark of Gosselies (south of Brussels). The loan is to be repaid in full at the maturity date being 30 June 2028. The loan carries a market-based interest rate payable on a quarterly basis. There are no securities provided by SCTS SA in respect of this subordinated loan. The contract was entered into on 10 April 2013. On the date of the prospectus this loan has not been used and is as such not reflected in the accounts ending 30 September 2014.
- BNP Paribas Fortis SA/NV and ING Belgique SA/NV provided long term investment credit facilities to finance the infrastructure project, each for an amount of € 1,625,000 euro.

Although the terms and conditions of the investment credit facilities are different, they have a term of 15 years which can be called upon in function of the progress of the completion of the project. In principle, the applicable interest rate amounts to EURIBOR 3M (the reference rate) increased with a market-based interest rate. SCTS SA has the option to negotiate fixed interest rates for periods up to the end of the contracts. The capital will be repaid in fixed amounts payable on a quarterly basis. The first reimbursement of  $\in$  31,250 to BNP Paribas Fortis SA/NV is foreseen for 30 September 2015 and the first reimbursement of  $\in$  31,250 to ING Belgique SA/NV is foreseen for 30 September 2015. As of date of the Prospectus, those two facilities have not yet been used.

In addition to the long term credit facilities, both banks provided a straight loan facility, each for an amount of  $\in 1,450,000$  to pre-finance the investment premium granted by the Walloon Region (see also Section 6.7 "Investments" and Section 6.17 "Properties and facilities"). The contracts were entered into on 27 May 2014.

For the straight loan facility interest rates and terms are decided based on what is appropriate for the chosen term. On the date of this Prospectus, these facilities are used.

BNP Paribas Fortis SA/NV has, amongst other things, requested the following security in respect of the above loans/facilities to be granted in parity with the security granted to ING Belgique SA/NV:

- a first ranking mortgage granted by SCTS on the assets built with the funds provided for an amount of  $\in 27,500$  ( $\in 25,000$  for ING Belgique SA/NV);
- a mandate to a first ranking mortgage granted by SCTS on the assets built with the funds provided for an amount of € 1,760,000 (€ 1,600,000 for ING Belgique SA/NV);
- a pledge on the subsidies provided by the Walloon Region to SCTS and resulting receivables in the framework of the construction of the infrastructure;
- a pledge on the receivables resulting from services provided by SCTS to SISE SA and to HCTS SA:
- a pledge on the shares held by SCTS in SISE SA (2,800 shares representing 30.9% of the shareholding);
- a pledge on the shares held by the Company in SCTS (12,750 shares representing 49.9% of the shareholding);
- a pledge on an amount of € 22,750 placed on a savings account by SCTS representing 6 months of
  interest on the Roll-over credit facility (annual review as of 30 June 2015) in favor of BNP Paribas
  Fortis SA/NV; and
- a pledge on an amount of € 22,750 placed on a savings account by SCTS SA representing 6 months of interest on the Roll-over credit facility (annual review as of 30 June 2015) in favor of ING Belgique SA/NV.

# 6.11 Grants and subsidies





### 6.11.1 Bone Therapeutics

From incorporation until 30 September 2014, the Company has been awarded non-dilutive financial support from the Region totalling  $\in$  18,563,361. This financial support has been granted in the form of recoverable cash advances ("**RCAs**") for an amount of  $\in$  15,162,552.93 of which  $\in$  10,609,354 has been paid out to the Company as of 30 September 2014, and in the form of (non-refundable) subsidies for an amount of  $\in$  3,400,808 of which  $\in$  1,984,909 has been paid out to the Company as of 30 September 2014. The Company intends to continue to apply for RCAs and subsidies to fund its development and research programs.

Each subsidy is defined by a contract number and a name (subsidy name).

#### 6.11.1.1 Recoverable cash advances

RCAs are dedicated to support specific research and development programs. After approval/grant, RCA contracts consist of three steps, i.e., the "research phase", the "decision phase" and the "exploitation phase". During the research phase, the Company receives funds from the Region based on statements of expenses. At the end of the research phase, the Company should within a period of six months decide whether or not to exploit the results of the research program (decision phase). The exploitation phase has a duration of 10 years. In the event the Company decides to exploit the results under an RCA, the relevant RCA becomes refundable. The reimbursements of the RCAs to the Region consist of two elements, i.e., turnover-dependent reimbursements (a percentage of turnover) and turnover-independent reimbursements (an annual lump-sum independent of the Company's turnover). The accounting treatment for RCA's, following IFRS guidelines, is different for the turnover-independent reimbursements in

function of the likelihood of the reimbursement of the last ones. The turnover-independent part will be considered as a "government loan", whilst the turnover-dependant part of the RCA will be considered as "forgivable loan". For a detailed description of the respective accounting treatments we refer to the notes to the consolidated financial statements 6.1 "Other operating income – Forgivable loans".

The Company owns the results of the subsidized research. Subject to certain exceptions, the Company cannot grant to third parties, by way of license or otherwise, any right to use the results of the subsidized research without the prior consent of the Region. A similar prior consent by the Region is needed in case of a transfer by the Company of an intellectual property right resulting from the subsidized research or a transfer or license of a prototype or installation. Obtaining such consent from the Region could give rise to a review of the applicable financial terms.

In case the Company decides not to exploit (or not to continue to exploit) the results under an RCA, then such RCA does not become refundable (or respectively is no longer refundable as of the calendar year after such decision) provided that the Company notifies the Region of such decision and transfers the rights relating to the relevant field of research to the Region or an entity designated by it. In such case, the Company may also have to grant (or cause to be granted) an exclusive license to the Region to the underlying patent(s). Also, in case the Company decided to renounce to its rights to patents which may result from the research, title to such resulting patents will need to be transferred to the Region. Furthermore, the Company is prohibited from conducting any research on behalf of a third party in the relevant field of research during 72 months or 36 months (as the case may be) following the Company's decision not to exploit the results obtained from the research in the relevant field.

Certain RCAs are governed by the currently applicable Walloon regulations (the "New Contracts"), and certain RCAs are governed by the previously applicable Walloon regulations (the "Old Contracts"). The Old Contracts and the New Contracts differ in certain respects.

Certain specific characteristics of the **Old Contracts** (contracts 5369 and 5827) are the following:

- Funding by the Region covers 70% of the budgeted costs;
- Certain activities have to be performed within the Region;
- In case of an out-licensing agreement or a sale to a third party, the Company will have to pay in principle 10% of the payments received (excl. of VAT) to the Region;
- Turnover-independent reimbursements, turnover-dependent reimbursements, and amounts due in case
  of an out-licensing agreement or a sale to a third party, are, in the aggregate, capped (except for
  interests) at 100% of the principal amount paid out by the Region;
- Turnover-dependent reimbursements, 5% (including accrued interest) of the principal amount of the RCA, payable in any given year can be set-off against turnover-independent reimbursements already paid out during that year.

Certain specific characteristics of the **New Contracts** are the following:

- Funding by the Region covers 60% of the budgeted costs (contracts 6064, 6187, 6700, 6446, 6337, 6539, 6805, 6834, 6855, 7029, 7028, 7187 and 7217); or covers 75% of the budgeted project costs is there is a collaboration with a Company established in Region (contracts 5993, 6081 and 7186);
- Certain activities have to be performed within the European Union;
- Turnover-independent reimbursements represent in the aggregate 30% of the principal amount;
- Turnover-dependent reimbursements range between 0.007% and 1.28% (including accrued interest) of the principal amount of the RCA depending on the actual outcome of the project compared to the outcome projected at the time the RCA has been granted (below or above projections);
- Interests (at Euribor 1 year (as applicable on the first day of the month in which the decision to grant the relevant RCA was made) + 100 basis points) accrue as of the 1st day of the exploitation phase;
- Turnover-independent reimbursements and turnover-dependent reimbursements are, in the aggregate (including the accrued interests), capped at 200% of the principal amount paid out by the Region;
- In case of bankruptcy, the research results obtained by the Company under the New Contracts are expressed to be assumed by the Region by operation of law.

The Company has contracted the following RCAs with the Region:

Contract N°	Subsidy Names	Initial budget (k€)	Exploitation phase	Turnover- independent reimbursement (k€)	Total reimbursed 09/2014 (k€)	Turnover- dependent reimbursement
5369	HOMING*	650	2012-2021	648	648 215	
5827	MATOB*	800	2012-2021	744	190	5%
6064	PREOB*	998	2013-2022	299	51	0.051%
6446	METHODES*	660	2014-2023	198	7	0.073%
5993	JOINTAIC*	432	2014-2023	130	0	0.085%
6834	STABCELL*	411	2015-2024	118	0	0.04%
6805	ALLOB NU	600	2015-2026	180	0	0.2%
6337	PREOB NU	2,961	2015-2024	888	0	0.59%
6187-6700	ALLOB	1,363	2015-2029	409	0	1.2%
6081	GXP	1,567	2015-2024	470	0	0.007%
6539	MAXBONE	690	2015-2024	207	0	0.08%
6855	JTA	600	2016-2025	180	0	0.042%
7029	CRYO	550	2016-2025	165	0	0.37%
7028	PREOB ON3	1.000	2016-2025	300	0	0.05%
7187	BANK	260	2016-2025	78	0	0.175%
7186	ALLOB IF	620	2017-2026	186	0	1.28%
7217	MXB BIOPRINTING	1,000	2017-2026	300	0	0.1093%
TOTAL		15,162		5,500	463	

<sup>\*</sup>Exploitation already signified to the Region

Out of these contracted RCAs, up to 30 September 2014,  $\in$  10,609,354 has been effectively paid out. The remaining  $\in$  4,553,199 is expected to be received before mid-2017.

On 5 January 2015, the Company announced that the government of the Walloon Region granted  $\in$  1,000,000 of non-dilutive funding to the Company, in the form of recoverable cash advances, to finance the project "MXB Biorpinting". This project consists in investigating in novel combined osteoblastic cell-matrix products for the treatment of large bone defects.

A brief description of the Company's subsidies is given in the Table below.

Subsidy Names	Related Company's Projects & Activities	Description
HOMING	PREOB®	Study of homing properties of PREOB®
MATOB	PREOB®	Study of secretion of extracellular matrix proteins of PREOB®
PREOB	PREOB®	Phase IIB clinical study in osteonecrosis with PREOB®
METHODES	Quality control	Optimisation of QC analytical methods
JOINTAIC	JTA	Pharmaceutical development of JTA
STABCELL	PREOB® & ALLOB®	Optimisation of PREOB® and ALLOB® stability
ALLOB NU	ALLOB®	Preclinical and clinical development of ALLOB®
PREOB NU	PREOB®	Non-union clinical study with PREOB®
ALLOB	ALLOB®	Preclinical and clinical development of ALLOB®

Subsidy Names	Related Company's  Projects & Activities	Description
GXP	Quality system	Set-up of preclinical, clinical and quality control quality systems
MAXBONE	MXB	Pharmaceutical development of MXB
JTA	JTA	Pharmaceutical development of JTA
CRYO	ALLOB®	Development of cryopreservation of ALLOB
PREOB ON3	PREOB®	Phase III clinical study in osteonecrosis with PREOB®
BANK	ALLOB®	Optimization of human biological material supply
ALLOB IF	ALLOB®	Preclinical and clinical development of ALLOB® in spine fusion
MXB BIOPRINTING	MXB	Preclinical development of 3D MXB cell-matrix products

#### 6.11.1.2 Subsidies

Subsidies granted by the Region are dedicated to funded research programs and patent applications.

Subsidies granted by the Region and amounting to € 3,400,808 are related to patent applications (contracts 820020, 920572, 820018, 920571, 820060, 820126, 920569, 820127, 820125, 920570, 1120242, 1320011, 1320145, 1320190, 820019, 820046, 820047, 1120198, 1220075, 1320146, 1120197, 1220076, 1320144, 1220028, and 1220029) together the "**Patent Subsidies**") and research programs (contracts  $n^{\circ}$  1017112, 6559, 1217891, 1318272, 1318269 and 1318215).

As of 30 September 2014, the Company has been granted subsidies related to patent applications totalling € 1,101,889 of which € 806,383 has been received. The balance will be granted based on statements of expenses to be submitted to the Region.

The Company has also been granted subsidies by the Region to fund 70% of costs of research programs for an amount of € 1,930,693 (contracts  $n^{\circ}$  1017112, 6559, 1217891, 1318272, 1318269 and 1318215) (together, the "Research Subsidies"), and by the European Commission to fund 100% of costs of research programs for an amount of € 368.225 (contract  $n^{\circ}$  607051). These Region and European Commission subsidies for research are in principle not refundable. Out of the subsidies contracted as of 30 September 2014 for research programs, € 1,178,526 has been effectively paid out. The remaining € 1,120,392 is expected to be received before end of 2017.

The Company owns the intellectual property rights which would result from the research programs or with regard to a patent covered by a subsidy. Subject to certain exceptions, the Company cannot grant to third parties, by way of license, transfer or otherwise, any right to use the patents (with regard to the Patent Subsidies) or the results (with regard to Research Subsidies) without the prior consent of the Region. In addition, certain subsidies contain an obligation for the Company to exploit the patent in the countries where the protection was granted and to make an industrial use of the underlying invention.

In case of bankruptcy, liquidation or dissolution, the rights to the patents covered by the Patent Subsidies relating thereto will be assumed by the Region by operation of law unless the subsidy is reimbursed, in case of liquidation or dissolution. If the Company would lose its qualification of "small or medium-sized enterprise", the subsidies under the Patent Subsidies will terminate and no additional expenses will be covered by such Patent Subsidies.

As it is still growing, the Company may lose its SME status in 2015, the consequences of which will be (i) a decrease in subsidies levels from 60% currently to 50% and (ii) a decrease in professional tax reduction which will be limited to master or higher education degrees. This will not affect already granted subsidies. The Company has taken the aforementioned decreases into account in its business plan.

### **6.11.2** Skeletal cell therapy support (SCTS)

Since incorporation, SCTS has been awarded non-dilutive financial support from the Region totalling  $\in 1,807,979$ . This financial support has been granted in the form of RCAs for an amount of  $\in 1,413,000$  of which  $\in 617,751$  has been paid out to SCTS as of 30 September 2014, and in the form of (non-refundable) subsidies for an amount of  $\in 394,979$  of which  $\in 98,745$  has been paid out to the SCTS as of 30 September 2014.

#### 6.11.2.1 Recoverable cash advances

RCAs are dedicated to support specific research and development programs. After approval/grant, RCA contracts consist of three steps, i.e., the "research phase", the "decision phase" and the "exploitation phase". During the research phase, SCTS receives funds from the Region based on statements of expenses.

The research and development programs conducted by SCTS relate to two products owned by the Company, being PREOB® and JTA B Separate License Agreements have been agreed between the Company and for PREOB® and JTA in this respect. The RCA contracts 6804 and 7253 refer, respectively, to the License Agreements PREOB® and JTA. The Company is a party to both RCA contracts as guarantor for the obligations of SCTS under the respective RCA contracts.

At the end of the research phase, SCTS and Bone Therapeutics should within a period of six months decide whether or not to exploit the results of the research program (decision phase). The exploitation phase has a duration of 10 years. In the event SCTS decides to exploit the results under an RCA, the relevant RCA becomes refundable. The reimbursements of the RCAs to the Region consist of two elements, i.e., turnover-dependent reimbursements (a percentage of turnover) and turnover-independent reimbursements (an annual lump-sum independent of SCTS' turnover). The accounting treatment for RCA's, following IFRS guidelines, is different for the turnover-independent reimbursements in function of the likelihood of the reimbursement of the last ones. The turnover-independent part will be considered as a "government loan", whilst the turnover-dependant part of the RCA will be considered as "forgivable loan". For a detailed description of the respective accounting treatments we refer to the notes to the consolidated financial statements 6.1 "Other operating income – Forgivable loans".

Subject to certain exceptions, SCTS and Bone Therapeutics cannot grant to third parties, by way of license or otherwise, any right to use the results of the subsidized research without the prior consent of the Region. A similar prior consent by the Region is needed in case of a transfer by SCTS of an intellectual property right resulting from the subsidized research or a transfer or license of a prototype or installation. Obtaining such consent from the Region could give rise to a review of the applicable financial terms.

In case SCTS decides not to exploit (or not to continue to exploit) the results under an RCA, then such RCA does not become refundable (or respectively is no longer refundable as of the calendar year after such decision), provided that SCTS notifies the Region, of such decision and transfers the rights *in rem* relating to the relevant field of research to the Region or an entity designated by it. In such case, SCTS may also have to grant (or cause to be granted) an exclusive license to the Region to the underlying patent(s). Also, in case SCTS would decide to renounce to its rights to patents which may result from the research, title to such resulting patents will need to be transferred to the Region. Furthermore, SCTS is prohibited from conducting any research on behalf of a third party in the relevant field of research during 72 months following the SCTS's decision not to exploit the results obtained from the research in the relevant field.

The RCAs are governed by the currently applicable Walloon regulations from which certain specific characteristics are the following:

- Funding by the Region covers 60% of the budgeted project costs (contracts 6804 and 7253);
- Certain activities have to be performed within the European Union;
- Turnover-independent reimbursements represent in the aggregate 30% of the principal amount;
- Turnover-dependent reimbursements are 1.28% and 0.10% respectively for contracts 6804 and 7253 (including accrued interest) of the principal amount of the RCA depending on the actual outcome of the project compared to the outcome projected at the time of grant of the RCA (below or above projections);
- Interests (at Euribor 1 year (as applicable on the first day of the month in which the decision to grant the relevant RCA was made) + 100 basis points) accrue as of the 1st day of the exploitation phase;
- Turnover-independent reimbursements and turnover-dependent reimbursements are, in the aggregate (including the accrued interests), capped at 200% of the principal amount paid out by the Region;
- In case of bankruptcy, the research results obtained under the New Contracts are expressed to be assumed by the Region by operation of law.

SCTS has contracted the following RCAs with the Region:

Contract N°	Subsidy Names	Initial budget (k€)	Exploitation phase	Turnover- independent reimbursement (k€)	Total reimbursed 09/2014 (k€)	Turnover- dependent reimbursement
6804	PROFAB	735	2015-2024	221	0	1,28%
7253	JTA PROD	678	2017-2026	203	0	0,1%
TOTAL		1,413		424	0	

Out of these contracted RCAs, as of 30 September 2014, € 617,751 has been effectively paid out. The remaining € 795,249 is expected to be received before end of 2016.

A brief description of SCTS' subsidies is given in the Table below.

Subsidy Names	Related Company's Projects & Activities	Description
PROFAB	PREOB®	Optimisation of PREOB® production
JTA PROD	JTA	Optimisation of JTA production

#### 6.11.2.2 Subsidies

SCTS has also been granted a subsidy by the Region to fund 90% of the costs of a research program for an amount of  $\in$  394,979 (contract n°7120). The subsidy is in principle not refundable. As of 30 September 2014,  $\in$  98,745 has been effectively paid out. The remaining  $\in$  296,234 is expected to be received before end of 2015.

SCTS owns the intellectual property rights which would result from the research program. Subject to certain exceptions, SCTS cannot grant to third parties, by way of license, transfer or otherwise, any right to use the results without the prior consent of the Region.

SCTS does not expect to lose its SME status in a foreseeable future (i.e., next 3 to 4 years).

## 6.11.3 SISE and GIE BOCEGO

SISE and Groupement d'Intérêt Economique BOCEGO (consisting of the Company and SCTS) ("GIE BOCEGO") have been granted (i) subsidies specifically aimed to support the creation of employment opportunities and added production values of SMEs and (ii) an exemption from property tax in relation to an investment programme for the creation of new job units, under two agreements dated 16 September 2013 between the Region and SISE and 24 April 2014 between the Region and GIE BOCEGO. The subsidies granted under these agreements amount to  $\in$  830,370.00, and respectively  $\in$  2,907,692.30. The exemption from property tax is valid for a 5-year period in relation to a maximum amount relating to investments in tangible capital assets.

The Company and SCTS have been awarded a subsidy in the amount of € 2,907,692.30 (financed directly by the Walloon Region for an amount of € 1,890,000 and for an amount of € 1,017,692.30 by the European Union), which covers 32.31% of the € 9,000,000 million construction cost of the building. The total projected cost represents € 9.5 million, taking into consideration the related participation in SISE SA, landlease agreements and related costs. The payment of the subsidy will take place gradually in accordance with the investment programme and the progress of the construction (after 40% of the investment, after 70% of the investment and after finalisation of the investment). The grant of the subsidy was made subject to a number of Companyrelated conditions, which could give rise to a (partial) claim-back by the Walloon Region and the European Union in case of non-compliance therewith. For example, the Company (in its capacity as member of GIE BOCEGO) will need to employ (on average) an additional minimum number of employees (39) at its site in Gosselies, as of 1 January 2018 until 31 December 2021. The subsidy could also be claimed back in the event of non-realisation of at least 80% of the investment programme or if the Company transfers, does not use or ceases to use the facility (for its intended purpose) within a 5-year period following the realisation of the investments. In addition to the aforementioned specific conditions related to the Company, the subsidy agreement also contains more general conditions which are customary for subsidies, such as conditions in relation to information- and publicity related obligations and conditions related to compliance with fiscal, social and environmental regulations.

# **6.12** Intellectual property

## 6.12.1 Patents and patent applications owned or licensed by the Company

The Company's research programs and product candidates are covered by several patent families (patents and patents applications), which are either owned by the Company or licensed to the Company. There is one key PREOB® product patent (ULB-028) currently granted in Japan, Singapore, the US and Canada, and one key product ALLOB® patent (BONE-001) granted in Japan, Singapore and Australia.

In total, the Company's intellectual property portfolio comprises 9 patent families:

- 1. ULB-028 (WO 2007/093431): Cell populations comprising osteoblastic cells characterised by the expression of certain cell markers, and further comprising endothelial cells, and also concerns derived products, in particular pharmaceutical compositions and surgical devices comprising said cell populations.
- 2. BONE-001 (WO 2009/087213): Method for obtaining osteoprogenitors, osteoblasts or osteoblast phenotype cells.
- 3. BONE-002 (WO 2009/080749): The BONE-002 patent applications concern the therapeutic use of isolated bone-forming cells in the treatment of the inflammatory component of inflammatory rheumatic diseases (IRD).
- 4. BONE-004 (WO 2009/135905): Isolated mesenchymal stem cells derived from bone marrow and expressing certain cell-surface markers, methods for obtaining such MSC, and related subject matter.
- 5. BONE-006 (WO 2009/135914): Therapeutic use of isolated bone-forming cells in the treatment of bone diseases or conditions associated with immunodeficiency or immunosuppression.
- 6. BONE-011 (WO 2014/049063): Discovery of advantageous properties of solvent/detergent-treated plasma in pharmaceutical formulations, which render the formulations particularly suitable for administration to bone or joints, such as to treat musculoskeletal diseases.
- 7. BPBONE-001 (WO 2009/101194): Intra-articular pharmaceutical composition for use in the treatment and/or the prevention of acute or chronic osteoarticular diseases, such as osteoarthritis, and acute or chronic osteoarticular symptoms (i.e., pain, loss of mobility and/or function).
- 8. BPBONE-002 (WO 2009/101210): Pharmaceutical composition for use in the treatment and/or the prevention of acute or chronic osteoarticular diseases and acute or chronic osteoarticular symptoms, especially osteoarthritis.
- 9. ULB-061 (WO 2012/168482): Novel biomarker for the prediction, diagnosis, prognosis and/or monitoring of impaired bone fracture healing.

The Company owns the exclusive worldwide license of ULB-028 and ULB-061.

Overview of patents and patent applications.

Reference	Publication No	Title (product)	Priority date	Territory	End of term
ULB-028	WO 2007/093431	Method for cell differentiation	16 Feb 2006	JP	16 Feb 2027
		and use thereof		SG	16 Feb 2027
		(PREOB®)		US	30 Aug 2028
				CA	16 Feb 2027
					under
				(EP, HK, IN)	examination
BONE-001	WO 2009/087213	Osteogenic differentiation of	11 Jan 2008	JP	9 Jan 2029
		bone marrow stem cells and mesenchymal stem cells using a combination of growth factors (ALLOB®)		SG	9 Jan 2029
				AU	9 Jan 2029
				(AU-DIV, CA,	under
		(ALLOB )		CN, EP, HK, IN,	examination
				KR, US, US-DIV)	
BONE-002	WO 2009/080749	Human bone-forming cells in the	21 Dec 2007	AU	19 Dec 2028
		treatment of inflammatory		EP	19 Dec 2028
		rheumatic diseases (PREOB® & ALLOB®)		НК	19 Dec 2028

Reference	Publication No	Title (product)	Priority date	Territory	End of term
				JP SG (CA, KR, US)	19 Dec 2028 19 Dec 2028 under
BONE-004	WO 2009/135905	Mesenchymal stem cells and bone-forming cells (PREOB® & ALLOB®)	7 May 2008	SG AU (CA, EP, HK, IN, JP, KR, US, US- DIV)	7 May 2029 7 May 2029 under examination
BONE-006	WO 2009/135914	Human bone-forming cells in the treatment of conditions and bone diseases associated with immunodeficiency or immunosuppression (PREOB®)	7 May 2008	SG AU (CA, EP, HK, JP, KR, US)	7 May 2029 7 May 2029 under examination
BONE-011	WO 2014/049063	Formulations involving solvent/detergent-treated plasma (S/D plasma) and uses thereof (MXB & JTA)	26 Sep 2013	International Phase	-
BPBONE- 001	WO 2009/101194	Pharmaceutical composition for use in the treatment and/or the prevention of osteoarticular diseases (JTA)	13 Feb 2009	CN HK SG AU (BZ, CA, EP, IL, IN, JP, KR, US)	13 Feb 2029 13 Feb 2029 13 Feb 2029 13 Feb 2029 under examination
BPBONE- 002	WO 2009/101210	Pharmaceutical composition for use in the treatment and/or prevention of osteoarticular diseases (JTA)	16 Feb 2009	SG AU (BZ, CA, EP, IL, IN, JP, KR, US)	16 Feb 2029 16 Feb 2029 under examination
ULB-061	WO 2012/168482)	Markers for impaired bone fracture healing	10 Jun 2011	(AU, CA, EP, HK, IL, JP, SG, US)	under examination

 $Overview\ of\ patent\ ownership\ and\ related\ contracts.$ 

Reference	Product / Clinical stage	Owner(s)	Contract(s)
ULB-028	PREOB® / Phase II/III	Université Libre de Bruxelles (ULB)	Exclusive, worldwide license to the Company Royalty-free sublicense to SCTS* for manufacturing with an exclusive worldwide back- licence to the Company
BONE-001	ALLOB® / Phase II	Bone Therapeutics SA	
BONE-002	PREOB® & ALLOB® / Phase II/III	Bone Therapeutics SA	
BONE-004	PREOB® & ALLOB® / Phase II/III	Bone Therapeutics SA	
BONE-006	PREOB <sup>®</sup> /Phase II/III	Bone Therapeutics SA	
BONE-011	MXB & JTA / Preclinical	Bone Therapeutics SA (50%) Enrico Bastianelli SPRL (50%)	Free worldwide exclusive rights on cell therapy applications for the Company

Reference	Product / Clinical stage	Owner(s)	Contract(s)
BPBONE- 001	JTA / Preclinical	Bone Therapeutics SA	Formerly owned by Enrico Bastianelli SPRL – transferred to the Company subject to payment by the Company of royalties when applied in the field of joint diseases and applications Royalty-free sublicense to SCTS* for manufacturing with an exclusive worldwide backlicence to the Company
BPBONE- 002	JTA / Preclinical	Bone Therapeutics SA	Formerly owned by Enrico Bastianelli SPRL – transferred to the Company subject to payment by the Company of royalties when applied in the field of joint diseases and applications Royalty-free sublicense to SCTS* for manufacturing with an exclusive worldwide backlicence to the Company
ULB-061		Université Libre de Bruxelles (70%) University de Liège /Centre Hospitalier Universitaire de Liège (15%) Bone Therapeutics SA (15%)	Exclusive, worldwide license to the Company

<sup>\*</sup> SCTS is an affiliate of the Company (which holds 49.9% of SCTS' share capital).

## 6.12.2 Trademarks and designs

On the date of this prospectus, the Company obtained trademarks for both its PREOB® and ALLOB® products. International registration of PREOB® under class 5 (goods) and class 42 (services) was obtained in April 2012 in the Benelux, the EU, the US and Japan and is currently ongoing for Canada. ALLOB® was internationally registered under class 5 and class 42 in February 2012 and in the Benelux, the EU, the US, Japan and South Korea and application is currently ongoing in Canada.

## 6.12.3 Orphan Drug Designation

Orphan Drug Designation (ODD) provides a special status to a drug developed for the treatment of rare diseases or rare medical conditions. When obtaining orphan designation, the Company benefits from a number of incentives, including regulatory assistance and market exclusivity (10 years in Europe and 7 years in the US) once the medicine is approved for commercialisation. Through the ODD scheme, the Company benefits from significant fee reductions (90% or more) in respect of the protocol development and scientific advice and product registration procedure in Europe as well as in the US. The Company received ODD for PREOB® and ALLOB® for the treatment of (non-traumatic) osteonecrosis. PREOB® received ODD for osteonecrosis from the EMA in October 2007 and from the FDA in March 2008. ALLOB® received ODD for osteonecrosis from the EMA in July 2013 and from the FDA in January 2014.

# 6.13 Manufacturing

- The Company aims to achieve the following objectives through its manufacturing process:
  - Provide adequate production capacity at all stages of the development of the Company;
  - Continuous optimization of processes to reduce costs and increase capacity of the available infrastructure;
  - Protection of knowhow through in-house production and strictly manage relations with potential contract manufacturers producing for other territories.
- The products manufactured by the Company have the following product specifications:
  - PREOB® and ALLOB® are cellular-based products consisting respectively in viable human autologous or allogeneic osteoblastic cells derived from *ex vivo* cultured bone marrow mesenchymal stromal cells. They are not genetically modified and not combined.
  - Both products are medicinal products which have been developed in compliance with the European legislation and have been classified as a tissue engineered product within the European regulatory framework governing the advanced therapy in Europe (Regulation 1394/2007). Under Regulation 1394/2007, a tissue engineered product means a product that contains or consists of engineered cells (cells that have been subject to substantial manipulation or are not intended to be used for the same function in the recipient as in the donor), administered to human beings with a view to regenerating, repairing or replacing a human tissue.

- In the US, PREOB® and ALLOB® will fall under the Biological License Application regulation.
- In Japan, PREOB® and ALLOB® will fall under the new legislation for regenerative medicine. This
  new legislation creates opportunities for an accelerated conditional market access for cell products
  based on Phase II clinical trial results.
- The manufacturing process of the Company's products is as follows:
  - Two steps can be defined in PREOB® and ALLOB® manufacturing process:
    - 1. The obtaining (autologous for PREOB® and allogeneic for ALLOB®) of the human bone marrow (starting material);
    - 2. The manufacturing of PREOB® and ALLOB® in dedicated accredited facilities.
  - PREOB® and ALLOB® are manufactured in certified facilities<sup>73</sup>.
  - Bone marrow donation is performed in accordance with the specific regional legislation governing cell and tissue collection. Bone marrow is harvested by a trained and qualified physician from patients (PREOB®) or from adult alive healthy volunteer donors (ALLOB®). Bone marrow is collected in compliance with Good Tissue Practice and based on specific criteria and methods for tests or examinations (this may be subject to change upon new legislation). The patient or donor selection criteria include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to the recipients or to themselves. The traceability of the human biological material is maintained from bone marrow procurement to PREOB® or ALLOB® administration. Eligibility criteria for donor selection are based (i) on serology, (ii) on medical history and anamnesis and (iii) on physical/clinical examination. After obtaining written informed consent, bone marrow is aseptically harvested from the posterior iliac crest under local anaesthesia. The bone marrow is collected in a sterile bag (blood bag) and sent out under controlled conditions to the manufacturing facilities<sup>74</sup>.
  - The PREOB® and ALLOB® manufacturing process consists in the *ex vivo* culture of human bone marrow-derived mesenchymal stromal cells in order to generate human osteoblastic cells. The manufacturing process has been developed in order to minimize cell manipulation and to reduce the number of raw materials and disposable entering in the process. PREOB® and ALLOB® are manufactured following standardized and validated manufacturing process by trained operators. Manufacturing process includes 3 key steps (i) bone marrow and culture medium preparation, (ii) *ex vivo* culture in specific proprietary culture medium and (iii) cells recovering and conditioning in drug product. At the end of manufacturing, PREOB® and ALLOB® cells are collected, controlled and resuspended in excipients.
  - PREOB® and ALLOB® are provided in a single-use, pre-filled, ready-to-use syringe. They can be provided in several dosages depending on the indication and the size of the bone defect to be treated. They are conditioned to be sent to hospitals under controlled conditions for administration.
  - PREOB® and ALLOB® manufacturing processes have been developed to minimize the number of cell
    manipulations and to limit the number of reagents entering in contact with the cells.
- Facilities and capacity:

- The Company is currently producing at its current facilities based at the Galactic Innovation Campus (GIC) building in Brussels with two production lines (PREOB® and ALLOB®) which are both GMP approved. The available capacity meets the requirements for both the current pre-clinical and clinical developments.
- The Company's production activities are contemplated to be transferred to the new facilities at the BioPark of Gosselies (south of Brussels) mid-2016 after obtaining GMP accreditation, which are currently under construction. Initially two new manufacturing units should be available. The modular

<sup>&</sup>lt;sup>73</sup> The company received a GMP agreement for its current facilities at the Galactic Innovation Campus (GIC) building in Brussels from the FAMPH on January 23, 2012. A renewal of the authorization was received following an inspection on January 26 and 27, 2014. The company received authorization under number 1698 IMP for the manufacturing, quality control and intra-EU distribution for both ALLOB® and PREOB®.

<sup>&</sup>lt;sup>74</sup> For its PREOB® product the Company has a license as a Tissue Bank/Production Establishment for human autologous tissue-derived materials by the FAMPH received on July 18, 2011. The license was renewed following inspection on May 22, 2014. For its ALLOB® product the Company has a license as a Tissue Bank/intermediary Structure by the FAMPH for human allogeneic tissue-derived materials delivered on February 19, 2013.

design of the facility will allow for a progressive – on-demand - increase in commercial production capacity with up to 5,000 batches for PREOB® and 12,000 batches for ALLOB®. As of 2018 four more production units should be commissioned to meet the production requirements for the ongoing clinical trials, pre-commercial and the first commercial activities. Further production modules can be added in future to increase capacity in line with demand.

• In the long term, it is envisaged that production will be organized in a de-centralized way to cover the 3 key regions (EU, US and Japan), in particular in respect of the production of the autologous product PREOB® (patient himself to provide bone marrow as the first step in the production process). With respect to the production of the allogeneic product ALLOB® (product made from bone marrow from independent donors) a further centralized production approach remains possible.

# 6.14 Regulatory framework

In each country where it conducts its research and intends to market its products and product candidates, the Company has to comply with regulatory laws and regulations (hereinafter, collectively the Regulatory Regulations), including regulations laid down by regulatory agencies and by other national or supra-national regulatory authorities (hereinafter, collectively the Competent Authorities), as well as industry standards incorporated by such Regulatory Regulations, that regulate nearly all aspects of the Company's activities. The Competent Authorities notably include the European Medicines Agency (EMA) in Europe – as well as the national agencies – and the Food and Drug Administration (FDA) in the US.

The Company's pharmaceutical product candidates are subject to substantial requirements that govern among other things their testing, manufacturing, quality control, safety, efficacy, labelling, storage, record keeping, marketing approval, advertising, promotion, pricing, and reimbursement. The process of maintaining continued compliance with the regulatory requirements requires the expenditure of substantial amounts of time and money.

#### 6.14.1 Medicinal product and clinical study regulations

PREOB® and ALLOB® are advanced therapy medicinal products (ATMPs) which have been developed in compliance with the European legislation and are considered tissue engineered products within the European regulatory framework governing advanced therapy in Europe (Regulation 1394/2007). Under Regulation 1394/2007, a "tissue engineered product" means a product that contains or consists of engineered cells (cells that have been subject to substantial manipulation or are not intended to be used for the same function in the recipient as in the donor) or tissues, and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue. In the US, PREOB® and ALLOB® will fall under the Biological Licence Application regulation. In Japan, PREOB® and ALLOB® will fall under the new legislation for regenerative medicine which allows for conditional marketing approval after Phase II clinical trials.

The testing, storage, and distribution of human tissues and cells (intended for human use) and of manufactured products derived from human tissues and cells (intended for human use) is specifically regulated (in Europe by Directive 2004/23/EC, which e.g., requires the licensing of tissue establishments).

Bone Therapeutics is registered as a "Tissue Establishment" (according to the Belgian RD2 of September 28th 2009 and the Belgian Law of December 19th 2008 to transposing the Directive).

Bone Therapeutics' Manufacturing Site has been inspected by the regional competent authorities (Federal Agency for Medicines and Health Products, Belgium) and is registered as a "Pharmaceutical Establishment" and accredited as a "GMP" facility under the number 1698 by the Belgian Competent Authorities (Federal Agency for Medicines and Health Products), as requested by the Directive 2001/83/EC, 2009/120/EC and regulation EC 1394/2007.

Overview of manufacturing authorizations

Agreement / license	Competent Authority*	Date of approval	
Manufacturing authorization and intra-EU distribution authorization for PREOB® & ALLOB®	Federal Agency for Medicines and Health Products	Agreement updated on: 8 Jan 2013	
GMP agreement	Federal Agency for Medicines and Health Products	23 Jan 2012 (renewal received Oct 2014)	
Tissue Bank / Production Establishment (PREOB®)	Federal Agency for Medicines and Health Products	18 Jul 2011	
Tissue Bank / Intermediary Structure (ALLOB®)	Federal Agency for Medicines and Health Products	19 Feb 2013	

Competent Authorities are aware of the specificities of cell-based product candidates, and give much attention to their upfront characterisation and to the development of assays to measure their biological activity. The preclinical and clinical development paths are broadly similar in Europe (governed by Directive 2001/20) and in the US. Initially, non-clinical studies are conducted to evaluate the mode of action and safety through *in vitro* and *in vivo* studies. Upon successful completion of preclinical studies, a request for a Clinical Trial Authorisation (CTA, in the EU) or an Investigational New Drug application (IND, in the US), needs to be approved by the relevant Competent Authorities and Ethics Committee for clinical trials to be allowed to start. Clinical trials are typically conducted in sequential phases, Phases I, II and III, with Phase IV studies conducted after marketing approval. Phase IV trials are generally required for products that receive conditional and/or accelerated approval (but may be required for other products as well). These phases may be compressed, may overlap or may be omitted in some circumstances.

The rate of completion of the Company's clinical trials may be delayed by many factors, including slower than anticipated patient enrolment or adverse events occurring during clinical trials.

Competent Authorities typically have between one and six months from the date of receipt of the CTA or IND application to raise any objections to the proposed trial for ATMPs. Competent Authorities may also require additional data before allowing studies to commence and could demand that studies be discontinued, for example if there are significant safety issues. In addition to obtaining Competent Authority approval, clinical trials must receive Ethics Committee (in the EU) or Institutional Review Board, "IRB" (in the US) approval for every research site (e.g., hospital) where the clinical trials are conducted.

For most of its studies, the Company sought EMA scientific advice before designing its clinical trials in order to incorporate the requirements of the EMA.

The Company received orphan drug status for PREOB® (EMA: 2007; FDA: 2008) and ALLOB® (EMA: 2013; FDA: 2014) for the treatment of (non-traumatic) osteonecrosis. When obtaining orphan designation, the Company benefits from a number of incentives, including protocol assistance, a type of scientific advice specific for designated orphan medicines, and market exclusivity (10 years in Europe and 7 years in the US) once the medicine is on the market. Fee reductions are also available depending on the status of the sponsor and the type of service required.

# 6.14.2 Marketing approval

Although different terminology is used, the data requirements, overall compliance to GMP, GCP and other regulatory requirements and the assessment and decision making process for marketing approval are similar in the EU and in the US. Upon availability of initial efficacy data from Phase II clinical trials *and* confirmatory Phase III clinical trial data, the Company may submit a request for marketing authorization to the Competent Authorities (a Marketing Authorization Application (MAA) to EMA in the EU; a Biologics License Application (BLA) to FDA in the US). FDA and/or EMA may grant approval if the quality, safety *and* efficacy of the medicinal product are proven, deny the approval or request additional studies or data. Following favourable assessment and decision, the products may be commercially launched in the relevant territory. There can be no guarantee that such approval will be obtained or maintained. In practice, effective market launch is often further conditioned upon completion of pricing and reimbursement negotiations with Competent Authorities involved in healthcare and pharmaceutical expenditure at the national or regional level.

When granting marketing authorization, Competent Authorities may impose upon the Company an obligation to conduct additional clinical testing, sometimes referred to as Phase IV clinical trials or other post-approval commitments, to monitor the product after commercialization. Additionally, marketing authorization may be subjected to limitations on the indicated uses for the product. Also, after marketing authorization has been obtained, the marketed product and its manufacturer and marketing authorization holder will continue to be subject to Regulatory Regulations and monitoring by Competent Authorities. The conditions for marketing authorization include requirements that the manufacturer of the product complies with applicable legislation including GMP, related implementing measures and applicable guidelines that involve, amongst others, ongoing inspections of manufacturing and storage facilities.

# 6.14.3 Pricing and reimbursement

In Europe, pricing and reimbursement for pharmaceuticals are not harmonized and fall within the exclusive competence of the national authorities, provided that basic transparency requirements defined at the European level are met as set forth in the EU Transparency Directive 89/105/EEC, which is currently under revision. As a consequence, reimbursement mechanisms by private and public health insurers vary from country to country. In

<sup>\*</sup> In the EU, the national Competent Authority is entitled to grant accreditation to the whole of the EU.

public health insurance systems, reimbursement is determined by guidelines established by the legislator or a competent national authority. In general, inclusion of a product in reimbursement schemes is dependent upon proof of the product efficacy, medical need, and economic benefits of the product to patients and the healthcare system in general. Acceptance for reimbursement comes with cost, use and often volume restrictions, which again vary from country to country.

The pricing and reimbursement level for the Company's products will depend on the strength of the clinical data set and, as for most novel therapies, restrictions may apply. In most countries, national Competent Authorities ensure that the prices of registered medicinal products sold in their territory are not excessive. In making this judgment, they usually compare the proposed national price either to prices of existing treatments and/or prices in other countries also taking into account the type of treatment (preventive, curative or symptomatic), the degree of innovation, the therapeutic breakthrough, volume of sales, sales forecast, size of the target population and/or the improvement (including cost savings) over comparable treatments. Given the growing burden of medical treatments on national health budgets, reimbursement and insurance coverage is an important determinant of the accessibility of medicines. The various public and private plans, formulary restrictions, reimbursement policies, patient advocacy groups, and cost-sharing requirements may play a role in determining access to products marketed by the Group. The national Competent Authorities may also use a range of policies and other initiatives intended to influence pharmaceutical consumption. To address the above, the Company integrates as part of its clinical development programs the collection of data aimed at facilitating the evaluation of therapeutic benefit, in terms of efficacy and/or reduction in side effect profile, and of its cost. Concomitantly with marketing authorization applications, the Company will engage in a dialogue with key decision makers at different payers in order to identify unique preferences and concerns by payer type and to obtain insight in the perceived value drivers, reimbursement barriers and price elasticity for its products.

# 6.15 Information technology

The Company uses adequate commercial platforms to support its operations, such as an ERP platform for finance and production purposes. Maintenance agreements are in place to guarantee continuity of the operations and the platforms remaining up to date.

Data storage occurs in a differentiated way, with data stored simultaneously at 3 different secured locations (one in-house location and 2 offshore locations, operated by service providers).

IT maintenance has occurred regularly and was outsources to a service provider which has the capacity to address all areas in which the Company needed IT-related assistance.

# 6.16 Environment and health & safety

The Company complies in all material respects with the rules on the protection of health and safety of its employees. Such rules provide for measures which in particular aim to eliminate risk factors and accidents at work. The Company aims to ensure the safety and health of employees in all work-related aspects, including when it calls upon persons or services outside the Company, using means and measures of protection of employees. Such means and measures include information and training sessions for the employees, in particular on how to avoid risks or manage risks that cannot be avoided, by giving appropriate instructions to the employees, by promoting collective protection measures and by adapting working conditions, equipment and work methods.

First aid, fire-fighting and employee evacuation related activities are co-ordinated with the owner and co-occupier of the building at the Galactic Innovation Campus (GIC) in Brussels. The Company ensures training for a number of employees in respect of first aid.

The Company has set up a service for protection and prevention at its premises, such as the monitoring of the health of employees, provided by an independent health service company. Employees receive an annual medical check-up.

Every employee must take care of his/her safety and health, as well as the safety and health of persons potentially affected by his/her actions or omissions at work. In accordance with the training and instructions given, employees must use equipment, tools and materials related to their business activity properly, must use the personal protection equipment properly and must not disable, arbitrarily change or remove safety devices and must immediately report any work situation that poses a serious and immediate threat.

Similarly, the Company complies in all material respect with environmental rules and regulations with respect to waste, waste management and biological hazard. For example, biological wastes are sterilized, appropriately packages and handled for destruction by specialized external companies.

The Company has an environmental permit, delivered by the IBGE (Institut Bruxellois pour la Gestion de l'Environnement, the ministry for environment of the Brussels Region), for the exploitation of the laboratories at its current site, the Galactic Innovation Campus (GIC) building in Brussels. The necessary permits will be applied for before the Company moves its operations to the new premises in the BioPark of Gosselies (south of Brussels).

#### 6.17 **Properties and facilities**

The Company has its registered offices at Gosselies (south of Brussels). Currently the Company runs its operations out of facilities it rents at the Galactic Innovation Campus (GIC) in Brussels. Here, the Company has access to a total of dedicated space of 1180m² for administrative, R&D and production purposes.

In respect of production the Company has at its current facilities two production units at its disposal accommodating two GMP approved production lines for its products PREOB® and ALLOB®. The available capacity meets both the requirements for the current clinical programs.

As of second quarter of 2015, the Company will gradually move all its operational activities to BioPark of Gosselies (south of Brussels) where new facilities, owned by SCTS SA75, are currently under construction. This new facility approximately covers 3000m<sup>2</sup> in total. Almost 1700m<sup>2</sup> are for administrative and R&D purposes including an animal house and 1300m<sup>2</sup> are foreseen for production activities.

Mid-2016 the production activities will be transferred to the new facilities at the BioPark of Gosselies (south of Brussels). Initially two manufacturing units will be available. As of 2018 four more production units will be commissioned to meet the production requirements for the ongoing clinical trials, pre-commercial and the first commercial activities. Further production modules can be added in future on the same plot of land to increase capacity in line with demand.

The facility fits in a larger project known as PWTC or the "Plateforme Wallonne de Thérapie Cellulaire" whereby two cell therapy companies<sup>76</sup> have joined forces to build facilities at a joined location on the Industrial Park « Aéropôle » at Gosselies (50 km south of Brussels near the airport Brussels South). PWTC comprises three service companies: SCTS (Skeletal Cell Therapy Support), HCTS (Hepatic Cell Therapy Support) and SISE (Société d'Infrastructures, de Services et d'Energies) (See Section 9.3, "Holdings"). SCTS and HCTS will make a maximum use of shared services provided through SISE SA to establish their industrial project, but on the same time maintaining full control of their proprietary production processes and know-how by having their own physically separated building infrastructure. The project allows for both companies to considerably expand their production capacity in future.

Next to providing services SISE SA is also the landowner on which the infrastructure of SCTS SA is constructed. There is long term (99 years) lease agreement in place between SISE SA and SCTS SA which started on 12 June 2013.

Both the new infrastructure under constructions and the long term land lease right of 99 years are reported as property, plant and equipment in the consolidated financial statements of the Company and further details are provided in section 5.2 "Property, plant and equipment" and in section 3 "Disclosures to the condensed consolidated financial statements" for the nine month period ended 30 September 2014 under item 3.1 "Property, plant and equipment".

#### 6.18 **Insurance**

The Company has insurance covers in place both for insurance risks in the ordinary course of business as well as business specific insurances. Overall, the Company makes sure to have all coverage in place as required by law and when considered necessary, additional insurance policies were concluded to ensure continuity of business or to ensure that safeguarding or reimbursing third parties from damages occurred through its activities would not put the Company at risk. At all times, the Company considers the scope of the coverage and related the costs of the insurances against the potential risk of damages.

The Company is insured to cover work accidents, both for itself as well as for SCTS, as required by law. In addition, the Company concluded a supplementary policy to ensure it is covered for an amount exceeding the

<sup>75</sup> SCTS SA was established in 2011 to provide support in respect of providing facilities and related services, logistic services for both R&D and production operations, process development activities, pilot production and scale up of such production activities up to commercial stage for companies engaged in the field of cell therapy for bone or skeletal applications (Skeletal Cell Therapy Support). SCTS SA is

company (under application of IFRS) controlled by Bone Therapeutics SA.

The Bone Therapeutics SA through SCTS SA and Promethera SA through its subsidiary HCTS (Hepathic Cell Therapy Support) SA.

legal minima. In addition, the Company has a policy in place which covers both professional as well as third party liability.

All ongoing clinical trials are covered by insurance policies in accordance with the regulations in place in all countries where these trials are taking place.

Property owned by the Company is insured for fire and theft.

The Company has also concluded a D&O policy for the benefit of its directors.

# 6.19 Legal proceedings

The Company is not involved in any litigation, arbitration nor contentious administrative proceedings which have had or which, to the best of the Company's knowledge, may have, a material effect on its financial conditions and/or result of operations, nor have any such proceedings have been threatened in writing by or against the Company.

# 6.20 Employees

As of 31 December 2014, the Company employs 36 people and SCTS employs 36 people. The table below shows the evolution of employment since 2012.

As of December 31	2012		2013		2014	
As of December 51	BT	SCTS	BT	SCTS	BT	SCTS
R&D	35	9	37	13	34	35
Administration	2	0	2	0	2	1
Total	37	9	39	13	36	36
Total of BT and SCTS	4	46		52	,	72

In the first semester of 2014, the Company saw its clinical and production departments grow. The Company recruited additional staff to support the development of its preclinical products as well as the on-going clinical programs.

31% of employees are qualified to PhD level. Scientific specialization domains include cellular and molecular biology, pharmaceutical sciences, veterinary medicine, physiology and life sciences. The staff is represented by eight different nationalities.

# **7** Key financial information

The following table includes information relating to the Company's statement of comprehensive income for the years ended 31 December 2013 and 2012 and for the nine months period ended 30 September 2014 and 2013. The statements of comprehensive income for the years ended 31 December 2013 and 2012 has been audited. The statements of comprehensive income for the nine months period ended 30 September 2014 and 2013 have been reviewed by the auditor.

(in thousands of euros)	9 month end	n period led	Year ended 31 December	
	30/09/14	30/09/13	2013	2012
Revenue	0	0	0	0
Other operating income	2,644	2,418	3,394	3,057
Total operating income	2,644	2,418	3,394	3,057
Research and development expenses	(5,523)	(4,647)	(6,816)	(6,371)
General and administrative expenses	(865)	(502)	(621)	(348)
Operating profit/(loss)	(3,743)	(2,731)	(4,043)	(3,662)
Interest income	110	96	150	172
Financial expenses	(201)	(115)	(190)	(189)
Exchange gains/(losses)	(63)	()	(1)	(3)
Share of profit/(loss) of associates	0	31	19	(17)
Result Profit/(loss) before taxes	(3,897)	(2,720)	(4,066)	(3,698)
Income taxes	0	0	0	0
PROFIT/(LOSS) FOR THE PERIOD	(3,897)	(2,720)	(4,066)	(3,698)
Other comprehensive income	0	0	0	0
TOTAL COMPREHENSIVE INCOME OF THE				
PERIOD	(3,897)	(2,720)	(4,066)	(3,698)

The table below shows the balance sheet on 1 January 2012, 31 December 2012, 31 December 2013 and 30 September 2014. The opening balance sheet on 1 January 2012, the balance sheet as per 31 December 2012 and the balance sheet as per 31 December 2013 have been audited. The balance sheet as per 31 December 2014 has been reviewed by the auditor.

	9 month period ended	Year ended	Year ended	Opening balance
ASSETS (in thousands of euros)	30/09/14	31/12/13	31/12/12	01/01/12
Non-current assets	4,230	4,724	2,650	2,004
Intangible assets	42	60	19	4
Property, plant and equipment	2,074	2,869	1,277	1,137
Investments in associates	282	282	263	280
Financial assets	181	180	163	59
Deferred tax assets	1,652	1,333	927	523
Current assets	8,741	8,087	11,767	13,049
Trade and other receivables	6,861	5,513	6,834	7,220
Other financial assets	0	0	0	203
Other current assets	145	134	112	67
Cash and cash equivalents	1,735	2,440	4,822	5,559

	<i>,</i>		, -	- ,
	9 month period ended	Year ended	Year ended	Opening balance
EQUITY AND LIABILITIES (in thousands of euros)	30/09/14	31/12/13	31/12/12	01/01/12
Equity				
Equity attributable to owners of the Company	(1,810)	63	2,637	3,812
Share capital	10,466	9,288	8,417	6,943
Share premium	7,480	6,635	6,014	4,966
Retained earnings	(19,757)	(15,860)	(11,794)	(8,097)
Non-controlling interests	0	0	0	0
Total equity	(1,810)	63	2,637	3,812
Non-current liabilities	6,570	6,502	5,926	4,840
Financial liabilities	5,082	5,052	4,115	3,090
Deferred tax liabilities	0	0	0	0
Other non-current liabilities	1,488	1,450	1,811	1,750
Current liabilities	8,212	6,246	5,854	6,400
Financial liabilities	3,340	509	192	152
Trade and other payables	1,852	1,458	1,116	789
Current tax liabilities	0	0	0	0
Other current liabilities	3,020	4,279	4,546	5,459
Total liabilities	14,782	12,748	11,780	11,241
TOTAL EQUITY AND LIABILITIES	12,971	12,811	14,418	15,053

12,971

12,811

14,418

15,053

TOTAL ASSETS

The following table sets forth the Company's consolidated cash flow statement for the years ended 31 December 2013 and 2012 as well as the nine month period ended 30 September 2014 and 2013. The consolidated cash flow statements for the years ended 31 December 2013 and 2012 have been audited. The consolidated cash flow statement for the nine months period ended 30 September 2014 and 2013 have been reviewed by the auditor.

(in thousands of euros)	9 montl end	-	Year ended 31 December	
-	30/09/14	30/09/13	2013	2012
CASH FLOW FROM OPERATING ACTIVITIES				
Operating profit/(loss)	(3,737)	(2,731)	(4,043)	(3,662)
Adjustments for:				
Depreciation, Amortisation and Impairments	305	296	407	402
Grants income related to forgivable loans	(1,733)	(1,681)	(2,383)	(1,939)
Grants income related to patents	(96)	(66)	(87)	(113)
Grants income related to tax credit	(320)	(327)	(405)	(404)
Other	(26)	23	0	1
Movements in working capital:				
Trade and other receivables (excluding government grants)	(98)	(14)	(86)	(136)

(in thousands of euros)	9 month period ended			
	30/09/14	30/09/13	2013	2012
Trade and Other Payables	327	(74)	337	324
Cash generated from operations	(5,376)	(4,573)	(6,261)	(5,528)
Cash received from grants related to forgivable loans	1,454	1,993	2,913	1,395
Cash received from grants related to patents	9	65	75	83
Cash received from grants related to tax credit	0	0	0	0
Income taxes paid	0	0	0	0
Discontinued operations	0	0	0	0
Net cash used in operating activities	(3,913)	(2,515)	(3,274)	(4,050)
CASH FLOW FROM INVESTING ACTIVITIES				
Interests received	18	29	39	78
Purchases of property, plant and equipment	(2,371)	(889)	(1,710)	(533)
Purchases of intangible assets	(4)	(46)	(61)	(24)
Proceeds from other current financial assets	()	0	0	203
Payments to acquire financial investments	()	13	(17)	(104)
	0	0	0	0
Discontinued operations	0	0	0	0
Net cash used in investing activities	(2,357)	(893)	(1,748)	(380)
CASH FLOW FROM FINANCING ACTIVITIES				
Proceeds from government loans	623	854	1,248	598
Repayment of government loans	(203)	(135)	(135)	(125)
Reimbursements of other non-current liabilities	0	(375)	(375)	0
Reimbursements of financial liabilities	0	0	0	0
Proceeds from loans from related parties	3,228	500	500	750
Reimbursements of financial lease liabilities	(49)	(52)	(37)	(35)
Interests paid	(57)	(22)	(52)	(18)
Proceeds from issue of equity instruments of the Company (net of issue costs)	2,024	1,491	1,491	2,522
Discontinued operations	(1)	(1)	0	0
Net cash provided by financing activities	5,565	2,261	2,641	3,692
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(705)	(1,148)	(2,381)	(737)
CASH AND CASH EQUIVALENTS at beginning of year	2,440	4,822	4,822	5,559
CASH AND CASH EQUIVALENTS at end of year	1,735	3,674	2,440	4,822

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

_	Attributable to	ny				
(in thousands of euros)	Share capital	Share premium	Retained earnings	Total equity attributable to owners of the Company	Non- controlling interests	TOTAL EQUITY
Balance at 31 December 2012	8,417	6,014	(11,795)	2,636	0	2,637
Total comprehensive income of the period	0	0	(2,730)	(2,730)	10	(2,720)
Issue of share capital	871	629	0	1,500	0	1,500
Transaction costs for equity issue	0	(9)	0	(9)	0	(9)
Additional non-controlling interests	0	0	10	10	(10)	0
Balance at 30 September 2013	9,288	6,635	(14,515)	1,408	0	1,407
Balance at 31 December 2013	9,288	6,635	(15,860)	63	0	63
Total comprehensive income of the period			(3,853)	(3,853)	(44)	(3,897)
Issue of share capital	1,179	852		2,031		2,031
Transaction costs for equity issue		(6)		(6)		(6)
Additional non-controlling interests			(44)	(44)	44	0
Balance at 30 September 2014	10,466	7,481	(19,757)	(1,810)	0	(1,810)

#### 8 **Operating and financial review**

The following operating and financial review should be read in conjunction with the Company's audited consolidated financial statements and interim condensed consolidated financial statements (and notes to those consolidated financial statements, included in this Prospectus. Certain statements in this section are forwardlooking and should be read in conjunction with Section 2.6"Forward looking statements". The Company's consolidated financial statements have been prepared and have been restated in accordance with IFRS as adopted by the EU as well as with the legal and regulatory requirements applicable in Belgium. The figures used in this section refer to the financial statements which have been prepared in accordance with IFRS as adopted by the EU.

#### 8.1 **Overview**

Bone Therapeutics is a biotechnology company with an advanced pipeline of clinical programs (2 pivotal IIB/III Phase III and 3 Phase II), founded in 2006, with a unique approach towards the development and commercialization of cell products for bone fracture repair and fracture prevention. characterized by high unmet medical needs<sup>77</sup> due to the lack of innovative, non-invasive treatments and where, despite large markets, competition is limited<sup>78</sup> (see Section 6.3, "The high unmet medical needs for bone disorders"). The Company is creating a new and unique treatment concept using differentiated bone-forming cells (with its two products PREOB® and ALLOB®) administered via a minimally invasive percutaneous procedure, expected to offer significant benefits over the current standard-of-care that often involves heavy surgery and long recovery periods. Solid preclinical foundations and clinical experience support its research and development programs. The Company has extensive knowledge of bone physiology and pathophysiology and collaborates closely with prestigious academic and medical institutions.

The Company aims to be a leading regenerative company providing innovative cell products for conditions with high unmet medical needs in the fields of bone fracture repair and prevention. To achieve this objective, the Company is currently conducting clinical trials in five indications: 3 (non-union, delayed union, spinal fusion) in fracture repair and 2 (osteonecrosis and osteoporosis) in fracture prevention.

Up to 30 September 2014, the Company has been able to fund its operations with a long term perspective through the following funding instruments:

- € 18 million in net proceeds from private equity placements in Bone Therapeutics SA (see condensed consolidated statement of financial position at 30 September 2014 – Annex C – Financial information);
- € 1.3 million in invested cash through the non-controlling interest held by third parties in its affiliate SCTS SA (shown as other non-current liabilities, as explained in Annex C - note 5.10 - notes relating to the consolidated financial statements for the year ended 31 December 2013);
- € 20.4 million of non-dilutive funding, mainly through recoverable cash advances provided by the Walloon Region and to lesser extent through regular grants. In total, € 18.6 million was granted to Bone Therapeutics SA (of which € 6 million was still outstanding at the end of September 2014 - see Section 6.11.1.1 "Recoverable cash advances" and Section 6.11.1.2 "Subsidies") and € 1.8 million was granted to SCTS SA (of which € 1.1 million was still outstanding at the end of September 2014 - see Section 6.11.2.1 "Recoverable cash advances" and Section 6.11.2.2 "Subsidies");
- € 3.25 million as a long term investment credit provided by BNP Paribas Fortis SA/NV and ING Belgique SA/NV (each for half of the amount) for the construction of the SCTS building at the Biopark of Gosselies (South of Brussels) (not yet used);
- € 1.6 million in loans, provided by related parties (regional investment vehicles) which have been recorded as current and non-current financial liabilities (see condensed consolidated statement of financial position at 30 September 2014 – Annex C – Financial information); and
- € 2.9 million through an investment grant provided by the Walloon Region on the SCTS building (see Section 6.11.3 "SISE and GIE BOCEGO").

<sup>&</sup>lt;sup>77</sup> Defined as a medical need that is not addressed adequately by an existing therapy, FDA Guidance for Industry – Available Therapy, July

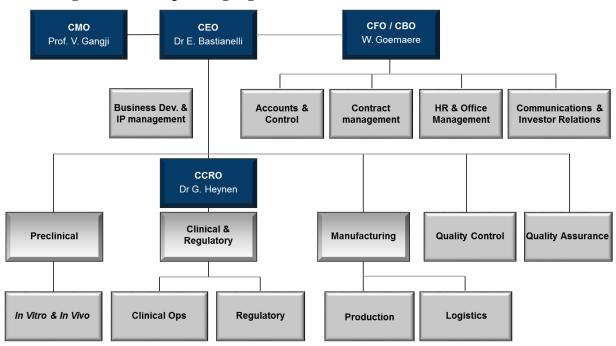
<sup>&</sup>lt;sup>78</sup> Competition can be can be considered as limited if there are only a few (less than 5) competing clinical programs (as from phase I) with other products in the same indication; products at an early (preclinical) stage of development are not considered due to the very long development time of these products.

SCTS SA was established in 2011 to provide support in respect of facilities and related services, logistic services for both R&D and production operations, process development activities, pilot production and scale up of such production activities up to commercial stage for companies engaged in the field of cell therapy for bone or skeletal applications (Skeletal Cell Therapy Support).

Bone Therapeutics SA and SCTS SA have their registered offices at Gosselies in the Walloon region of Belgium. Currently the Company runs its operations out of its facilities at the Galactic Innovation Campus (GIC) building in Brussels. As of the second quarter of 2015, the Company is expected to gradually move all its operational activities to the BioPark of Gosselies (south of Brussels) where new facilities, owned by SCTS SA, are currently under construction.

Bone Therapeutics intends to pursue ongoing European clinical trials on Phase III and Phase I/II and launch clinical trials Phase III in the US.

# 8.2 Organization & operating segments



The group does not make the distinction between different operating segments, neither on a business or geographical basis in accordance with the internal reporting provided to the chief operating decision-maker. The Board has delegated the day-to-day management of the Company to the CEO and the CFO. In this capacity they are in charge of the day to day operations of the Company under the supervision of the Board.

# 8.3 Factors affecting the result of operations

The successful development of research programs and product candidates is uncertain and the Company expects to continue to incur operating losses for the foreseeable future as it proceeds with clinical trials for its two products PREOB® and ALLOB® as well as with other potential product candidates. At this time, the Company cannot reasonably estimate the precise timing and detailed costs of the efforts that will be necessary to complete the remainder of the development of these research programs and product candidates. The Company is also unable to predict when material cash inflows will commence from sales of PREOB® and ALLOB® and or other product candidates.

Set forth below is a discussion of factors that the Company believes will materially impact the Company's results in future periods. As the Company is not yet commercializing any of its products, all costs incurred qualify as either Research and Development expenses or General and Administrative expenses. The discussion below however provides more detailed operational insights in the composition of its Research and Development expenses.

## 8.3.1 Other operating income

To date, the Company did not generate revenue from its operations. However, its operating income consists of grants, tax incentives and recoverable cash advances (*avances récupérables*, presented as forgivable loans in the Consolidated financial statements) mainly granted by the Walloon Region. In the future, the Company believes it will be able to benefit further from such schemes to support its R&D activities. Income could vary from year to year, depending on Company's size and activity and local authority's policy.

The Company will seek to generate regular revenues in future through both product sales and through collaborations which could result in research and development fees, upfront and milestone payments and royalties. Such income could never materialize or fluctuate from period to period as a result of the terms and timings of such potential collaboration agreements and to the extent that the Company is successful in commercializing its products for the respective indications and the volumes and timings of such potential product sales.

# 8.3.2 Clinical development

In the short and medium term the key focus for the Company will consist in developing its two products PREOB® and ALLOB® through the Phase III and the Phase II clinical trials. Direct (treatment and follow-up of patients) and indirect (study management) costs related to clinical trials will represent over 65% (including the relevant share of the below mentioned production costs) of the expenditure of the Company in the years to come.

These costs furthermore include regulatory and clinical expenses, such as CRO and CRA (for study management and monitoring) activities, medical imaging, data management and hospital patient fees, and milestone payments in relation to in-licensed technology from the Université Libre de Bruxelles (ULB) in connection with the PREOB® product, next to staff costs. All clinical costs are expensed as incurred as the policy of the Company is not to capitalize development expenditure as long as a project has not completed Phase III. Also with the ongoing Phase III trials, the overall clinical expenses are expected to increase significantly compared to previous years.

#### 8.3.3 Production costs

The Company's production expenses are to a large extent directly attributable to the ongoing clinical trials, more specifically for the production of the clinical batches of PREOB® and ALLOB® needed for treating patients in the clinical studies. The other production expenses are related to continuous efforts to improve the production efficiency. This effort will allow the Company to produce at the most optimal cost possible and to make optimal use of the available capacity in future. The Company's manufacturing expenses includes salaries of the manufacturing team, production supplies, maintenance and utilities for the GMP manufacturing zone and equipment, depreciation of the infrastructure and regulatory expenses. The Company currently leases production facilities from a third party at the Galactic Innovation Campus (GIC) building in Brussels (Belgium). Upon completion and following the commissioning of the new manufacturing facilities (planned for midsummer 2016) at the BioPark of Gosselies (south of Brussels), the production will be transferred to this new location. The current facility meets the requirements for clinical trials. The new facility at Gosselies allows for gradual expansion to meet the requirements for clinical trials and is ultimately scalable to meet first years' commercial requirements whereby additional units can be added at the same location in the future. It is expected that production costs per unit can be significantly reduced once first commercial capacity will be achieved. It is important to note that until the Company goes into commercial phase the production costs will be reported as part of the Research and Development expenditure.

# 8.3.4 Quality assurances, quality control

Expenditure related to quality assurance and quality control mainly relates to people cost for the teams ensuring these activities. Next to people costs external costs are incurred as today some of the quality control tests are performed by sub-contractors specialised in quality control testing. In future the Company is planning to perform these tests in-house in order to realize important cost reductions. Quality control and quality assurance expenses are related manufacturing expenditure. As long as the Company is in development mode, these costs will be considered as research and development expenditure. Once products are made for commercial purposes these costs will become part of COGS in function of the volumes produced for this purpose.

## 8.3.5 Preclinical research and development expenses

The Company's research and development expenses reflect costs incurred for research projects, including the salaries of project managers, scientists and technicians, the laboratory supplies for both *in vitro* and *in vivo* research and the costs of the outsourced research and development services. All clinical research costs are expensed as incurred.

The Company believes that research expenses will remain important in the future. The current pre-clinical work supports to a large extent projects which are in the clinic, gathering further data to support ongoing filing of dossiers. The preclinical research also further explores opportunities to leverage on opportunities with the current products PREOB® and ALLOB® as new programs addressing other indications in the field of bone diseases and orthopaedic conditions.

# **8.3.6** Protection of intellectual property

R&D expenses also include the costs of maintaining and overseeing the Company's intellectual property portfolio including the costs of legal counsel and associated filing and maintenance fees.

#### **8.3.7** *General and administrative expenses*

The Company's general and administration expenses consist of salaries and other related costs for staff in executive, finance, human resources, accounting and investor relations and communication functions. It also includes expenditure for general facilities and maintenance and outsourced activities such as audit, legal and IT. General and administrative expenses are expected to increase with the expansion of the Company and its management team (amongst others business development activities) and with the additional expenses in relation to comply with operating as a public entity.

#### 8.3.8 Taxation

Since its incorporation, the Company has not made any profits and thus not paid any corporate income taxes. The Company's accumulated tax losses amounted to € 11.08 million as per the fiscal declaration up to the end of 31 December 2013. These tax losses can in principle be used to offset future tax profits. However, because of the development stage of the Company and the lack of visibility that the Company will generate taxable profits within the foreseeable future, no tax losses carried forward have been recorded as deferred tax assets in the Company's financial statements (IFRS) to date.

Besides the use of the exemption from professional withholding taxes on part of the remuneration paid to scientific personnel, the Company applies for an income tax credit that corresponds to a percentage of qualifying R&D costs to which the income tax rate (33.99%) is applied. In case of (insufficient current) corporate income taxes payable against which to set off the tax credit, the latter is carried-forward to the following four years and recognized as a deferred tax asset. At the end of this period, the balance of the unused tax credit is paid by the tax authorities. Revenues in this respect are presented as Other Operating Income referred to above as tax incentives.

On 27 April 2007, a law was approved in Belgium which allows Belgian companies to exempt 80% of their patent income from corporate income tax starting from the 2008 tax assessment year if such income is deemed to derive from intellectual property which is internally generated. In the case of acquired intellectual property, the patent income that will be eligible for tax reduction will be reduced by the relevant depreciation on the acquired intellectual property. In the future, the Company intends to apply for the necessary ruling to optimize its corporate tax rate by benefiting to a certain extent from this favourable tax regime which allows for such revenues to be subject to a tax rate of approximately 6.87% instead of the nominal rate of 33.99%.

# 8.4 Analysis of the consolidated statement of comprehensive income

The following table includes information relating to the Company's statement of comprehensive income for the years ended 31 December 2013 and 2012 and for the nine months period ended 30 September 2014 and 2013.

(in thousands of euros)	9 month end		Year ended 31 December	
	30/09/14	30/09/13	2013	2012
Revenue	0	0	0	0
Other operating income	2,644	2,418	3,394	3,057

(in thousands of euros)	9 month end	_	Year ended 31 December	
	30/09/14	30/09/13	2013	2012
Total operating income	2,644	2,418	3,394	3,057
Research and development expenses	(5,523)	(4,647)	(6,816)	(6,371)
General and administrative expenses	(865)	(502)	(621)	(348)
Operating profit/(loss)	(3,743)	(2,731)	(4,043)	(3,662)
Interest income	110	96	150	172
Financial expenses	(201)	(115)	(190)	(189)
Exchange gains/(losses)	(63)	()	(1)	(3)
Share of profit/(loss) of associates	0	31	19	(17)
Result Profit/(loss) before taxes	(3,897)	(2,720)	(4,066)	(3,698)
Income taxes	0	0	0	0
PROFIT/(LOSS) FOR THE PERIOD	(3,897)	(2,720)	(4,066)	(3,698)
Other comprehensive income	0	0	0	0
TOTAL COMPREHENSIVE INCOME OF THE				
PERIOD	(3,897)	(2,720)	(4,066)	(3,698)

#### 8.4.1 Other operating income

The other operating income reported relates to the different grants received by the Group and can be summarized as follows:

	9-month pe	eriod ended	Year ended 31 Decembe		
(in thousands of euros)	30/09/2014	30/09/2013	2013	2012	
Grants income related to forgivable loans	1,733	1,681	2,383	1,939	
Grants income related to exemption on withholding taxes	402	297	430	501	
Grants income related to tax credit	320	327	405	404	
Grants income related to patents	96	66	87	113	
Other grants income	92	47	88	100	
Total	2,644	2,418	3,394	3,057	

Other operating income over 2013 amounts to  $\in$  3.40 million. This is an increase of  $\in$  0.34 million or 10% compared to the previous year mainly resulting from the increase in grant income related to forgivable loans from the Walloon Region.

Other operating income for the first nine months of 2014 amounts to € 2.64 million compared to 2.42 million for the same period in 2013.

#### **8.4.2** Research and development expenses

Research and development expenses amounted to  $\in$  6.82 million for the full year 2013, showing an increase of  $\in$  0.45 million (+7%) from 2012 to 2013. The R&D expenses over 2013 mainly related to the completion of the Phase II trials with the Company's PREOB® product for osteonecrosis and non-union as well as the preparation of the dossier filing for the Phase III trials. Furthermore the Company has been proceeding with pre-clinical work around the development of its new allogeneic product ALLOB®.

For the nine months period ending 30 September 2014, Research & Development expenses amounted  $\in$  5.52 million compared to  $\in$  4.65 million for the same period of 2013. The increase of  $\in$  0.88 million from 2013 to 2014 is mainly resulting from the increase in activity in respect of clinical programs by both accelerating existing programs (Phase III) as well as in initiating new Phase II programs.

## **8.4.3** General and administrative expenses

General and administrative expenses amounted to  $\in$  0.62 million for the full year 2013, which represents an increase of  $\in$  0.27 million (+78%) from 2012 to 2013. The increase in general and administrative expenses in

2013 is explained by an increase in employee benefits expenses (strengthening of the management team), infrastructure services performed by the associate Company, increased public relation and investor relation activities and other outsourced activities.

General and administrative expenses for the nine months period ending 30 September 2014 amounted to  $\in$  0.87 million and have increased by  $\in$  0.36 million compared to the same period in 2013. This increase is mainly a further result of the strengthening of the management team both in salaries as in operational supporting expenditure (increased international activity).

#### 8.4.4 Financial income and expenses

The financial results are detailed in the table below and further discussed in note 6.5 to the consolidated financial statements for the period ended 31 December 2013.

	9-month pe	riod ended	Year ended 31 December		
(in thousands of euros)	30/09/2014	30/09/2013	2013	2012	
Interest income on bank deposits	7	7	29	63	
Interest income in relation to government loans	103	89	121	109	
Total interest income	110	96	150	172	
Interest on borrowings	(43)	(22)	(31)	(13)	
Interest on government loans	(103)	(89)	(121)	(109)	
Interest on obligations under finance leases	(14)	0	(20)	(5)	
Fair value gain or losses	(38)	(1)	(14)	(61)	
Other	(4)	(5)	(4)	(1)	
Total financial expenses	(201)	(116)	(190)	(189)	
Exchange gains/(losses)	(63)	0	(1)	(3)	
Share of profit/(loss) of associates	0	31	19	(17)	
Total financial result	(154)	10	(22)	(36)	

Financial income for the first 9 months of 2014 amounts to  $\in$  0.11 million in line with the  $\in$  0.1 million over the same period in 2013. Financial expenses amount to  $\in$  0.20 million compared to  $\in$  0.1 million for the same period in 2013. Including an exchange loss of  $\in$  63,000, the financial result up to the end of September 2014 amounts to a loss of  $\in$  154,000.

Financial income for the full year 2013 amounts to  $\in$  0.15 million in line with the income generated in 2012 amounting to  $\in$  0.17 million. This relates mainly to income recognition on non-interest bearing government loans. Financial expenses for the full year 2013 amount to  $\in$  0.20 million compared to  $\in$  0.19 million for the full year 2012.

## 8.4.5 Loss for the period

As a result of the foregoing, the Company's loss for the full year 2013 amounted to  $\in$  4.07 million, an increase of  $\in$  0.37 million compared to the year 2012. The increase of R&D expenditure was to a large extent offset by increased revenues received to finance R&D programs. As such the increase in loss for the period comes almost entirely on account of the increase in general and administrative expenditure.

The loss for the nine months ending 30 September 2014 amounts to  $\in$  3.89 million versus a loss of  $\in$  2.72 million for the same period in 2013. The increase in loss of  $\in$  1.17 million is on account of increased research and development costs and partially also to the strengthening of the management team.

# 8.5 Analysis of the consolidated statement of financial position

The table below shows the balance sheet on 1 January 2012, 31 December 2012, 31 December 2013 and 30 September 2014.

#### **8.5.1** *Assets*

	9 month period ended	Year ended	Year ended	Opening balance
ASSETS (in thousands of euros)	30/09/14	31/12/13	31/12/12	01/01/12

	9 month period ended	Year ended	Year ended	Opening balance
Non-current assets	4,230	4,724	2,650	2,004
Intangible assets	42	60	19	4
Property, plant and equipment	2,074	2,869	1,277	1,137
Investments in associates	282	282	263	280
Financial assets	181	180	163	59
Deferred tax assets	1,652	1,333	927	523
Current assets	8,741	8,087	11,767	13,049
Trade and other receivables	6,861	5,513	6,834	7,220
Other financial assets	0	0	0	203
Other current assets	145	134	112	67
Cash and cash equivalents	1,735	2,440	4,822	5,559
TOTAL ASSETS	12,971	12,811	14,418	15,053

The Company's assets are mainly relating to property, plant and equipment, deferred tax assets, other receivables and cash and cash equivalents amounting to € 12,32 million or 95% of total assets at the end of September 2014 (compared to € 12.16 million or 94.8% of total assets at the end of 2013). Property, plant and equipment amounts to € 2.07 million compared to € 2.87 million at the end of December 2013. The decrease is explained by the fact that the Company received confirmation of the capital grant for an amount of € 2.91 million to finance its new facilities based at he BioPark of Gosselies (south of Brussels). This amount more than offsets new investment made during the period for this same project. Apart from the capital grant property, plant and equipment contains the cost for the building under construction (not depreciated yet) for an amount of € 4.25 million, a long term land lease valued at a fair value of € 0.23 million and € 0.43 million of laboratory and production equipment. Deferred tax assets totalling € 1.65 million are representing a tax credit reimbursable in the foreseeable future (3 to 4 years). The other receivables amounting to € 6.86 million relate to on the one the hand the capital grant mentioned above still be received from the Walloon Region for an amount of € 2.91 million (being the main reason for the increase in value of this item) and on the other hand an amount of € 3.62 million forgivable loans (being the amount receivable of the so called "Avance récupérables" which are classified as forgivable loans - see also note 4 to the Condensed financial statements for the nine-months period ended 30 September 2014). The remaining amount of refers patent grants to be received for an amount of € 0.13 million and tax to receive for an amount of € 0.2 million. Cash and cash equivalents at the end of September 2014 amount to € 1.735 million. The reduction is mainly due to increased expenditure offset only partially by the capital increases which took place in February and July 2014.

## 8.5.2 Equity and liabilities

	9 month period ended	Year ended	Year ended	Opening balance
EQUITY AND LIABILITIES (in thousands of euros)	30/09/14	31/12/13	31/12/12	01/01/12
Equity				
Equity attributable to owners of the Company	(1,810)	63	2,637	3,812
Share capital	10,466	9,288	8,417	6,943
Share premium	7,480	6,635	6,014	4,966
Retained earnings	(19,757)	(15,860)	(11,794)	(8,097)
Non-controlling interests	0	0	0	0_
Total equity	(1,810)	63	2,637	3,812
Non-current liabilities	6,570	6,502	5,926	4,840
Financial liabilities	5,082	5,052	4,115	3,090
Deferred tax liabilities	0	0	0	0

	9 month period ended	Year ended	Year ended	Opening balance
Other non-current liabilities	1,488	1,450	1,811	1,750
Current liabilities	8,212	6,246	5,854	6,400
Financial liabilities	3,340	509	192	152
Trade and other payables	1,852	1,458	1,116	789
Current tax liabilities	0	0	0	0
Other current liabilities	3,020	4,279	4,546	5,459
Total liabilities	14,782	12,748	11,780	11,241
TOTAL EQUITY AND LIABILITIES	12,971	12,811	14,418	15,053

Equity amounts to a negative amount of  $\in$  1.81 million at the end of September 2014 compared to  $\in$  0.06 million (positive) at the end of December 2013. The increase of share capital and share premiums of  $\in$  2.024 million (capital increases of February and July 2014) are more than entirely offset by the negative result for the period. Total negative retained earnings exceed the share capital and share premium amount and result in negative equity as of 30 September 2014. The non-controlling interest in the Company's affiliate SCTS has been set at "0" and has been represented as a liability on the balance sheet for an amount of  $\in$  1.49 million on 30 September 2014. This represents the value of the put option the parties representing the non-controlling have, to sell their interest to the Company as per the conditions further detailed in the notes (5.10) to the consolidated financial statements of the Company.

Liabilities totalling € 14.78 million at the end of September 2014 compared to € 12.75 million at the end of December 2013.

The non-current liabilities remained almost unchanged at  $\in$  6.57 million and are representing forgivable loans – reimbursable part recognized at the start of the contract ("Avances récupérables" from the Walloon Region) for an amount  $\in$  3.54 million, loans from related parties (regional investment offices) represent  $\in$  1.45 million and finance lease contracts (for laboratory equipment) amount to  $\in$  0.06 million. A long term debt has been recognized for an amount of  $\in$  0.03 million in relation to the long term land lease at the BioPark of Gosselies (south of Brussels). Other non-current liabilities for an amount of  $\in$  1.49 million represent the put option explained above.

Current liabilities amount to  $\in$  8.21 million at 30 September 2014 compared to  $\in$  6.25 million at the end of December 2013 resulting in an increase of  $\in$  1.97 million. The financial liabilities amounted to  $\in$  3.34 million and did increase with  $\in$  2.83 million. This is mainly due to SCTS withdrawing tranches from a straight loan facility provided by ING and BNP Paribas Fortis to pre-finance the subsidies to be received from the Walloon Region for the infrastructure project at the BioPark of Gosselies (south of Brussels) (see also Section 6.10 "Financing Agreements") for an amount of  $\in$  2.36 million. In addition Bone Therapeutics has withdrawn a first tranche of  $\in$  0.5 million from a bridge loan facility provided by BNP Paribas Fortis to pre-finance funding for research activities covered by contracts with the Walloon Region (see also Section 6.10 "Financing Agreements"). Trade and other payables amounted to  $\in$  1.85 million which represented an increase with  $\in$  0.39 million compared to the end of December 2013 in line with the increase in activity of the Company and amounted to  $\in$  1.85 million at the end of September 2014. Other current liabilities amount to  $\in$  3.02 million at the end of September 2014 compared to  $\in$  4.28 million at the end of December 2013, showing a decrease of  $\in$  1.26 million. Other current liabilities represent mainly deferred income related to the forgivable loans and patent grants. The decrease results from the higher spending rate (higher activity) over the last 9 months which was not compensated to the same extent by money received from new contracts.

# 8.5.3 Impact of inflation

The results of the Company's operations for the year-ends and periods discussed have not been materially affected by inflation.

# 8.6 Liquidity and capital resources

#### 8.6.1 General

The Company's liquidity requirements primarily relate to the funding of its preclinical and clinical programs and the related support activities In particular this represents the funding of its:

- ongoing clinical programs;
- manufacturing activities related to the ongoing clinical programs including quality assurance and quality control
- regulatory activities both related to clinical trials and production activities;
- pre-clinical activities related to the ongoing clinical programs;
- production development and optimisation (reduction of COGS and optimization of use of capacity);
- pre-clinical activities allowing the Company to leverage on its existing product platform;
- general and administrative expenses to support the growth of the Company;
- capital expenditure in particular specialized equipment;
- repayments of outstanding loans provided by banking institutions or by regional investment bodies considered as related parties) – repayable portion of the non-dilutive funding provided by the Walloon Region and some outstanding finance leases;
- working capital requirements.

The ongoing clinical trials relate to the two pivotal Phase III (including the acceleration of patient enrolment) trials and three Phase II trials

- Completion of patient enrolment of the Phase III osteonecrosis trial and completion of the interim analysis (PREOB®) – including an acceleration of the patient enrolment program;
- Completion of patient enrolment of the Phase III non-union trial (PREOB®) including an acceleration of the patient enrolment program;
- Completion of the Phase IIA osteoporosis trial (PREOB®);
- Completion of the Phase I/IIA delayed union trial (ALLOB®) and preparation of the Phase IIB or Phase III trial;
- Completion of the spine fusion Phase IIA trial (ALLOB®) and preparation of the Phase IIB or Phase III trial;
- The Company also envisages launching clinical trials in the US for osteonecrosis (Phase III) and non-union (Phase III).

The Company has expensed all its clinical and research and development costs till date (under IFRS) and will continue to do as long as this expenditure relates to development work until completion of the Phase III studies. In case the Board of Directors believes there are reasons to deviate from this rule in future due to particular conditions allowing to obtain greater certainty about the revenue potential of products developed by the Company, the Board of Directors will do so and motivate this decisions to activate such expenses where appropriate.

Up to the end of September 2014, Bone Therapeutics SA has been funded through several equity funding rounds. At the end of September 2014 the issued share capital and share premium amounted to a total of  $\in$  17.95 million

In addition Bone Therapeutics SA received non-dilutive funding for an amount of  $\in$  18.56 million of which  $\in$  12.59 million received till date and  $\in$  5.97 million still outstanding (receivable) mainly from the Walloon Region.

On 18 December 2014 and on 8 January 2015 the Company has issued convertible bonds for a total amount of € 10.35 million. This considerably strengthens the financial position of the Company. This transaction is further described in Section 8.9 "Events after the statement of financial position".

The long term financing requirements for SCTS SA are totalling approximately  $\in$  9.50 million intended for the construction of the new facilities to accommodate the production, R&D and G&A functions for both SCTS SA and Bone Therapeutics SA. Next to equity funded by Bone Therapeutics (49.9%) for amount of  $\in$  1.27 million other third party shareholders provided equity funding for an amount of  $\in$  1.28 million which resulted in a total equity of  $\in$  2.55 million at the level of SCTS SA. SCTS SA has, together with Bone Therapeutics SA under the form of GIE (*groupement d'intérêt économique*), secured government funding through the Walloon Region under the form of an investment credit for a total amount of  $\in$  2.91 million (still to be paid). In addition SCTS SA concluded two long term loans with commercial banks for a total of  $\in$  3.25 million and two loans with related parties (regional investment bodies) for a total amount of  $\in$  0.87 million (paid and recognized at the end of December 2013 for an amount of  $\in$  0.50 million) See section 6.10 "Financing Agreements". Next to this SCTS SA received  $\in$  0.87 million in loans from related parties (regional investment bodies). As such the total foreseen investment of  $\in$  9.50 million is fully financed. In order to pre-finance however the funding to be received from the Walloon Region the Company has withdrawn an amount of  $\in$  2.40 million euro from the short term loan facilities provided by both ING and BNP (50/50) for this purpose. On receipt of the government funding the amounts will be reimbursed to both banks.

In addition SCTS SA was granted non-dilutive funding to co-finance operating activities for an amount of  $\in$  1.81 million of which  $\in$  0.72 million received till date and  $\in$  1.09 million still outstanding (receivable) from the Walloon Region.

#### 8.6.2 Cash flows

The following table sets forth the Company's consolidated cash flow statement for the years ended 31 December 2013 and 2012 as well as the nine month period ended 30 September 2014 and 2013. This table is presented in further detail under the section "Consolidated statement of cash flows" of the Consolidated financial statements for the period ended December 31.2013 and in the Condensed consolidated financial statements for the 9-mont period ended 30 September 2014 under the section Condensed consolidated statement of cash flows.

> monum portou		Year ended 31 December	
30/09/14	30/09/13	2013	2012
(3,913)	(2,515)	(3,274)	(4,050)
(2,357)	(893)	(1,748)	(380)
5,565	2,261	2,641	3,692
(705)	(1,148)	(2,381)	(737)
2,440 <b>1.735</b>	4,822 <b>3.674</b>	4,822 2,440	5,559 4,822
	(3,913) (2,357) 5,565	ended 30/09/14 30/09/13  (3,913) (2,515)  (2,357) (893)  5,565 2,261  (705) (1,148)  2,440 4,822	ended Decen 30/09/14 30/09/13 2013  (3,913) (2,515) (3,274)  (2,357) (893) (1,748)  5,565 2,261 2,641  (705) (1,148) (2,381) 2,440 4,822 4,822

**Cash flow from operating activities** represents mainly the net cash used by the Company to finance both the clinical developments and pre-clinical developments after taking into account:

- cash received through grants and forgivable loans from the Walloon Region in support of these developments;
- adjustments for working capital movements; and
- adjustments for noncash items such as depreciation and tax credits.

Cash used for operating activities during the first nine months of 2014 amounts to  $\in$  3.91 million compared to  $\in$  2.52 million over the same period last year and  $\in$  3.27 million for the full year 2013 and  $\in$  4.05 million for the full year 2012. Higher net expenditure in 2014 (for the first nine months) is driving the cash use whilst in 2013 the cash used in operating activities was favourably impacted by higher amounts received from the Walloon Region (in cash).

Cash flow from investing activities shows a net use of cash for the first nine months of 2014 of  $\in$  2.36 million compared to  $\in$  0.89 million over the same period last year and  $\in$  1.75 million for the full year 2013 and  $\in$  0.38 million for the year 2012. Cash used for investing activities clearly reflect the spending in respect of the construction of the new facilities at the BioPark of Gosselies (south of Brussels) (which will become operational for R&D and administrative purposes in the course of 2015 and as of the middle of 2016 for production activities). These investments were made through the Company's affiliate SCTS.

# Cash flow from financing activities represents on the one hand cash inflows from:

- capital increases for an amount of € 2.03 million during the first nine months of 2014, € 1.49 million in 2013 and an amount of € 2.52 million in 2012:
- loans provided by related parties (regional investments bodies) for an amount of € 0,37 million during the first nine months of 2014, € 0.50 million in 2013 and € 0.75 million in 2012;
- short term loans (see also above under 8.5.2 equities and liabilities) provided by the banks for an amount of € 2.86 million during the first nine months of 2014; and
- non-forgivable loans provided to the Company by the Walloon Region (R&D project financing) for an amount of € 0.62 million during the first nine months of 2014, € 1.25 million in 2013 and € 0.60 million in 2012.

and on the other hand cash outflows for:

- reimbursements of non-forgivable loans for an amount of € 0.20 million during the first nine months of 2014, € 0.14 million in 2013 and € 0.13 million in 2012;
- other reimbursements (lease contracts) and interest paid for an amount of € 0.11 million during the first nine months of 2014, € 0.09 million in 2013 and € 0.05 million in 2012;
- and a capital decrease and reimbursements to (some) of the shareholders of SCTS SA for an amount of
  € 0.37 million in 2013.

Together these in- and out-flows are resulting in net cash generated by financing activities for a total amount of € 5.57 million during the first nine months of 2014, € 2.64 million in 2013 and € 3.69 million in 2012.

# 8.7 Disclosures about interest rates, credit and currency risk

The Company has limited interest rate risk. Besides forgivable loans (non-interest bearing on a cash basis) the Company has a number of medium term loans provided by regional investments bodies at fixed market interest rates. SCTS SA has long term loans with two commercial banks with an interest rate linked to the Euribor 3M and short term loans to pre-finance investment grants to be received in respect of the building under construction (until these grants are paid) at similar short term rates. For the long-term loan the Company is permanently monitoring the short-term interest rates versus options to swap these rates versus a long term interest rate (IRS) in function of the remaining term of the loan.

The Company believes that its credit risk, relating to receivables, is limited because currently almost all of its receivables are with public institutions.

The Company is currently not exposed to any significant foreign currency risk. However should the Company enter into long term collaboration agreements with third parties for which revenues would be expressed in a foreign currency which should not compensate for expenses to be done by the Company, the Company might in such case consider entering into a hedging arrangement to cover such currency exposure.

# 8.8 Significant accounting policies and estimates

In the application of the Group's accounting policies, management is required to make judgments, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and related 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 years:

- The investment in SCTS in respect of having a de facto controlling interest or not;
- The put option on the non-controlling interest in SCTS;

- Recognition of development costs as intangible assets;
- Forgivable loans;
- Recognition of deferred tax assets.

## 8.9 Events after the statement of financial position

The annual consolidated financial statements on 31 December 2013 were authorised for issue by the Board of Directors of the Company on 8 January 2015. Accordingly, events after the reporting period are those events that occurred between 1 January 2014 and 8 January 2015.

For those events after the reporting period until 30 September 2014, we also refer to the condensed consolidated financial statements for the 9 month period ended on 30 September 2014 that are included in the following section.

## 8.9.1 Issue of share capital

On 24 February 2014, the shareholders of the Company resolved upon a share split, dividing the 314,960 shares, without nominal value, each representing 1/314,960th of the share capital of the Company by 10, creating 3,149,600 shares, without nominal value, each representing 1/3,149,600th of the share capital of the Company. On the same day, the share capital was increased by a contribution in cash in the amount of  $\in$  580,000 with issuance of 152,000 shares. The aggregate share premium amounted to  $\in$  420,000. Following the capital increase, the share capital of the Company amounted to  $\in$  9,868,000 and was represented by 3,301,600 shares.

On 10 July 2014, the share capital was increased by a contribution in cash in the amount of  $\in$  598,000 with issuance of 156,640 shares. The aggregate share premium amounted to  $\in$  432,000. Following the capital increase, the share capital of the Company amounted to  $\in$  10,466,000 and was represented by 3,458,240 shares.

#### 8.9.2 Straight loan facility

On 18 August 2014, a straight loan facility was provided by BNP Paribas Fortis for a total amount up to € 1,500,000 and is running until 30 June 2015. This facility allows to pre-finance amounts due by the Walloon Region on recoverable cash advances ("avances récuperables" referred to as "forgivable loans" under IFRS) and subsidies (see Section 6.11 "Grants and subsidies") granted by the Walloon Region. In respect of this arrangement the Company has pledged the amounts to be received from the Walloon Region during the term of this credit facility as well as granted a business pledge mandate ("mandat de fonds de commerce") in respect of the Company for as long the Company wants to use this credit facility.

This facility bears a Euribor-based interest rate that amounts to 2.76% per year for the last drawing made early December 2014. Consistently with accounting policies, this straight loan facility is recognised as a financial liability and measured at amortised cost using the effective interest rate method.

Until 30 September 2014 an amount of  $\in$  0.5 million was drawn and accounted for. The remainder of the available was drawn between October and Mid-December. The Company has repaid in full the outstanding amount of  $\in$  1.50 million on 31 December 2014. Post IPO the Company will discontinue the facility.

On 27 May 2014 BNP Paribas Fortis SA/NV and ING Belgique SA/NV provided both a straight loan facility, each for an amount of  $\in$  1,450,000 to pre-finance an investment premium granted by the Walloon Region (see also Section 6.7 "Investments" and 6.17 "Properties and facilities"). The applicable interest rates and terms are decided based on what is appropriate for the chosen term at the time funds are withdrawn. Up to the end of end of September 2014 an amount of  $\in$  2.36 million was drawn on these facilities (50/50) and up to the end of December 2014 an additional amount of  $\in$  0.54 million was drawn resulting in a total liability of  $\in$  2.9 million or the entire amount. Repayment will be done following the receipt of the grant from the Walloon Region. The Company expects to receive 70% of this grant in 2015, and the remainder of the amount of the grant to which the Company is entitled is expected to become payable in 2016.

#### 8.9.3 Government subsidy related to the construction of the new facilities

The Company and SCTS have been awarded a subsidy in the amount of  $\in$  2,907,692.30 (financed directly by the Walloon Region for an amount of  $\in$  1,890,000 and for an amount of  $\in$  1,017,692.30 by the European Union), which covers 32.31% of the  $\in$  9,000,000 million construction cost of the building. The total projected cost represents  $\in$  9.5 million, taking into consideration the related participation in SISE SA, landlease agreements and related costs. The payment of the subsidy will take place gradually in accordance with the investment programme and the progress of the construction (after 40% of the investment, after 70% of the investment and

after finalisation of the investment). The grant of the subsidy was made subject to a number of Company-related conditions, which could give rise to a (partial) claim-back by the Walloon Region and the European Union in case of non-compliance therewith. For example, the Company (in its capacity as member of GIE BOCEGO) will need to employ (on average) an additional minimum number of employees (39) at its site in Gosselies, as of 1 January 2018 until 31 December 2021. The subsidy could also be claimed back in the event of non-realisation of at least 80% of the investment programme or if the Company transfers, does not use or ceases to use the facility (for its intended purpose) within a 5-year period following the realisation of the investments. In addition to the aforementioned specific conditions related to the Company, the subsidy agreement also contains more general conditions which are customary for subsidies, such as conditions in relation to information- and publicity related obligations and conditions related to compliance with fiscal, social and environmental regulations.

Consistently with accounting policies, this grant is deducted from the carrying amount of the related asset and will be recognised in the statement of profit or loss consistently with the depreciation expense of the related asset.

No payment has yet been received.

#### **8.9.4** Automatically convertible bonds

On 18 December 2014 and 8 January 2015, the Company issued automatically convertible bonds for an aggregate amount of  $\in$  10,350,000 (the "**Bonds**"). The Bonds are issued in registered form. Each Bond has a nominal value of  $\in$  1,000. The Bonds bear interest as from their issue date, at the rate of 7% per annum. Transaction costs amounting to  $\in$  470,000 euro have been incurred on the issuance of the Bonds.

The Bonds will automatically be converted into Shares at the earliest date between (i) the completion of the Offering and (ii) and 30 September 2015.

If the conversion occurs on the completion of the Offering, the number of Shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 166.5% of the nominal value of the Bonds, and the denominator is equal to the Offer Price. The exact number of shares to be issued upon conversion of the Bonds is unknown at the date of this Prospectus. On the basis of hypothetical offer prices, the potential dilution can be calculated as follows:

- if the Offer Price is set at the low end of the Offer Price Range, i.e. € 14.5, 1,188,465 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the mid-point of the Offer Price Range, i.e. € 15.5, 1,111,790 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the high end of the Offer Price Range, i.e. € 16.5, 1,044,409 Shares will be issued upon conversion of the Bonds.

If the conversion occurs on 30 September 2015, 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  $\in$  11.

The Bonds were subscribed to as follows:

- 35.5% of the Bonds were subscribed by existing shareholders (and their affiliates) of the Company; and
- 64.5% of the Bonds were subscribed by certain new investors, including SFPI SA.

Each investors subscribing to the Bonds have 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 case the conversion occurs on the completion of the Offering. As a result, the Bonds will not be classified as equity instruments of the Company before the Bonds are converted into Shares, including in the annual financial statements ended 31 December 2014.

#### 8.9.5 Offering related costs

After the reporting period, the Company has incurred several costs in connection with the Offering. The commitments of the Company in that include legal, consulting, administrative, audit, and other costs ( $\in$  786,000), remuneration of the Belgian Financial Services and Market Authority ( $\in$  20,000), legal publications, printing of the prospectus ( $\in$  35,000), advisors, management, placing and selling fees (estimated at

6-7% of the gross proceeds of the offering) and the fees payable to Euronext Brussels and Euronext Paris (€ 70,000).

Considering that the Offering is also expected to result in the issuance of new shares, a rationale allocation of the above mentioned costs will be determined between (i) costs linked to equity transactions that are immediately deducted from the equity of the Company, and (ii) and other costs relating to the Offering that are expensed in the statement of profit or loss.

#### 8.9.6 Share-based payments

After the reporting period, the Company has issued the following three warrant plans:

- Warrant Plan A for employees, directors or consultants: 113,760 warrants available for issuance but no warrants were granted to designated beneficiaries after the reporting period.
- Warrant Plan B for two executive members of key management personnel: 46,000 warrants available for issuance with 14,800 warrants granted to designated beneficiaries after the reporting period on 18 December 2014. These warrants are exercisable at a strike price of € 11 and are subject to a vesting period starting on the grant date and ending at the earliest of the completion of the Offering and the first anniversary of the grant. Warrants expire in February 2019.
- Warrant Plan C for three executive members of key management personnel: 145,000 warrants granted to designated beneficiaries after the reporting period on 18 December 2014. These warrants are exercisable at a strike price of € 11 and are subject to the following graded vesting: 25% at the completion of the Offering (or 1 January 2016 if the Offering is not completed prior thereto), 25% on 1 January 2016, 25% on 1 July 2016 and 25% on 1 January 2017. Warrants expire in December 2019.

Consistently with accounting policies, above warrants are equity settled share-based payment transactions. As a result, the fair value of warrants will be measured at grant date and recognised as an expense against equity over the related vesting period.

## 8.10 Off-balance sheet transactions

None to be reported.

# 9 Description of the issuer, the share capital and shares

## 9.1 General

This Section summarises the corporate purpose, share capital and corporate structure of the Company and the rights attached to the Offered Shares. It is based on the article of association of the Company, as amended by the extraordinary general shareholders' meeting held on 16 January 2015. Some of these amendments will only become effective as of the completion of the Offering.

The Company is a limited liability company (*société anonyme*) which has been incorporated as a private limited liability company (*société privée à responsabilité limitée*) on 16 June 2006 for an indefinite period under the name "Bone Therapeutics". The Company was founded by Mr Enrico Bastianelli and his spouse, Mrs Valérie Shirin Gangji. The Company was converted in a limited liability company (*société anonyme*) on 7 March 2007.

The Company's registered office is located at Rue Adrienne Bolland 8, 6041 Gosselies, Belgium and is registered with the Belgian register for legal entities (*registre des personnes morales*) under number 0882.015.654 (Charleroi) (+32 2 529 59 90). The publicly available documents relating to the Company, as referred to in this Prospectus, can be reviewed and/or obtained at the registered office of the Company, free of charge.

During the extraordinary general shareholders' meeting held on 16 January 2015, the shareholders of the Company have adopted, amongst others, the following resolutions:

- the amendment of the Company's articles of association; and
- the replacement of certain directors.

The abovementioned resolutions were adopted subject to the condition precedent of the completion of the Offering.

The description provided below is a summary only and does not purport to provide a complete overview of the Company's articles of association, nor of the relevant provisions of Belgian law, and it should not be considered as legal advice regarding these matters.

Furthermore, the aforementioned description assumes that the amendments to the Company's articles of association, as approved on 16 January 2015 subject to the condition precedent of the completion of the Offering, have become effective.

## 9.2 Corporate purpose

In accordance with article 3 of the Company's articles of association, its corporate purpose is as follows:

The Company has as its purpose, both in Belgium as well as abroad, in its own name or on behalf of third parties, for its own account or for the account of others or in collaboration with third parties:

- research and development of products and processes in the pharmaceutical, bio-technological, cellular or derived domains, that are able to have an economical value for human or animal health, diagnostic and therapeutic, in neutraceuticals or cosmetics, based, amongst others, on genetics, cell biology and *in vitro* or *in vivo* pharmacology;
- commercialisation of products or processes in the abovementioned fields of application;
- acquisition, disposal, exploitation, valorisation, commercialisation and management of any intellectual property rights whatsoever, property rights, usage rights, trademarks, patents, blueprints, licenses, etc;
- file and exploit patents, drawings and models, trademarks and other intellectual and patrimonial rights in relation to the abovementioned items;
- preparation, information, publications and editing in all media in relation to the abovementioned items;

The Company may carry out, in Belgium as well as abroad, all industrial, commercial, financial, movable and immovable transactions, of a nature directly or indirectly enlarge or promote its business. It can acquire all any movable or immovable assets, even if those assets do not have a direct or indirect connection with the Company's purpose.

The Company may consent with any form of surety guaranteeing obligations of related or associated companies, companies in which it has participation or all third parties in general.

The Company may, by any means whatsoever, take up interests in, cooperate or merge with other associations, businesses, firms or companies that have an identical, similar or related corporate purpose, or that are likely to promote their business or to facilitate the sale of its products or services.

## 9.3 Holdings

The Company holds 49.9% of the shares issued by Skeletal Cell Therapy Support, a limited liability company (*société anonyme*) with registered office at avenue Georges Lemaitre 62, 6041 Gosselies, Belgium and with company number 0841.570.812 (RLE Charleroi) ("SCTS") (see Section 8.1 "Overview").

The rest of the shares of SCTS are held, directly or indirectly, by certain shareholders of the Company, being Sofipôle SA (23.48%) and Sambrinvest SA (12.72%) and seven other private investors.

Until 31 December 2019, the Company has the right to acquire the shares held by the other shareholders of SCTS, for a price generating an internal rate of return of 8% for these shareholders, taking into account the net dividends received (call option). As of 1 January 2020, the other shareholders have the right to sell to the Company their shares in SCTS, at net asset value, with a minimum of 90% of the subscription price (put option).

SCTS is part of a Walloon Cell Therapy Platform ("PWTC") comprising three service companies:

- SCTS:
- Hepatic Cell Therapy Support ("HCTS"), a limited liability company (société anonyme) with registered office at avenue Georges Lemaitre 62, 6041 Gosselies, Belgium and with company number 0841.727.891 (RLE Charleroi); and
- Société d'Infrastructures, de Services et d'Energies ("SISE"), a limited liability company (société anonyme) with registered office at avenue Georges Lemaitre 62, 6041 Gosselies, Belgium and with company number 0841.727.101 (RLE Charleroi).

SCTS holds 28.43% of the shares issued by SISE. The rest of the shares of SISE are held by HCTS, Sofipôle SA and Sambrinvest SA.

## 9.4 Share capital and shares

## 9.4.1 Securities issued by the Company

At the date of this Prospectus, the Company's capital amounts to € 10,466,302.63, represented by 3,458,240 ordinary shares without nominal value.

The Company has issued 304,760 warrants which give right to subscribe to an equal number of Shares. On the date of this Prospectus 159,800 warrants have been granted.

The Company has issued automatically convertible bonds for a total amount of  $\in 10,350,000^{79}$  which will automatically convert, on completion of the Offering, into a number of Shares to be determined on the basis of the Offer Price (see Section 9.4.3 "Automatically convertible bonds").

## 9.4.2 History of capital

At the occasion of the incorporation of the Company (at the time, a private limited liability company (société privée à responsabilité limitée) on 16 June 2006, the share capital amounted to  $\in$  18,550.00, represented by 1,855 shares with a nominal value of  $\in$  10, of which one third was paid-up in cash.

On 5 September 2006, the share capital was increased by a contribution in cash in the amount of  $\in$  356,450.00 with issuance of 35,645 shares without nominal value, of which two thirds was paid-up in cash. Following the capital increase, the share capital of the Company amounted to  $\in$  375,000 and was represented by 37,500 shares.

On 7 March 2007, the Company was converted into a limited liability company (société anonyme) and the share capital was increased by a contribution in cash in the amount of  $\in$  525,000.00 with issuance of 52,500 shares without nominal value, of which two thirds was paid up in cash. At the occasion of the capital increase, two classes of shares were created, whereby the shares existing prior to the aforementioned capital increase were

 $<sup>^{79}</sup>$  € 10,000,000 were issued on 18 December 2014 and € 350,000 on 8 January 2015.

allocated to class A, and the shares issued pursuant to the aforementioned capital increase were allocated to class B. The nominal value of the class A shares was cancelled, and all class A shares were paid-up in cash for two thirds. Following the capital increase, the share capital of the Company amounted to  $\in$  900,000.00 and was represented by 90,000 shares (of which 37,500 shares were class A shares and 52,500 shares were class B shares).

On 12 November 2008, the existing classes of shares were abolished and the share capital was increased by a contribution in kind in the amount of  $\in$  84,800.00 with issuance of 8,480 shares. The new shares were issued at a price of  $\in$  73.11 per share (of which  $\in$  10 in capital and  $\in$  63.11 in issuance premium). The aggregate issuance premium amounted to  $\in$  535.00 and was subsequently incorporated in the share capital by another capital increase without issuance of new shares. Following both capital increases, the share capital of the Company amounted to  $\in$  1,520,000.00 and was represented by 98,480 shares.

On the same day, the share capital of the Company was again increased by a contribution in cash of  $\in$  650,197.96 with issuance of 42,126 shares. The new shares were issued at a price of  $\in$  91.39 per share (of which  $\in$  15.43 in capital and  $\in$  75.96 in issuance premium). The aggregate issuance premium amounted to  $\in$  3,199,802.04 and was subsequently incorporated in the share capital of the Company by another capital increase without issuance of new shares. Following both capital increases, the share capital of the Company amounted to  $\in$  5,370,000.00 and was represented by 140,606 shares.

On 13 January 2011, the share capital was increased by a contribution in cash in the amount of  $\in$  992,825.00 with issuance of 25,997 shares. The new shares were issued at a price of  $\in$  160 per share (of which  $\in$  38.19 in capital and  $\in$  121.81 in issuance premium). The aggregate issuance premium amounted to  $\in$  3,166,695.00. Following the capital increase, the share capital of the Company amounted to  $\in$  6,362,825.00 and was represented by 166,603 shares.

On 24 November 2011, the share capital was increased by a contribution in cash in the amount of  $\in$  580,258.86 with issuance of 15,194 shares. The new shares were issued at a price of  $\in$  160 per share (of which  $\in$  38.19 in capital and  $\in$  121.81 in issuance premium). The aggregate issuance premium amounted to  $\in$  1,850,781.14. Following the capital increase, the share capital of the Company amounted to  $\in$  6,943,083.86 and was represented by 181,797 shares. On the same day, the Company approved a stock option plan, with issue of a pool of 12,000 warrants to the benefit of the key personnel of the Company.

On 27 November 2012, the share capital was increased by a contribution in cash in the amount of  $\in 1,473,790.29$  with issuance of 38,591 shares. The new shares were issued at a price of  $\in 65.79$  per share (of which  $\in 38.19$  in capital and  $\in 27.60$  in issuance premium). The aggregate issuance premium amounted to  $\in 1,065,111.60$ . Following the capital increase, the share capital of the Company amounted to  $\in 8,416,874.47$  and was represented by 220,388 shares. On the same day, the Company issued two anti-dilution warrants to 32 shareholders following an agreement between the existing shareholders, the first of which was exercised on the same day and the share capital was increased following such exercise in the amount of 32 eurocents with issuance of 71,772 shares and the second of which was subsequently cancelled (see below). Following the capital increase, the share capital of the Company amounted to  $\in 8,416,874.47$  and was represented by 292,160 shares.

On 10 June 2013, the share capital was increased by a contribution in cash in the amount of  $\in$  870,732.00 with issuance of 22,800 shares. The new shares were issued at a price of  $\in$  65.79 per share (of which  $\in$  38.19 in capital and  $\in$  27.60 in issuance premium). The aggregate issuance premium amounted to  $\in$  629,280.00. Following the capital increase, the share capital of the Company amounted to  $\in$  9,287,606.47 and was represented by 314,960 shares.

On 24 February 2014, the shareholders of the Company resolved upon a share split, dividing the 314,960 shares, without nominal value, each representing  $1/314,960^{th}$  of the share capital of the Company by 10, creating 3,149,000 shares, without nominal value, each representing  $1/3,149,600^{th}$  of the share capital of the Company. On the same day, the share capital was increased by a contribution in cash in the amount of  $\varepsilon$  580,488.00 with issuance of 152,000 shares. The new shares were issued at a price of  $\varepsilon$  6.579 per share (of which  $\varepsilon$  3.819 in capital and  $\varepsilon$  2.760 in issuance premium). The aggregate issuance premium amounted to  $\varepsilon$  419,520.00. Following the capital increase, the share capital of the Company amounted to  $\varepsilon$  9,868,094.47 and was represented by 3,301,600 shares.

On 10 July 2014, the share capital was increased by a contribution in cash in the amount of  $\in$  598,208.16 with issuance of 156,640 shares. The new shares were issued at a price of  $\in$  6.579 per share (of which  $\in$  3.819 in capital and  $\in$  2.760 in issuance premium). The aggregate issuance premium amounted to  $\in$  432,326.40. Following the capital increase, the share capital of the Company amounted to  $\in$  10,466,302.63 and was represented by 3,458,240 shares.

On 18 December 2014, the extraordinary general shareholders' meeting of the Company resolved to abolish the second anti-dilution warrants issued on 27 November 2012, further to a waiver by the holders thereof.

On 8 January 2015, the extraordinary general shareholders' meeting of the Company resolved to cancel the stock option plan (and the outstanding pool of 12,000 warrants) issued on 24 November 2011.

Date	Transaction	Number and class of shares issued	Issue price per share (€) including issuance premium	Capital increase (€)	Share capital after transaction (€)	Aggregate number of shares after capital increase
16/06/2006	Incorporation	1,855	10	18,550	18,550.00	1,855
05/09/2006	Capital increase	35,645	10	356,450	375,000	37,500
07/03/2007	Capital increase	52,500 B	10	525,000	900,000	37,500 A 52,500 B
12/11/2008	Capital increase	8,480	73.11	84,800	984,800	98,480
12/11/2008	Incorporation issuance premium	None	Not applicable	535,200	1,520,000	98,480
12/11/2008	Capital increase	42,126	91.38	650,197.96	2,170,197.96	140,606
12/11/2008	Incorporation issuance premium	None	Not applicable	3,199,802.04	5,370,000.00	140,606
13/01/2011	Capital increase	25,997	160	992,825	6,362,825	166,603
24/11/2011	Capital increase	15,194	160	580,258.86	6,943,083.86	181,797
27/11/2012	Capital increase	38,591	65.79	1,473,790.29	8,416,874.15	220,388
27/11/2012	Capital increase	71,772	0.01	0.32	8,416,874.47	292,160
10/06/2013	Capital increase	22,800	65.79	870,732.00	9,287,606.47	314,960
24/02/2014	Share split	None	Not applicable	Not applicable	Not applicable	3,149,600
24/02/2014	Capital increase	152,000	6.579	580,488	9,868,094.47	3,301,600
10/07/2014	Capital increase	156,640	6.579	598,206	10,466,302.63	3,458,240

The following members of the Board of Directors, members of the Management Team or their affiliates have acquired securities in the Company in the course of the year preceding the Offering at an issue price below the Offer Price:

- Capital increase dated 24 February 2014 at an issue price of €6.579 per Share: Jacques Reymann and Jean-Jacques Verdickt (JJ Verdickt & Consorts).
- Capital increase dated 10 July 2014 at an issue price of €6.579 per Share: Jacques Reymann and Jean-Jacques Verdickt (JJ Verdickt & Consorts).
- Grant of warrants with an exercise price of € 11 per Share: Enrico Bastianelli, Wim Goemaere and Guy Heynen.
- Issue of Bonds (see Section 9.4.3 "Automatically convertible bonds" below), whereby the number of Shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 166.5% of the nominal value of the Bonds, and the denominator is equal to the Offer Price: Jacques Reymann, SFPI SA, Jean-Jacques Verdickt (JJ Verdickt & Consorts) and Marc Nolet de Brauwere van Steeland (Alegrecha SDC).

## 9.4.3 Automatically convertible bonds

On 18 December 2014 and 8 January 2015, the Company has issued a total of 10,350 automatically convertible bonds for an aggregate amount of  $\in$  10,350,000 (the "**Bonds**").

The Bonds were subscribed by existing shareholders of the Company and by certain new investors, including SFPI SA and Sofipôle SA.

The Bonds are issued in registered form. Each Bond has a nominal value of € 1,000. The Bonds bear interest as from their issue date, at the rate of 7% per annum. The maturity date of the Bonds is the earliest of (i) the completion of the Offering and (ii) 30 September 2015.

The Bonds will automatically be converted into Shares on the Closing Date. The number of Shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 166.5% of the nominal value of the Bonds, and the denominator is equal to the Offer Price.

The exact number of Shares to be issued upon conversion of the Bonds is unknown at the date of this Prospectus. On the basis of hypothetical offer prices, the potential dilution can be calculated as follows:

- if the Offer Price is set at the low end of the Offer Price Range, i.e. € 14.5, 1,188,465 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the mid-point of the Offer Price Range, i.e. € 15.5, 1,111,790 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the high end of the Offer Price Range, i.e. € 16.5, 1,044,409 Shares will be issued upon conversion of the Bonds.

The Bonds are issued with anti-dilution warrants to protect the holders thereof against a possible down round private placement by the Company. The anti-dilution warrants will expire upon completion of the Offering and become void. In the event the Offering is not completed, the anti-dilution warrants continue to exist until 30 September 2017. Each anti-dilution warrant has an exercise price of EUR 0.01 and can be exercised in case of a down round, i.e. a transaction which is completed prior to 30 September 2017 whereby the Company would issue shares at a price per share below  $\in$  11. Each anti-dilution warrant entitles the investor to subscribe to a number of shares equal to the difference between the number of shares issued to the investor upon conversion of the Bond and the number of shares the investor would have obtained if the conversion of the Bond would have occurred at the price of the down round. Upon completion of the Offering, the Bonds will be automatically converted into Shares and the anti-dilution warrants will be automatical cancelled.

Each investor subscribing to the Bonds has committed (i) to subscribe to Shares in the Offering (and, if the Offering is not completed prior to 30 September 2015, in a subsequent capital increase) for an amount equal to the amount subscribed to in Bonds at the Offer Price (see Section 15.7 "Intentions of the shareholders, bondholders, directors and managers") and (ii) to enter into a lock-up undertaking with respect to the Shares issued upon conversion of the Bonds (see Section 15.10 "Lock-up and standstill arrangements").

The subscribers to the Bonds benefit, with respect to the Shares issued upon conversion of the Bonds (i.e. 50% of their investment), from a discount compared to the Offer Price (see conversion ratio above). This discount is explained by the risk related to the uncertain outcome of the envisaged Offering and the lack of liquidity in case the listing of the Shares would not take place and by the one year lock-up undertaking.

## 9.5 Form and transferability of the shares

The shares of the Company can take the form of registered shares or dematerialised shares. As described in Section 15.3.6 "Form of the Shares", the Offered Shares will be delivered in dematerialised (book-entry) form and will be dematerialised shares.

Belgian company law and the Company's articles of association entitle shareholders to request, in writing and at their expense, the conversion of their dematerialised shares into registered shares and vice versa. Any costs incurred as a result of the conversion of shares into another form will be borne by the shareholder.

All of the Company's shares, including the Offered Shares upon delivery, are fully paid up and freely transferable, subject, however, to the lock-up arrangements described in Section 15.10 "Lock-up and standstill arrangements" and the transfer restrictions set out in article 11 of the Royal Decree of 17 May 2007 on Primary Markets.

## 9.6 Increase and reduction of share capital

## 9.6.1 Changes to the share capital by the shareholders of the Company

The shareholders' meeting can at any given time decide to increase or decrease the share capital of the Company. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association, as described under Section 9.9.1.6 "Quorums and majorities".

## 9.6.2 Capital increases by the Board of Directors of the Company

Subject to the same quorum and majority requirements that apply to an amendment of the articles of association, as described under Section 9.9.1.6 "Quorums and majorities", the shareholders' meeting can authorise the Board

of Directors, within certain limits, to increase the Company's share capital without any further approval of the shareholders. This authorisation needs to be limited in time (i.e. it can only be granted for a renewable period of maximum five years) and in scope (i.e. the authorised share capital may not exceed the amount of the share capital at the time of the authorisation).

On 16 January 2015, the extraordinary shareholders' meeting of the Company granted the authorisation to the Board of Directors to increase the Company's share capital, in one or several times, with a maximum amount that cannot exceed the amount of the Company's share capital upon completion of the Offering (excluding issuance premiums, if any).

If the Company's share capital is increased within the limits of the authorised share capital, the Board of Directors is authorised to request payment of an issuance premium. This issuance premium will be booked on a non-available reserve account, which may only be decreased or disposed of by a resolution of the shareholders' meeting subject to the same quorum and majority requirements that apply to an amendment of the articles of association, as described under Section 9.9.1.6 "Quorums and majorities".

The Board of Directors can make use of the authorised share capital for capital increases subscribed for in cash or in kind, or effected by incorporation of reserves, issuance premiums or revaluation surpluses, with or without issue of new shares. The Board of Directors is authorised to issue convertible bonds, bonds *cum* warrants or warrants within the limits of the authorised share capital and with or without preferential subscription rights for the existing shareholders.

The Board of Directors is authorised, within the limits of the authorised share capital, to limit or cancel the preferential subscription rights granted by law to the existing shareholders in accordance with article 596 and following of the Belgian Company Code. The Board of Directors is also authorised to limit or cancel the preferential subscription rights of the existing shareholders in favour of one or more specified persons, even if such persons are not members of the personnel of the Company or its subsidiaries.

This authorisation will become effective upon completion of the Offering and will be granted for a term of five years commencing from the date of the publication of the resolution in the Annexes to the Belgian Official Gazette (*Moniteur belge*), and can be renewed.

In principle, from the date of the FSMA's notification to the Company of a public takeover bid on the financial instruments of the Company, the authorization of the Board of Directors to increase the Company's share capital in cash or in kind, while limiting or cancelling the preferential subscription right, is suspended. However, the Company's extraordinary shareholders' meeting held on 16 January 2015 expressly granted the Board of Directors the authority to increase the Company's share capital, in one or several times, from the date of the FSMA's notification to the Company of a public takeover bid on the financial instruments of the Company and subject to the limitations imposed by the Belgian Company Code. This authorization will become effective upon completion of the Offering and will be granted for a period of three years from the date of the publication of the resolution in the Annexes to the Belgian Official Gazette (*Moniteur belge*).

## 9.7 Pre-emptive rights

In the event of a capital increase in cash with issue of new shares, or in the event of an issue of convertible bonds or warrants exercisable in cash, the shareholders have a preferential right to subscribe for the new shares, convertible bonds or warrants, pro rata to the part of the share capital represented by the shares that they already hold. The shareholders' meeting may decide to limit or cancel such preferential subscription right, subject to specific substantive and reporting requirements. Such decision must satisfy the same quorum and majority requirements as the decision to increase the Company's share capital (see Section 9.6 "Increase and reduction of share capital").

The shareholders can also decide to authorise the Board of Directors to limit or cancel the preferential subscription right within the framework of the Authorised Capital, subject to the terms and conditions set forth in the Belgian Company Code. In principle, the authorisation of the Board of Directors to increase the share capital of the Company through contributions in cash with cancellation or limitation of the preferential right of the existing shareholders is suspended as of the notification to the Company by the FSMA of a public takeover bid on the shares of the Company. The shareholders' meeting can, however, authorise the Board of Directors to increase the share capital by issuing further shares, not representing more than 10% of the shares of the Company at the time of such a public takeover bid.

On 16 January 2015, the shareholders' meeting of the Company decided to authorise the Board of Directors to increase the Company's share capital, including with limitation or cancellation of the shareholders' preferential subscription rights, in one or more times and including the authorisation to make use of such Authorised Capital

in the framework of a public takeover bid (see Section 9.6.2 "Capital increases by the Board of Directors of the Company").

## 9.8 Acquisition of shares by the Company

In accordance with the Belgian Company Code, the Company can only purchase and sell its own shares by virtue of a special shareholders' resolution approved by at least 80% of the votes validly cast at a shareholders' meeting where at least 50% of the share capital and at least 50% of the profit certificates, if any, are present or represented. The prior approval by the shareholders is not required if the Company purchases its own shares to offer them to its personnel.

In accordance with the Belgian Company Code, an offer to purchase shares must be made by way of an offer to all shareholders under the same conditions. This does not apply to (i) the acquisition of shares by companies listed on a regulated market and companies whose shares are admitted to trading on a multilateral trading facility (an "MTF"), provided that the company ensures equal treatment of shareholders finding themselves in the same circumstances by offering an equivalent price (which is assumed to be the case: (a) if the transaction is executed in the central order book of a regulated market or MTF; or (b) if it is not so executed in the central order book of a regulated market or fire dprice is lower than or equal to the highest actual independent bid price in the central order book of a regulated market or (if not listed on a regulated market) of the MTF offering the highest liquidity in the share); or (ii) the acquisition of shares that has been unanimously decided by the shareholders at a meeting where all shareholders were present or represented.

A company can only acquire its own shares with funds that would otherwise be available for distribution to the company's shareholders pursuant to Article 617 of the Belgian Company Code (see Section 13.1 "Entitlement to dividends").

The total amount of own shares held by a company can at no time be higher than 20% of its share capital. At the date of this Prospectus, the Board of Directors of the Company was not authorised by the shareholders' meeting to purchase its own shares and neither do the articles of association authorise the Board of Directors to purchase own shares in case of imminent serious harm to the Company in accordance with Article 620, §1, paragraph 3 of the Belgian Company Code.

## 9.9 Shareholders' meeting

## 9.9.1 Right to participate in shareholders' meeting and voting rights

## 9.9.1.1 Ordinary shareholders' meetings

The ordinary shareholders' meeting is held each year on the fourth Thursday of May at 4:00 p.m. (Brussels time), or if not a business day, on the next business day.

At the ordinary shareholders' meeting, the Board of Directors submits the audited statutory financial statements under Belgian GAAP, the audited consolidated financial statements under IFRS, as adopted by the European Union, and the reports of the Board of Directors and of the auditor with respect thereto to the shareholders.

The ordinary shareholders' meeting typically decides on:

- the approval of the audited statutory financial statements under Belgian GAAP;
- the proposed allocation of the Company's profit or loss;
- the discharge of liability to the directors and the auditor;
- the approval of the remuneration report included in the annual report of the Board of Directors;
- the (re-) appointment or dismissal of all or certain directors (as the case may be); and
- the (re-) appointment or dismissal of the auditor (as the case may be).

In addition, as relevant, the shareholders' meeting must also decide on the approval of the remuneration of the directors and the 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 Management Team and other executives providing (as the case may be) for severance payments exceeding 12 months' remuneration (or, subject to a motivated opinion by the Nomination and Remuneration Committee, 18 months' remuneration).

## 9.9.1.2 Other shareholders' meetings

The Board of Directors or the auditor (or the liquidator(s), as the case may be) may, whenever the interest of the Company so requires, convene a shareholders' meeting.

The Board of Directors must convene a shareholders' meeting if one or more shareholders representing 20% of the Company's issued share capital so request. Said request shall specify the agenda items to be included in the convocation notice.

#### 9.9.1.3 Convening notices

The convocation notice for the shareholders' meeting must include:

- the place, date and hour of the meeting; and
- the agenda of the meeting indicating the items to be discussed as well as any draft resolutions.

The notice needs to contain a description of the formalities that shareholders must fulfil in order to be admitted to the shareholders' meeting and exercise their voting right, information on the manner in which shareholders can put additional items on the agenda of the shareholders' meeting and table draft resolutions, information on the manner in which shareholders can ask questions during the shareholders' meeting, information on the procedure to participate to the shareholders' meeting by means of a proxy or to vote by means of a remote vote, and the registration date for the shareholders' meeting.

The notice must also mention where shareholders can obtain a copy of the documentation that will be submitted to the shareholders' meeting, the agenda with the proposed draft resolutions or, if no resolutions are proposed, a commentary by the Board of Directors, updates of the agenda if shareholders have put additional items or draft resolutions on the agenda, the forms to vote by proxy or by means of a remote vote, and the address of the webpage on which the documentation and information relating to the 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 Company's website at the same time as the publication of the convocation notice for the shareholders' meeting.

At least 30 days prior to the date of the shareholders' meeting, the convocation notice must be published:

- in the Belgian Official Gazette (Moniteur belge);
- in a nation-wide newspaper (except if the relevant meeting is an ordinary shareholders' meeting held at the municipality, place, date and hour mentioned in the articles of association and its agenda is limited to the review of the annual financial statements, the annual report of the Board of Directors, the report of the Auditor, the vote on the discharge of the directors and the Auditor and the matters described in article 554, paragraph 3 and 4 of the Belgian Company Code); and
- in media of which it reasonably can be expected that they will ensure an effective distribution of the information among the public in the EEA and which is accessible quickly and in a non-discriminatory manner.

Convocation notices must be sent 30 days prior to the shareholders' meeting to the holders of registered Shares, holders of registered bonds, holders of registered warrants, holders of registered certificates issued with the cooperation of the Company (if any), and, as the case may be, to the directors and auditor. This communication is made by letter unless the addressees have individually and expressly accepted in writing to receive the notice by another form of communication, in accordance with article 533 of the Belgian Company Code. The convocation notice and the other documents referred to above are also made available on the Company's website as of the date of the publication of the convening notice.

The term of 30 days prior to the date of the shareholders' meeting for the publication and distribution of the convening notice can be reduced to 17 days for a second meeting if 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.

#### 9.9.1.4 Formalities to attend the shareholders' meeting

All holders of shares, warrants and bonds issued by the Company and all holders of certificates issued with the co-operation of the Company (if any) may attend the shareholders' meeting. Only shareholders, however, may vote at shareholders' meetings. If any holder of securities other than shares wishes to attend a shareholders' meeting, it must comply with the same formalities as those imposed on the shareholders.

The fourteenth day prior to the shareholders' meeting, at 24:00 (Brussels time), constitutes the registration date. A shareholder can only participate to a shareholders' meeting and exercise its voting right provided that its shares are registered in its name on the registration date (and irrespective of the number of Shares the shareholder holds at the date of the shareholders' meeting). For registered shares, this is the registration of the shares in the Company's shareholders' register, and for dematerialized shares, this is the registration of the shares in the accounts of a certified account holder or settlement institution in accordance with article 536 of the Belgian Company Code. The convocation notice to the shareholders' meeting must explicitly mention the registration date.

The shareholder must also notify the Company (or any person so appointed by the Company) whether it intends to participate to the shareholders' meeting, at the latest on the sixth day before the date of such meeting.

Prior to participating to the shareholders' meeting, the holders of securities or their proxy holders must sign the attendance list, thereby mentioning: (i) the identity of the holder of securities, (ii) if applicable, the identity of the proxy holder and (iii) the number of securities they represent. The representatives of shareholders-legal entities must present the documents evidencing their quality as legal body or special proxy holder of such legal entity. In addition, the proxy holders must present the original of their proxy evidencing their powers, unless the convocation notice required the prior deposit of such proxies. The physical persons taking part in the shareholders' meeting must be able to prove their identity.

## 9.9.1.5 Voting by proxy and remote voting

Each shareholder has, subject to compliance with the requirements set forth above to attend shareholders' meetings, the right to attend a shareholders' meeting and to vote at such meeting in person or through a proxy holder. The Board of Directors can request the participants to the meeting to use a model of proxy (with voting instructions), which must be deposited at the Company's registered office or at a place specified in the notice convening the shareholders' meeting at the latest six days prior to the 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 articles of association also allow shareholders to vote by mail by means of a form that is made available by the Company.

## 9.9.1.6 Quorums and majorities

In general, there is no attendance quorum requirement for a shareholders' meeting and decisions are generally passed with a simple majority of the votes of the Shares present or represented at the meeting.

However, decisions regarding:

- amendments of the articles of association;
- an increase or decrease of the Company's share capital (other than a capital increase decided by the Board
  of Directors pursuant to the authorised share capital (See Section 9.6.2 "Capital increases by the Board of
  Directors of the Company");
- the Company's dissolution, mergers, de-mergers and certain other reorganisations of the Company;
- the issue of convertible bonds or bonds with warrants or the issue of warrants; and
- certain other matters referred to in the Belgian Company Code,

require a presence quorum of 50% of the share capital of the Company and a majority of at least 75% of the votes cast, with the exception of an amendment of the Company's corporate purpose and, subject certain exceptions, the acquisition of own Shares (see Section 9.8 "Acquisition of shares by the Company"), which require the approval of at least 80% of the votes cast at a shareholders' meeting, which can only validly pass such resolution if at least 50% of the Company's share capital 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 shareholders' meeting may validly deliberate and decide regardless of the number of Shares present or represented.

## 9.9.1.7 Right to add items to the agenda and file draft resolutions

In accordance with article 533ter of the Belgian Company Code, one or more shareholders holding at least 3% of the Company's share capital have the right to add new items on the agenda of a shareholders' meeting and to file draft resolutions concerning items that were or will be included on the agenda of a shareholders' meeting. This right does not apply to shareholders' meetings that are being convened on the grounds that the presence quorum was not met at the first duly convened meeting.

Shareholders who exercise this right must comply with the following two conditions for the proposal(s) to be eligible for consideration at the shareholders' meeting: (i) they must prove that they hold the abovementioned percentage of shares on the date of their request (either by producing a certificate of registration of those Shares in the Company's shareholders' register, or by producing a certificate from a certified account holder or settlement institution evidencing that the relevant number of dematerialised Shares are registered in their name in the accounts of such certified account holder or settlement institution) and (ii) they must demonstrate that they still hold the abovementioned percentage of shares on the registration date.

The Company must receive requests to add new items on the agenda of shareholders' meetings and to file draft resolutions at the latest 22 days prior to the date of the shareholders' meeting. The revised agenda must be published by the Company at the latest 15 days prior to the date of the shareholders' meeting.

## 9.9.1.8 Right to ask questions

In accordance with article 540 of the Belgian Company Code, shareholders have a right to ask questions to the directors in connection with the report of the Board of Directors or the items on the agenda of such shareholders' meeting. Shareholders can also ask questions to the auditor in connection with its report. Such questions can be submitted in writing prior to the meeting or can be raised at the meeting. Written questions must be received by the Company no later than the sixth day prior to the meeting.

Written and oral questions will be answered during the meeting 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 requirements set forth above to attend shareholders' meetings.

## 9.10 Voting rights

Each shareholder is entitled to one vote per Share.

Voting rights may be suspended in relation to Shares, in the following events, without limitation and without this list being exhaustive:

- which are not fully paid up, notwithstanding the request thereto by the Board of Directors;
- to which more than one person is entitled, except in the event that a single representative is appointed for the exercise of the voting right;
- which entitle their holder to voting rights above the threshold of 5%, 10%, 15% or any multiple of 5% of the total number of voting rights attached to the outstanding financial instruments of the Company on the date of the relevant shareholders' meeting, except in case the relevant shareholder has notified the Company and the FSMA at least 20 days prior to the date of the shareholders' meeting of its shareholding reaching or exceeding the thresholds above (see Section 9.13 "Transparency obligations"); and
- of which the voting right was suspended by a competent court or the FSMA.

Generally, the shareholders' meeting has sole authority with respect to:

- the approval of the audited statutory financial statements under Belgian GAAP;
- the appointment and dismissal of directors and of the auditor;
- the granting of discharge of liability to the directors and to the auditor;
- the determination of the remuneration of the directors and of the auditor for the exercise of their mandate:
- the determination of the remuneration of the directors and of the auditor for the exercise of their mandate, including inter alia, as relevant, (i) in relation to the remuneration of executive and non-executive directors, the approval of an exemption from the rule that, in accordance with article 520ter, subsection 1, of the Belgian Company Code, Share based awards can only vest during a period of at least three years as of the grant of the awards, (ii) in relation to the remuneration of executive directors, the approval of an exemption

from the rule that, in accordance with article 520ter, subsection 2, of the Belgian Company Code, (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 and (iii) in relation to the remuneration of non-executive directors, the approval of any variable part of the remuneration, in accordance with Article 554, subsection 7 of the Belgian Company Code;

- the approval of provisions of service agreements to be entered into with executive directors, members of the Management Committee and other executives providing for severance payments exceeding 12 months' remuneration (or, subject to a motivated opinion by the Nomination & Remuneration Committee, 18 months' remuneration);
- the approval of the remuneration report included in the annual report of the Board of Directors;
- the distribution of profits;
- the filing of a claim for liability against directors;
- the decisions relating to the dissolution, mergers, de-mergers and certain other reorganisations of the Company; and
- the approval of amendments to the articles of association.

## 9.11 Nomination rights

No shareholder of the Company is entitled to nominate persons for appointment as member of the Board of Directors.

## 9.12 Dissolution and liquidation

The Company can only be dissolved by a shareholders' resolution passed with a majority of at least 75% of the votes at an extraordinary shareholders' meeting where at least 50% of the share capital is present or represented (see Section 9.9.1.6 "Quorums and majorities").

If, as a result of losses incurred, the ratio of the Company's net assets (determined in accordance with Belgian GAAP) to share capital is less than 50%, the Board of Directors must convene a shareholders' meeting within two months from the date the Board of Directors discovered or should have discovered this undercapitalisation. At such shareholders' meeting, the Board of Directors must propose either the dissolution of the Company, or the continuation of the Company's activities, in which case the Board of Directors must propose measures to redress the Company's financial situation. Shareholders representing at least 75% of the votes validly cast at this meeting can decide to dissolve the Company, provided that at least 50% of the Company's share capital is present or represented at the shareholders' meeting.

If, as a result of losses incurred, the ratio of the Company's net assets to share capital is less than 25%, the same procedure must be followed, it being understood, however, that in such event shareholders representing 25% of the votes validly cast at the shareholders' meeting can decide to dissolve the Company.

If the amount of the Company's net assets fall below € 61,500 (the minimum amount of share capital of a Belgian public limited liability company (*société anonyme*)), each interested party is entitled to request the competent court to dissolve the Company. The court may order the dissolution of the Company or grant a grace period within which the Company is allowed to remedy the situation.

In case of dissolution of the Company for whatever reason, the shareholders' meeting shall appoint and dismiss the liquidator(s), determine their powers and the manner of liquidation. The shareholders' meeting shall fix the remuneration of the liquidator(s), if any.

The liquidators can only take up their function after confirmation of their appointment by the shareholders' meeting by the competent Commercial Court pursuant to Article 184 of the Belgian Company Code.

After settlement of all debts, charges and expenses relating to the liquidation, the net assets shall be equally distributed amongst all shares, after deduction of that portion of such shares that are not fully paid-up, if any.

## 9.13 Transparency obligations

Directive 2004/109/EC of the European Parliament and of the Council of 15 December 2004 on the harmonisation of transparency requirements in relation to information about issuers whose securities are admitted to trading on a regulated market and amending Directive 2001/34/EC has been implemented in Belgian law by, inter alia, the Belgian law of 2 May 2007 on the disclosure of major shareholdings in issuers whose securities are admitted to trading on a regulated market (*Loi du 2 mai 2007 relative à la publicité des participations importantes dans des émetteurs dont les actions sont admises à la négociation sur un marché réglementé et portant des dispositions diverses*) (the "Transparency Law") and the Royal Decree of 14 February 2008 on the disclosure of major shareholdings (*Arrêté royal du 14 février 2008 relatif à la publicité des participations importantes*) (the "Transparency Royal Decree").

Belgian law imposes disclosure requirements on any natural person or legal entity acquiring or disposing of, directly or indirectly, securities granting voting rights or securities which give a right to acquire existing securities granting voting rights, when, as a result of such acquisition or disposal, the total number of voting rights directly or indirectly held by such natural person or legal entity, alone or in concert with others, increases above or falls below a (legal) threshold of 5%, or any multiple of 5%, of the total number of voting rights attached to the Company's securities. Any future amendment to the disclosure thresholds must be made public and simultaneously notified to the FSMA.

Pursuant to article 6 of the Transparency Law, the above disclosure obligations will be triggered any time the above thresholds are crossed (downwards or upwards) as a result of, inter alia: (i) the acquisition or the disposal of securities granting voting rights, regardless of the way in which this acquisition or disposal takes place, e.g. through purchase, sale, exchange, contribution, merger, de-merger, or succession, (ii) the passive crossing of these thresholds (as a result of events that have changed the breakdown of voting rights even if no acquisition or disposal took place); or (iii) the execution, amendment or termination of an agreement of concerted action.

Pursuant to article 6 of the Transparency Law, the disclosure obligations apply to each natural person or legal entity that "directly" or "indirectly" acquires, disposes of or holds (at the time of passive crossing the threshold or at the time of execution, amendment or termination of an agreement of concerted action) voting securities or voting rights. In this respect, a natural person or legal entity is deemed to "indirectly" acquire, dispose of or hold voting securities of the Company: (i) when voting securities are acquired, disposed of or held by a third party that, regardless in whose name it is acting, acts on behalf of such natural person or legal entity, (ii) when voting securities are acquired, disposed of or held by an undertaking controlled (within the meaning of articles 5 and 7 of the Belgian Company Code) by such natural person or legal entity (the notion "control" implies that possibly several persons will be deemed to be a controlling person (e.g., the parent company, the parent company of such parent company, as well as the natural person controlling the latter) and therefore subject to the notification duty); or (iii) when such natural person or legal entity acquires or transfers the control over an entity holding voting rights in the Company in which case there is no acquisition or disposal of a shareholding in the Company itself, but an acquisition or transfer of control over an entity holding voting rights of the Company.

If a transparency notification is legally required, such notification must be made to the FSMA and the Company as soon as possible and at the latest within a period of four trading days as from the trading day following the day on which the event triggering the disclosure obligation took place.

The notification can be electronically transmitted to the Company and the FSMA. The forms required to make such notifications, as well as further instructions may be found on the website of the FSMA (www.fsma.be).

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 may also impose administrative sanctions.

The Company must publish all information contained in such notifications no later than three trading days after receipt of such notification. Furthermore, the Company must mention in the notes to its annual accounts, its shareholders structure (as it appears from the notifications received). Moreover, the Company must publish the total share capital, the total number of voting securities and voting rights (for each class of securities (if any)), at the end of each calendar month during which one of these numbers has changed, as well as on the day on which the shares of the Company will for the first time be admitted to trading on Euronext Brussels and Euronext Paris. Finally, the Company must disclose, as the case may be, the total number of bonds convertible in voting securities (if any), whether or not incorporated in securities, to subscribe to voting securities not yet issued (if any), the total number of voting rights that can be obtained upon the exercise of these conversion or subscription rights and the total number of shares without voting rights (if any).

#### 9.14 Public takeover bids

The Directive 2004/25/EC of the European Parliament and the Council dated 21 April 2004 on takeover bids (the "**Takeover Directive**") sets forth the principles governing the choice of laws applicable to the Company in the context of a takeover bid for the shares of the Company. Article 4-2(c) of the Takeover Directive provides that if the securities of the company subject to the offer were first admitted to trading on regulated markets in more than one Member State simultaneously, the offeree company shall determine which of the supervisory authorities of those Member States shall be the authority competent to supervise the bid by notifying those regulated markets and their supervisory authorities on the first day of trading.

Article 4.2 (e) of the Takeover Directive also provides that matters relating to the consideration offered in the case of an offer, in particular the price and matters relating to the offer procedure, in particular the information on the offeror's decision to make an offer, the contents of the offer document and the disclosure of the offer, shall be dealt with in accordance with the rules of the Member State of the competent authority. As to matters relating to the information to be provided to the employees of the offered company and matters relating to corporate law, in particular the percentage of voting rights which confers control and any exemption from the obligation to launch an offer, as well as the conditions under which the supervisory board of the offeree company may undertake any action which might result in the frustration of an offer, the applicable rules and the competent authority shall be those of the Member State in which the offeree company has its registered office.

These provisions have been implemented in Belgium by the Law of 1 April 2007 on public takeover bids (*Loi du 1er avril 2007 relative aux offres publiques d'acquisition*), as implemented by the Royal Decree of 27 April 2007 on public takeover bids (*Arrêté royal du 27 avril 2007 relatif aux offres publiques d'acquisition*) and the Royal Decree of 27 April 2007 on public squeeze-outs (*Arrêté royal du 27 avril 2007 relatif aux offres publiques de reprise*) (for the latter, see below under Section 9.15 "Squeeze-out and sell-out").

The Company has chosen the FSMA as competent authority. As a consequence, Belgian laws and regulations will fully apply and public takeover bids on the Company's shares and other securities granting access to voting rights (such as warrants or convertible bonds, if any) will be subject to supervision by the FSMA. In accordance with article 6.2 of the Takeover Directive, the takeover bid documents approved by the FSMA will be recognized in full in France, subject to any translation required, without the need to obtain the approval of the AMF. The AMF may however require the inclusion of additional information regarding the formalities to be complied with to accept the takeover bid and to receive the consideration due at the close of the takeover bid as well as to the tax arrangements to which the consideration offered to the holders of the securities will be subject.

Public takeover bids must be made for all of the Company's voting securities, as well as for all other securities issued by the Company that entitle the holders thereof to the subscription for, or the conversion in, voting securities. Prior to making an offer, an offeror must issue and disseminate an offer document, which must be approved by the FSMA. The offeror must also obtain approval of the relevant competition authorities, where such approval is legally required for the acquisition of the shares of the target.

All shareholders and warrantholders (and holders of other securities granting access to voting rights issued by the target company) must have equal rights to contribute their securities in any public takeover bid. Furthermore, whenever a person (as a result of its own acquisition or the acquisition by persons acting in concert with it or by persons acting for their account, directly or indirectly) acquires more than 30% of the voting securities of a company that are (at least in part) admitted to trading on a regulated market, such person must launch a mandatory takeover bid for all the voting securities and securities granting access to voting securities issued by the target company. In general and except for certain exceptions, the mere fact of exceeding the relevant threshold as a result of an acquisition will give rise to the obligation to launch a mandatory takeover bid, irrespective of whether or not the price paid in the relevant transaction exceeds the then current market price.

In such an event, the takeover bid must be launched at a price equal to the higher of the two following amounts: (i) the highest price paid by the offeror or the persons acting in concert with it for the acquisition of the relevant securities during the last 12 calendar months; and (ii) the average trading price during the last 30 days before the obligation to launch a takeover bid arose. No mandatory takeover bid is required, amongst other things, when the acquisition is the result of a subscription for a capital increase with application of the preferential subscription rights of the shareholders as decided by the shareholders' meeting.

The price for the acquisition of the shares can be in cash or in securities. In the event of a mandatory takeover bid or a voluntary takeover bid launched by an offeror who controls the target, if a price composed of securities is offered, a cash alternative must also be offered in the event that: (i) the price does not consist of liquid securities admitted to trading on a regulated market; or (ii) the offeror, or a person acting in concert with it, acquired shares for cash during a period of 12 calendar months preceding the publication of the takeover bid or

during the takeover bid period (whereby these shares, in the event of a voluntary takeover bid by a controlling shareholder, represent more than 1% of the outstanding voting securities).

Where the voluntary takeover bid is launched by a controlling shareholder, the price must be supported by a fairness opinion issued by an independent expert. In addition, in any cases, the Board of Directors of the target company is required to publish its opinion concerning the takeover bid, as well as its comments on the offer document.

The acceptance period for the takeover bid must be at least two weeks and may not exceed ten weeks.

In principle, from the date of the FSMA's notification to the Company of a public takeover bid on the financial instruments of the Company, the authorization of the Board of Directors to increase the Company's share capital in cash or in kind, while limiting or cancelling the preferential subscription right, is suspended. However, he Company's extraordinary shareholders' meeting held on 16 January 2015 expressly granted the Board of Directors the authority to increase the Company's share capital, in one or several times, from the date of the FSMA's notification to the Company of a public takeover bid on the financial instruments of the Company and subject to the limitations imposed by the Belgian Company Code. This authorization will become effective upon completion of the Offering and will be granted for a period of three years from the date of the publication of the resolution in the Annexes to the Belgian Official Gazette (*Moniteur belge*).

A Belgian public limited liability company (*société anonyme*) can acquire, dispose of, or pledge its own shares, profit certificates or any certificates relating thereto subject to compliance with the relevant legal provisions (See Section 9.8 "Acquisition of shares by the Company"). In particular, the shareholders' meeting can authorise the Board of Directors to, without any resolution of the shareholders' meeting, purchase and keep the Company's own shares when such is necessary to "to avoid imminent and serious danger to the Company" within the meaning of article 620 of the Belgian Company Code. If granted, such authorisation is valid for a period of three years as of the publication thereof in the Annexes to the Belgian Official Gazette (*Moniteur belge*). Such authorisation upon completion of the Offering has not been granted to the Board of Directors of the Company.

The articles of association of the Company do not provide for any other specific protective mechanisms against public takeover bids.

## 9.15 Squeeze-out and sell-out

Pursuant to Article 513 of the Belgian Company Code, a person or legal entity, acting alone or in concert, who owns 95% of the voting securities in a company having made a public call on savings, such as the Company, can acquire all of the outstanding voting securities or securities granting access to such voting securities in the Company following a squeeze-out offer. The securities that are not voluntarily tendered in response to such offer are deemed to be automatically transferred to the offeror at the end of the procedure. At the end of the procedure, the Company is no longer deemed to be a company having made a public call on savings, unless bonds issued by the Company, if any, are still spread across the public. The consideration paid for the securities must be in cash and must represent the fair value of the securities with a view to safeguarding the interests of the holders of voting securities and securities granting access to such voting securities.

The Takeover Law and the Takeover Decree provide for certain rules on the squeeze-out by majority shareholders of the minority shareholders and on the sell-out right of the minority shareholders. If, as a result of a (reopened) public takeover bid, a bidder (together with any person acting in concert with the bidder) holds 95% or more of the voting capital and 95% of the voting securities of the target company, and provided that, in case of a voluntary public takeover bid, the bidder acquired securities representing at least 90% of the voting capital to which the public takeover bid relates, then the bidder can proceed with a simplified squeeze-out in accordance with article 42 of the Takeover Decree, provided that all conditions for such simplified squeeze-out are met, to acquire the securities not yet acquired by the bidder (or any other person deemed to act in concert with the bidder).

Also, if, as a result of such a (reopened) public takeover bid, a bidder (together with any person acting in concert with the bidder) holds 95% or more of the voting capital and 95% or more of the voting securities of the target company, and provided that the bidder acquired securities representing at least 90% of the voting capital to which the public takeover bid relates, each security holder has the right to require the bidder take over its securities against the Offer Price in accordance with article 44 of the Takeover Decree.

## 10 Management and corporate governance

## 10.1 Introduction

This Section provides a summary of the corporate governance principles of the Company, as set forth in the Belgian Company Code, the articles of association and the Company's corporate governance charter.

Certain amendments to the articles of association were resolved upon during the extraordinary shareholders' meeting held on 16 January 2015, subject to the condition precedent of the completion of the Offering. Therefore, the description below of the management of the Company and its corporate governance structure and functioning shall, in certain respects, only take effect upon completion of the Offering.

## **10.2** Corporate Governance

Pursuant to the Belgian Act of 6 April 2010 on the reinforcement of the corporate governance of listed companies and autonomous government enterprises and the amendment of the rules on the exclusion of employment in the bank and financial sector (*Loi visant à renforcer le gouvernement d'entreprise dans les sociétés cotées et les entreprises publiques autonomes et visant à modifier le régime des interdictions professionnelles dans le secteur bancaire et financier*), as implemented by the Royal Decree of 6 June 2010 regarding the designation of the corporate governance code on listed companies (*Arrêté Royal portant désignation du Code de gouvernement d'entreprise à respecter par les sociétés cotées*), Belgian listed companies should comply with the Belgian Code for Corporate Governance issued on 12 March 2009 by the Belgian Corporate Governance Committee (the "Corporate Governance Code" or "CGC"), unless it discloses the justification why it has decided to deviate from the provisions of the Corporate Governance Code (the rule of *comply or explain*).

The Company's corporate governance charter (the "Corporate Governance Charter") was adopted in accordance with the recommendations included in the Corporate Governance Code.

The Board of Directors of the Company intends to comply with the Corporate Governance Code, except in relation to the following matters:

- Although at the date of this Prospectus, no options have been granted to non-executive directors, the Company has reserved the possibility to grant variable remuneration (upon advice of the Nomination and Remuneration Committee), such as long-term stock-related incentive plans, to non-executive directors, so that the Company, as a small-sized listed enterprise, could grant options or warrants to non-executive directors if it would be of the opinion that such grant is necessary to attract or retain (internationally) renowned experts with the most relevant skills, knowledge and expertise.
- The management agreement of Enrico Bastianelli SPRL provides for a notice period or corresponding compensatory payments of up to maximum 18 months (relating to a non-compete undertaking).

The Board of Directors will review the Corporate Governance Charter from time to time and adopt such amendments thereto as it deems necessary and appropriate. The Corporate Governance Charter and the Company's articles of association are available at the Company's website and at its registered office, and can be obtained free of charge.

#### 10.3 Board of Directors

## 10.3.1 General provisions

The Board of Directors is the main decision-making body of the Company, and has full power to perform all acts that are necessary or useful to accomplish the Company's corporate purpose, save for those acts for which only the shareholders' meeting of the Company has the required powers in accordance with applicable laws or the Company's articles of association. The responsibility for the management of the Company is entrusted to the Board of Directors as a collegial body.

The Board of Directors pursues the long-term success of the Company by providing entrepreneurial leadership, while assessing and managing the risks of the Company.

The Board of Directors is composed of minimum three members as set out in the articles of association and the Corporate Governance Charter.

At least half of the members of the Board of Directors are non-executive directors, and at least three members of the Board of Directors are independent directors, within the meaning of *inter alia* Article 526*ter* of the Belgian Company Code.

The members of the Board of Directors are appointed by the shareholders' meeting of the Company for a renewable term of maximum four years. If a director mandate becomes vacant, the remaining members of the Board of Directors will have the right to temporarily appoint a new director to fill the vacancy. The shareholders' meeting can revoke the mandate of any director at any time.

In principle the Board of Directors meets at least four times a year, and also whenever a meeting is deemed necessary or advisable for its proper functioning. A meeting of the Board of Directors is validly constituted if there is a quorum, which requires that at least half of the members of the Board of Directors or present or represented during the board meeting. In any event, the Board of Directors can only validly deliberate if at least two directors are present in person.

#### 10.3.2 Chairman

The Board of Directors appoints one of its members as chairman of the Board of Directors. The chairman is responsible for the leadership and the effectiveness of the Board of Directors in all aspects. He takes the measures necessary to develop a climate of trust within the Board of Directors, which promotes open discussion, constructive dissent and support. He promotes interaction between the Board of Directors and the Management Team of the Company and establishes a close relationship with the Executive Directors, providing support and advice, while fully respecting the executive responsibilities of the Executive Directors. Hence, the chairman of the Board of Directors can never be the CEO of the Company.

Within the Board of Directors, the Chairman is primarily responsible for:

- setting the agenda of the meetings of the Board of Directors, after consultation with the Executive Directors:
- ensuring that procedures relating to preparatory work, deliberations, passing of resolutions and implementation of decisions are properly complied with;
- ensuring that the members of the Board of Directors receive accurate, timely and clear information before
  the meetings and, where necessary, between meetings, and that all members of the Board of Directors
  receive the same information:
- chairing the meetings of the Board of Directors and ensure that the Board of Directors operates and takes decisions as a collegial body;
- monitoring the implementation of decisions taken and determines whether further consultation within the Board of Directors with regard to the implementation thereof is required;
- ensuring a regular assessment of the corporate structure and the corporate governance of the Company and assess whether their operation is satisfactory;
- ensuring that newly appointed directors receive an appropriate induction;
- leading the nomination process of directors, in consultation with the Nomination and Remuneration
   Committee, and ensuring that the Board of Directors appoints Committee members and chairmen;
- leading the self-evaluation process of the Board of Directors and its Committees with respect to their size, composition and performance; and
- being accessible to the directors, the members of the Management Team and the internal auditor (if any) to discuss issues relating to the management of the Company.

The Board of Directors may decide to entrust the chairman of the Board of Directors with additional responsibilities. In any event, the chairman of the Board of Directors has a permanent invitation to attend the meetings of any Committee. However, the chairman of the Board of Directors may not attend the meetings of the Nomination and Remuneration Committee during which his/her own reappointment or removal is discussed or during which his remuneration is discussed.

With regard to shareholders and third parties, the chairman of the Board of Directors is mainly responsible for chairing the annual general shareholders' meeting and ensuring that relevant questions from shareholders are answered.

#### 10.3.3 Independent directors

Directors are only considered as independent directors if they meet the criteria set out in the Corporate Governance Code and in Article 526*ter* of the Belgian Company Code. Each independent director may <u>not</u>:

- have been an executive director, member of the executive committee (comité de direction) (should such body exist), the CEO or a related company or person for a period of five years before their first appointment;
- have been a non-executive director for more than three terms of office (and for a period exceeding 12 years);
- be a senior management employee of the Company or a related company or person and having been in such
  a position during the three years before their nomination;
- receive remuneration or any other significant advantage from the Company, with the exception of remuneration received as a non-executive director or member of the supervisory body;
- have shareholding in the Company which exceeds 10% (directly or indirectly), or have a 10% of a class of shares, as applicable (or represent a shareholder who meets such criterion);
- if he/she has a shareholding of less than 10% in the Company (or of a class of shares), have subjected his/her acts of disposal of those shares or the exercise of rights connected with those shares to agreements or unilateral undertakings concluded by him/her (or represent a shareholder who meets such criterion);
- have or have had a significant business relationship with the Company or a related company or person either directly or indirectly as a shareholder, director or manager of a company or person with such a relationship during the past business year;
- have been a partner or employee of the current or previous statutory auditor or a related company or person during the last three business years;
- be an executive director in another company where any of the Company's executive directors is a non-executive director or member of the supervisory body, and may not have significant ties with the executive directors as a result of functions exercised with other companies or bodies; and
- be a spouse, legal partner, or family member in the second degree to a director or person exercising management duties in the Company or who meets one of the descriptions listed here above.

The Board of Directors discloses in its annual report which directors it considers to be independent.

#### 10.3.4 Composition of the Board of Directors

On completion of the Offering, the Board of Directors will be composed of eleven members.

Name	Position	Term of mandate	Nature of mandate	Professional address
Roland Baron	Director	2019	Independent	Milford Street 33, Boston MA 02118, Unites States of America
Enrico Bastianelli SPRL, with as permanent representative Enrico Bastianelli	Managing director	2019	Executive	Avenue Libération 41, 1640 Rhode- Saint-Génese, Belgium
Chris Buyse	Director	2017	Independent	Baillet Latourlei 119A, 2930 Brasschaat
SFPI SA, with as permanent representative François Fontaine	Director	2019	Non-executive	Avenue Louise 32- 46, 1050 Brussels, Belgium
Magenta Tree BVBA, with as permanent representative Thierry François	Director	2019	Independent	Ophemstraat 133, 3050 Oud-Heverlee, Belgium
Wim Goemaere BVBA, with as permanent representative	Managing director	2016	Executive	Zakstraat 72, 9112 Sinaai, Belgium

Name	Position	Term of mandate	Nature of mandate	Professional address
Wim Goemaere				
Michel Helbig de Balzac	Director	2016	Chairman	Avenue du Parc 61, 1310 La Hulpe, Belgium
Paul Magrez	Director	2019	Independent	Lindenhoekje 7, 1970 Wezembeek-Oppem, Belgium
Marc Nolet de Brauwere van Steeland	Director	2019	Independent	Avenue du Verger 35, 1640 Rhodes-Saint- Genèse, Belgium
Partigest-Garance SA, with as permanent representative Jacques Reymann	Director	2017	Non-executive	Rue Roberts Jones 58, 1180 Brussels, Belgium
Jean-Jacques Verdickt	Director	2016	Non-executive	Rue Jacques de Meeus 16, 1428 Lillois Witterzee, Belgium

A brief overview of the relevant experience of the non-executive directors is set out below. See Section 10.5.2.3 "Composition" for the resume of the Executive Directors.

**Pr. Roland Baron** is professor at the Harvard Medical School, Endocrine Unit, Massachusetts General Hospital, and chair of oral Medicine at the Harvard School of Dental Medicine from January 2008. He received his DDS and PhD degrees from the University of Paris, France. From 1977 to 2007, Pr. Roland Baron was a professor in the departments of orthopaedics and cell ciology at Yale University School of Medicine. From 1994 to 2002, he also held the position of vice president and head of the bone diseases group at Hoechst Marion Roussel and then Aventis. In 2002, he founded ProSkelia, a small pharmaceutical company devoted to the discovery and development of new drugs for bone and hormonal dependent diseases. He has held the positions of president and chief scientific officer of ProSkelia and then ProStrakan, until April 2006. He is the founder and current editor-in-chief of BONE, the official journal of the International Bone and Mineral Society. Pr. Baron has published over 300 scientific papers in the field of bone biology and bone diseases.

Chris Buyse holds a Master's degree in Applied Economics from the University of Antwerp and an MBA from Vlerinck Business School. From August 2006 to 2014, Chris was CFO and director of ThromboGenics, a biotechnology company listed on Euronext Brussels. Before joining ThromboGenics, he was CFO of CropDesign, where he coordinated the acquisition by BASF in July 2006. Prior to joining CropDesign, he served as finance manager WorldCom/MCI Belux, and CFO and CEO ad interim of Keyware Technologies. Before, Chris kept positions in finance at Spector Photo Group, Suez Lyonnaise des Eaux and Unilever. He currently holds a director position in several private companies.

François Fontaine (permanent representative of SFPI SA) obtained a Master's degree in Law at the Université Libre de Bruxelles, and a degree in Fiscal Sciences from ESSEF/ICHEC. François held several positions at federal government bodies, amongst others the office of the Vice Prime Minister Laurette Onkelinkx (1999-2007) and the center of expertise for tax matters of the Walloon Region. He currently holds the position of general advisor at the Federal Investment and Participation Company (SFPI). Next to his responsibilities as human resources manager, he manages the investment portfolio for new technologies, real estate, waste management and water. He has been director of the Loterie Nationale (up to 2006) and Government Commissioner at Infrabel (up to 2014). He currently holds the position of government commissioner at HR-Rail and Fluxys Belgium. He is the permanent representative of SFPI at the board or directors of multiple companies in which SPFI holds a participation.

Thierry François (permanent representative of Magenta Tree BVBA) holds a Master's degree of Science in Engineering and Management, as well as Guberna certificates. He is also a CFA charterholder and a Certified Financial Analyst (EFFAS). With more than 20 years of experience in corporate finance, sell side equity research and private equity, he is a true expert in financial analysis, with a strong background in competitive strategy, financial and legal structuring, and business valuation. He started his career in 1993 as a university trainee at the BNP Paribas Fortis Bank (Generale de Banque at the time), and worked his way up to corporate research officer (1994-1997). He then moved on to Vermeulen-Raemdonck (part of ING Bank), where he served as a senior financial analyst. In 2000, he returned to Fortis Bank, to take the position as director equity research (2000-2004) and later as head of investment analyst (2004-2011). Since, he operated as an independent

investment professional, for companies such as Korys, Sofindev II and III, and Re-Vive Brownfield Fund II. Finally, he is the founder and owner of Magenta Tree.

Michel Helbig de Balzac has a long-standing experience in venture capital as the Founder and Managing Partner of BAMS Angels Fund I SCA (founded in 2005) and Nausicaa Ventures SCA (2009), both investing in early stage and early growth new technology companies and located in Louvain-la-Neuve (Belgium). He has particular knowledge in the fields of biotech, medical devices and energy, and represents the funds at the board of several investee companies such as Spacebel, Ovizio, and Bio-Sourcing. He serves as the Chairman of the Board of Directors of Bone Therapeutics since June 2013. Previously, he was an acknowledged angel investor and entrepreneur with several high-growth companies. Complementary to venture capital, he has been very active in the development and financing of large-scale renewable energy development projects such as the North Sea offshore wind farm Northwester 2 consortium, comprised of Colruyt, TTR Energy (TPF Group), Incontrol, and his own company Wagram Invest, which was granted a 224 MW area concession in 2013. From 2002 to 2013 he was influential in helping to launch a range of wind farm projects in the Walloon Region. From 2009 to 2014, he was the Chairman of Edora, the Belgian Federation for Renewable Energy, of which he is currently Vice-Chairman, and more recently a board member of the Belgian Offshore Platform association. Michel started his professional career in 1985 with McKinsey, where he was active in the steel and paper industries and the insurance and hospital sectors before taking on the responsibility of Administrative Director and General Secretary of their Brussels Office. He then joined Dewaay Bank in 1994 where he led the development of various private banking and corporate finance projects. Michel has a broad academic background from UCL (Belgium) in philosophy, political sciences (with a focus on international relations), economic sciences, and European studies, and a MSc degree in Urban and Regional Planning (access to final work).

**Paul Magrez** is a medical doctor and computer scientist with more than 20 years of experience in diagnostics (personalized medicine), clinical biology, biotechnology (vaccines), and pharmaceutical industries. His experience mainly resides in the development of business plans, the search for private and public funding and the business & commercial development. After working at UCB as data management R&D Manager from 1988 to 1992, he moved on to GSK, to take the position of information resource director (from 1992 to 1997) and executive director business operations (from 1997 to 2001). In 2001, he became the COO and CEO ad interim of Innogenetics until 2007, when he took the position of CEO of Biomedical Diagnostics in Paris. From 2009 to 2011, he was CEO and chairman at BARC. In 2011, Paul founded his own consulting firm in support of SMEs and start-ups, Paul Magrez BVBA.

Marc Nolet de Brauwere van Steeland obtained his Master's degree as a Mining Civil Engineer from the Catholic University of Louvain (UCL) in 1982, then specialised as a civil engineer in industrial management at the Katholiek Universiteit Leuven (KUL) in 1983. He started his career in 1984, as manager of the engineering department at Petrofina (Kentucky Prince Coal Corporation). In 1978, he also took charge of the development of a downstream activity (gold mining) at Chemetech Corporation. He served for these two companies until 1989 and then moved on to McKinsey & Company, as an associate. In 1992, Marc created Dat International with an ex-colleague at McKinsey, and set up a distribution network specialised in supply parts from the EEC to local companies in East Africa. Finally, in 1997, he became CEO of Physiol. He was nominated director at ETEX group in 2003, where he served as chairman of the audit committee from 2006 to 2013. He became chairman of the nomination and remunerations committee in 2013. In addition, he became director of Mecatech (2011), Biotech Coaching (2011), MyMicroInvest (2013) and EndoTools Therapeutics (2013). Since 2011, he also is a member of Ashoka Support Network.

**Jaques Reymann** (permanent representative of Partigest-Garance SA) made his career in the international engineering and contracting sector. For over ten years, he served as managing director of Fabricom Group which was part of Tractebel (today part of GDF-Suez) He then became chairman of Entrepose Contracting until its initial public offering and furthermore contributed to the development of several innovative start-ups, among which Bone Therapeutics. Mr Reymann is one of the co-founders of Bone Therapeutics.

**Jean-Jacques Verdickt** holds a Master's degree in mechanical engineering from the Leuven Catholic University (UCL). He started his career in 1971 at the BNP Paribas Fortis Bank (Generale de Banque at the time), and worked his way up from management roles to director and senior advisor to the chairman of Fortis Bank. In 2003, he became the chief executive officer of Magotteaux (until December 2006). He served as non-executive director of various companies, such as Techspace Aero, FREE, Euroclear (Plc and Bank), IBA SA, and the Union Wallonne des Entreprises. Today he is still on the board of Logiver, Calyos and a number of non-profit organizations.

At the date of this Prospectus, none of the Directors and the members of the Management Team have at any time within at least the past five years:

- had any conviction in relation to fraudulent offences; or
- been adjudged bankrupt or entered into an individual voluntary arrangement; or
- been a director of any company at any time of, or within 12 months preceding, any receivership, compulsory liquidation, administration or partnership voluntary arrangement of such partnership; or
- had his assets from the subject of any receivership or has been a partner of a partnership at the time of, or within 12 months preceding, any assets thereof being the subject of a receivership; or
- been subject to any official public incrimination and/or sanctions by any statutory or regulatory authority;
- ever been disqualified by a court from acting as a director of a company or from acting in the management or conduct of the affairs of any company.

#### 10.4 Committees

#### 10.4.1 General

The Board of Directors has established a nomination and remuneration committee (the "Nomination and Remuneration Committee) and an audit committee (the "Audit Committee"). These committees (the "Committees") have a mere advisory role.

The Board of Directors has determined the terms of reference of each Committee with respect to its respective organisation, procedures, policies and activities.

#### 10.4.2 Audit Committee

#### 10.4.2.1 Role

The Audit Committee supports the Board of Directors in fulfilling its monitoring responsibilities in respect of control in the broadest sense.

## 10.4.2.2 Duties

The Audit Committee is the main contact point of the external auditor. Without prejudice to the legal duties of the Board of Directors, the Audit Committee is entrusted with the development of a long term audit programme encompassing all of the Company's activities, and is in particular entrusted with:

- monitoring the financial reporting process;
- monitoring the effectiveness of the Company's internal control and risk management systems;
- monitoring the internal audit and its effectiveness, including advising the Board of Directors on its annual assessment of the need for an internal auditor;
- monitoring the statutory audit of the annual and consolidated accounts, including any follow up on any questions and recommendations made by the external auditor;
- reviewing and monitoring the independence of the external auditor, in particular regarding the provision of additional services the Company may require; and
- monitoring the compliance with the legislation and regulations that apply to the Company.

The final responsibility for reviewing and approving the Company's interim and annual financial statements, as presented to the shareholders, remains with the Board of Directors.

#### 10.4.2.3 Composition

The Audit Committee will be composed of at least three members, all its members being non-executive directors. At least one of the members of the Audit Committee is an independent directors, who has accounting and auditing expertise. This expertise in accounting and auditing implies a degree of higher studies in economics or finance or relevant professional experience in those matters.

The Audit Committee is chaired by one of its members, who may not be the chairman of the Board of Directors.

The duration of the mandate of a member of the Audit Committee will not exceed the duration of his/her mandate as director of the Company.

Subject to and effective as of completion of the Offering, the following directors will be members of the Audit Committee:

Name	Position	Professional address
Chris Buyse	Chairman	Baillet Latourlei 119A, 2930 Brasschaat, Belgium
Magenta Tree BVBA, with as permanent representative Thierry François	Member	Ophemstraat 133, 3050 Oud- Heverlee, Belgium
Jean-Jacques Verdickt	Member	Rue Jacques de Meeus 16, 1428 Lillois Witterzee, Belgium

## 10.4.2.4 Operation

The Audit Committee meet at least four times a year and whenever a meeting is deemed necessary or advisable for its proper functioning. Decisions are be taken by a majority vote. The Chairman of the Board of Directors has a permanent invitation to attend the meetings of the Audit Committee. The Audit Committee may also invite other persons to attend its meetings.

The Audit Committee meets with the external auditor and the internal auditor (if any) at least twice a year, to discuss matters relating to its terms of reference, issues falling within the powers of the Audit Committee and any issues arising from the audit process and, in particular, any material weaknesses in the internal audit.

#### 10.4.3 Nomination and Remuneration Committee

#### 10.4.3.1 Role

The Nomination and Remuneration Committee makes recommendations to the Board of Directors with respect to the appointment of directors, the Executive Directors and other members of the Management Team. In addition, the Nomination and Remuneration Committee makes recommendations to the Board of Directors on the Company's remuneration policy, on any remuneration whatsoever granted to the directors and members of the Management Team and on any agreements or provisions relating to the early termination of employment or collaboration with the directors and members of the Management Team.

#### 10.4.3.2 Duties

The Nomination and Remuneration Committee must ensure in general that the appointment and re-election process of the members of the Board of Directors, the Executive Directors and the members of the Management Team is organised objectively and professionally and, in particular and notwithstanding the legal powers of the Board of Directors, has the following duties:

- draft (re)appointment procedures for members of the Board of Directors and the members of the Management Team;
- nominate candidates for any vacant directorships, for approval by the Board of Directors;
- prepare proposals for reappointments;
- periodically assess the size and composition of the Board of Directors and, if applicable, making recommendations with regard to any changes;
- analyse the aspects relating to the succession of directors;
- advise on proposals (including, of the management or of the shareholders) for the appointment and removal
  of directors and of members of the Management Team;
- advise the Board of Directors on proposals made by the Executive Directors for the appointment and removal of executive directors and of members of the Management Team;
- prepare and assess proposals to the Board of Directors on the remuneration policy for members of the Board of Directors, and, where applicable, on the resulting proposals to be submitted by the Board of Directors to the shareholders:

- prepare and assess proposals for the Board of Directors on the remuneration policy for the members of the Management Team, and, where applicable, on the resulting proposals to be submitted by the Board of Directors to the shareholders, at least with regard to the:
  - main contractual terms, including the main characteristics of the pension schemes and termination arrangements;
  - key elements of the remuneration, including the:
    - (i) relative importance of each component of the remuneration package;
    - (ii) performance criteria applicable to the variable elements (determination of milestones and their evaluation period); and
    - (iii) fringe benefits.
- prepare and assess proposals to the Board of Directors regarding the individual remuneration of members of the Board of Directors and the Management Team, including, depending on the situation, on variable remuneration and long-term incentives, whether or not stock-related, in the form of stock options or other financial instruments, and, where applicable, on the resulting proposals to be submitted by the Board of Directors to the shareholders;
- make proposals to the Board of Directors regarding arrangements on early termination and, where applicable, on the resulting proposals to be submitted by the Board of Directors to the shareholders;
- submit to the Board of Directors (a) a remuneration report which describes, amongst other things, the internal procedure for the development of a remuneration policy and the determination of the remuneration level for non-executive directors and members of the Management Team and (b) a declaration regarding the remuneration policy applied with respect to the members of the Management Team, including a description of any material changes thereto since the previous financial year;
- advise the Board of Directors on agreements relating to the appointment of the Executive Directors and other members of the Management Team; and
- verify that the variable criteria for setting remuneration for an executive director or a member of the Management Team are expressly stated in the agreement, and that the payment of this variable remuneration only takes place if such criteria are met during the relevant period.

When performing its duties relating to the composition of the Board of Directors, the Nomination and Remuneration Committee takes into account the criteria for the composition of the Board of Directors, as stated in the terms of reference of the Board of Directors.

#### 10.4.3.3 Composition

The Nomination and Remuneration Committee is composed of at least three directors. All members of the Nomination and Remuneration Committee are non-executive directors, with a majority being independent directors. The majority of the members has the necessary expertise with regard to remuneration policies, *i.e.* has a degree in higher education and has at least three years' experience in personnel management matters or matters related to the remuneration of directors and managers of companies. The Board of Directors considers that all members of the Nomination and Remuneration Committee have sufficient experience in personnel management and matters related to remuneration.

The Nomination and Remuneration Committee is chaired by the chairman of the Board of Directors or by another non-executive member of the Nomination and Remuneration Committee. The chairman of the Board of Directors does not chair the Nomination and Remuneration Committee when dealing with the designation of his or her successor.

The duration of the term of a member of the Nomination and Remuneration Committee will not exceed the duration of his mandate as director of the Company.

Subject to and effective as of completion of the Offering, the following directors will be members of the Nomination and Remuneration Committee:

Name	Position	Professional address
Paul Magrez	Chairman	Lindenhoekje 7, 1970 Wezembeek-
		Oppem, Belgium

Name	Position	Professional address
Chis Buyse	Member	Baillet Latourlei 119A, 2930
		Brasschaat, Belgium
Michel Helbig de Balzac	Member	Rue de Rodeuhaie 1, 1348
		Louvain-La-Neuve, Belgium

#### 10.4.3.4 Operation

The Nomination and Remuneration Committee meets at least twice a year, and whenever a meeting is deemed necessary and advisable for its proper functioning. Decisions are taken by a majority vote. The chairman of the Board of Directors has a permanent invitation to attend the meetings of the Nomination and Remuneration Committee, except for meetings at which his own appointment, removal or remuneration is discussed. The Nomination and Remuneration Committee may invite other persons to attend its meetings (it being understood that a member of the Board of Directors may not attend the meeting of the Nomination and Remuneration Committee which handles his remuneration).

## 10.5 Management Team

#### 10.5.1 *General*

The Board of Directors has established a management team (the "Management Team"), which advises the Board of Directors, and which therefore does not constitute a management committee (*comité de direction*) under article 524bis of the Belgian Company Code. The terms of reference of the Management Team have been determined by the Board of Directors.

#### 10.5.2 Management Team

#### 10.5.2.1 Role

The Management Team assists the Executive Directors in the management of the Company. The Management Team reports to and is accountable to the Board of Director for the discharge of its responsibilities.

#### 10.5.2.2 Duties

The Management Team has the following tasks:

- proposing, developing, implementing and monitoring the company strategy, taking into account the values of the Company, its risk profile and key policies;
- supervising compliance with the legislation and regulations that apply to the Company;
- develop, manage and assess internal control systems to allow identification, assessment, management and monitoring of financial and other risks;
- organising, coordinating and monitoring all functions of the Company;
- prepare complete, timely, reliable and accurate financial statements of the Company in accordance with the accounting standards and policies of the Company, and prepare the Company's required disclosure of the financial statements and other material financial and non-financial information;
- supporting the Executive Directors in the day-to-day management of the Company and with the performance of their other duties;
- investigate, draw up and develop policies proposals and strategic or structural projects to be presented to the Board of Directors for approval, report to the Board on their implementation, and provide informations that is necessary to the Board to enable it to carry out its duties;
- develop, manage and assess internal control systems to allow identification, assessment, management and monitoring of financial and other risks.
- The Management Team reports to and is accountable to the Board for the discharge of its responsabilities."

## 10.5.2.3 Composition

The Executive Directors (CEO and CFO), CMO and CCRO are members of the Management Team. The Management Team is chaired by the CEO of the Company and in his absence by the CFO. The Members of the Management Team are appointed and may be dismissed by the Board of Directors at any time. The Board of Directors appoints them on the basis of the recommendations of the Nomination and Remuneration Committee, which also assists the Board of Directors on the remuneration policy for the members of the Management Team, as well as their individual remunerations

The remuneration, duration and the conditions of resignation of the members of the Management Team are governed by the agreements entered into between the Company and each member of the Management Team in respect of their function within the Company.

The following persons are members of the Management Team:

Name	Title	Professional address
Enrico Bastianelli SPRL,	Chief Executive Officer and	8 rue Adrienne Bolland, 6041
represented by Enrico Bastianelli	Executive Director	Gosselies, Belgium
Wim Goemaere BVBA, represented	Chief Finance Officer and	8 rue Adrienne Bolland, 6041
by Wim Goemaere	Executive Director	Gosselies, Belgium
Enrico Bastianelli SPRL,	Chief Medical Officer	808 route de Lennik, 1070
represented by Valérie Gangji		Brussels, Belgium
Guy Heynen	Chief Clinical and Regulatory	8 rue Adrienne Bolland, 6041
	Officer	Gosselies, Belgium

Enrico Bastianelli SPRL, represented by Mr Enrico Bastianelli, (46) (CEO). Mr Bastianelli has a long-standing experience in pharmaceutical industry in fields as broad as Sales & Marketing, R&D, Licensing, Corporate Development and Strategy. His career started in the Pathology Department of the Erasme University Hospital in Belgium. Then he joined Procter & Gamble Pharmaceuticals in 1996, where he was involved in the marketing of ethical and over-the-counter drugs in the field of bone diseases. In 1999, he became a Consultant for McKinsey & Co, where he was involved in strategic and organizational missions for major pharmaceutical as well as biotechnology companies all over Europe. From its creation in 2002 until mid-2006, Mr Bastianelli worked as VP Corporate Development for ProSkelia, spin-out of Aventis focused on bone diseases and hormone disorders (which then became ProStrakan, after the merger with Strakan, a Scottish pharmaceutical company). As a member of the Executive Committee, he was responsible for the management of the R&D portfolio, resources allocation and planning, alliances, collaborations and downstream integration. He was one of the main contributors to the merger with Strakan. Since 2006, Enrico Bastianelli SPRL is the managing director of Bone Therapeutics.

Wim Goemaere BVBA, represented by Mr Wim Goemaere, (50) (CFO). Mr Goemaere is an experienced senior financial executive with over 25 years international business experience, the majority of which he spent within the biotechnology space. After graduating in Applied Economics from KU Leuven (Belgium) in 1987, he began his career at BP where he held various finance roles with increasing responsibility until leaving the Company in 1995, to join the Flanders Institute for Biotechnology (VIB) as CFO. Mr Goemaere played a key role in the Institute's development from start-up to one of the world's leading research bodies in life sciences. In 2008, he moved to Devgen, a Belgium-based multinational agro-biotech company listed on the NYSE Euronext Brussels, where he held the position of CFO for five years. Mr Goemaere was instrumental in ensuring endorsement of Devgen in the financial markets and in the take-over of Devgen by Syngenta for €403 million. Furthermore, he played an important role into the company's business expansion in Asia.

Enrico Bastianelli SPRL, represented by Mrs Valérie Gangji (46) (CMO). Mrs Gangji has acquired a broad experience in rheumatology in general and bone diseases in particular. She started her career in the Rheumatology Department of the Erasme University Hospital in Brussels, Belgium in 1993. After a general rheumatology path, Mrs Gangji further specialized in osteo-articular disorders and rehabilitation, and is now head of the bone and rehabilitation unit of the Rheumatology Department of Erasme University Hospital (Brussels, Belgium). She also recently became co-director of the pain clinic. In 1998, she started her pioneering works on stem cell transplantation, work from which she obtained her PhD degree. Since 1997, she has conducted several clinical studies in osteonecrosis, arthritis and osteoporosis (protocol design, submission, recruitment of patients, follow-up, publication of results...). She managed to show for the first time that the graft of bone marrow in the necrotic area improves the clinical symptoms and the evolution of the lesion to a fracture state. Each year, she is the main investigator in 3 to 4 clinical studies. She is a board member of

several professional rheumatology associations. From 2007 to 2012, Mrs Gangji was VP ARCO for Europe, the international osteonecrosis association. Mrs Valérie Gangji is Mr Enrico Bastianelli's spouse.

Mr Guy Heynen, (69) (CCRO). Mr Heynen started his career at the Belgian National Foundation for Research and in research roles at University Hospital, Liege, Belgium where he received his degree in medicine. Mr Heynen is a specialist in rheumatology and immunology, with extensive experience both in university medical practice and in the pharmaceutical industry. He has over 35 years' experience in medical affairs and regulatory functions at local, regional and international levels and has a particular focus on management, team building and leadership. The majority of his career has been with Pfizer Inc. where he held a number of senior roles including medical director for Pfizer Switzerland, European team leader for the Alzheimer's disease drug Aricept and Medical Team Leader for Pfizer's anti-inflammatory drug franchise based in New York, US. Mr Heynen also served as medical affairs director at Anbics AG, Switzerland from 2003-2006 and remains a Regional Medical Monitor for Pfizer GmbH Berlin.

#### 10.5.2.4 Operation

The Management Team meets regularly whenever it is required for its proper functioning.

At the date of the Prospectus, the CCRO works for the Company on a part-time basis (3 days a week). The Board of Directors will assess this arrangement from time to time in view of the Company's needs and may decide to extend the collaboration with Mr Heynen to a full time basis if required.

The CMO is an active practitioner and provides services to the Company on a regular basis.

#### 10.5.2.5 Executive Directors

The CEO and the CFO have been appointed as Executive Directors of the Company and can be removed by the Board of Directors of the Company. The CEO and the CFO are entrusted by the Board of Directors with the day-to-day management of the Company.

#### 10.6 Other mandates

Other than set out in the table below, no member of the Board of Directors or member of the Management Team has, at any time in the previous five years, been a member of the administrative, management or supervisory bodies or partner of any companies or partnerships. Over the five years preceding the date of this Prospectus, the members of the Board of Directors and the members of the Management Team hold or have held in addition to their function with the Company, the following main directorships of administrative, management or supervisory bodies and partnerships:

Board of Directors and/or Management Team Members	Current Mandates	Past Mandates
Roland Baron	Professor, Harvard Medical School and Mass. General Hospital	N/A
Enrico Bastianelli SPRL Enrico Bastianelli (permanent representative)	N/A N/A	N/A N/A
Valérie Gangji	Board member of the Belgian Society of Rheumatology Board member of the Belgian Society of Physical Medicine	N/A
Chris Buyse	Director at Life Sciences Research Partners VZW	Director at Thrombogenics NV Independent director at Cardio3 Biosciences SA Independent director at Keyware SA
Marc Nolet de Brauwere van Steeland	Managing director at PhysIOL SA Director at Etex SA	N/A
Magenta Tree BVBA Thierry François (permanent representative)	N/A Manager at Magenta Tree BVBA Director at Sofindev II NV Director at Sofindev III NV	N/A Director at Fortis Private Equity Belgium NV Director at Fortis Private Equity

Board of Directors and/or Management Team Members	Current Mandates	Past Mandates
	Director at Re-Bive Brownfield Fund II CVBA Director at the Belgian Venture Capital & Private Equity Association VZW	Expansion Belgium NV Director at Fortis Private Equity Venture Belgium NV Director at Fortis Private Equity Management NV Director at Velleman International NV Director at Colfridis NV Director at Artstone NV Director at Packing Invest NV Director at Packing Creative Systems NV
Paul Magrez	General Manager at Paul Magrez BVBA	Chief Executive Officer and chairman of the board of directors at BARC NV Chief Executive Officer and chairman of the board of directors at LBS NV Chief Executive Officer and chairman of the board of directors at CRI NV
Wim Goemaere BVBA Wim Goemaere (permanent representative)	Director at SISE SA N/A	N/A Chief financial officer at Devgen NV. Director at Devgen Inc. (US). Director and chief financial officer at Devgen Seeds and Crop Technology PvT (India) and Devgen Seeds and Crop Technology PTE (Singapore).
Guy Heynen	Chief executive officer at Guy Heynen Consulting Regional Medical Monitor at Pfizer GmbH President of the board and scientific advisor at Progenosis SA Independent board member and advisor at Euroscreen SA Independent board member at Pluriomics SA	N/A
Michel Helbig de Balzac	Chairman of the board of directors at Northwestern 2 SA Managing partner at Nausicaa Ventures SCA Managing director at BAMS Angel Fund I SCA Managing director at Wagram Invest SA Director at SPACEBEL SA Director at Ovizio SA Director at Biosourcing SA Director at Kyotech 1 SA Director at Belgian Offshore Platform	Deputy chairman of the board of directors of EDORA ASBL Director at Windeo Green Energy SA
SFPI SA	Director at Fluxys SA Observatory seat at Société	N/A

Board of Directors and/or Management Team Members	Current Mandates	Past Mandates
François Fontaine (permanent representative)	Walonne des Eaux SC SCRL Director at Comet Sambre Director at Comet Traitement Director at Xylowatt SA Director at Cissoid SA Director at Theodorus III SA Director at Biotech Tools SA Government commissioner at Infrabel SA Government commissioner at HR- Rail SA	Government commissioner at Fluxys Belgium SA
Jacques Reymann	Director at Enco 3 (France) Director at Be Pharbel SA Director at Be Pharbel Manufacturing SA Managing director at Partigest- Garance SA Director at Nuovo Director at ACCADIS Director at Alphamédias SA Co-manager at SCI Cana (France)	Co-manager at BIOMIM
Jean-Jacques Verdickt	Director at Logiver SA Manufacturing company director at Calyos SA Chairman of Fonds Verdickt Degroux ASBL Director of Foundation IRSA Director of Foundation Free	Deputy chairman of the board, chairman of the risk committee group, chairman of the audit committee of the bank and member of the Group nomination and remuneration committee at Euroclear Plc, SA and Euroclear Bank SA Director and member of the auditr committee at CBC Banque SA Director and chairman of the audit committee at Ion Beam Application SA Director at Snecma SA Director and chairman of the board at Techspace Aero SA Director and chairman of the nomination and remuneration committee at Banque Commerciale du Congo SA Manager at JJ Verdickt SPRL

# 10.7 Scientific advisory board

## 10.7.1 Role

The Company has established a scientific advisory board, which acts as the expert panel of the Company. This expert panel consists of the key thought leaders in fields of expertise relevant to the Company and assists the Company with the following matters:

- Provide strategic guidance for program development;
- Provide a neutral view on the progress of technology and science;
- Provide external validation of intellectual property or new technologies.

## 10.7.2 Composition

The scientific advisory board is currently composed of the following experts:

- Mr Roland Baron, Professor and chair at Harvard Medical School and Mass. General Hospital, founder and CSO ProSkelia (Paris) from 2002 to 2006, vice-president R&D "Bone Diseases & Hormonal Disorders" at Aventis Pharma from 1995 to 2002.
- Mr David Scadden, Professor and co-director at Harvard Stem Cell Institute, director at Centre for Regenerative Medicine, founder of Fate Therapeutics (Boston).
- Mr Joseph Lane, Professor and orthopaedic surgeon at the Hospital for Special Surgery in New York, assistant dean at Weill Cornell Medical College of New York, expert in orthopaedics and metabolic bone diseases.
- Mr Steven Goldring, Professor, chair and CSO at the Hospital for Special Surgery in New York, professor of medicine at Harvard Medical School (Boston) from 1996 to 2006, expert in Rheumatology.
- Mr Sundeep Khosla, Professor Physiology & Medicine at the Mayo Clinic in Minnesota, President of the American Society for Bone & Mineral Research from 2010 to 2011, expert in osteoporosis and bone biology.

## 10.8 Remuneration of directors and members of the Management Team

#### 10.8.1 General

In accordance with Article 554 of the Belgian Company Code, which applies to agreements with leaders entered into or extended after 3 May 2010, any such agreement which includes a provision providing for a severance package exceeding 12 months' remuneration, or, on motivated advice of the Nomination and Remuneration Committee, exceeding 18 months, must be submitted for prior approval to the next annual shareholders' meeting. Any proposal to grant a higher severance package must be communicated to the works council (or to other designated bodies or persons representing the employees, if this council does not exist; i.e., the employee representatives in the committee for the prevention and protection in the workplace or, in the absence of this committee, to the trade union delegation) at least thirty days prior to the publication of the convening notice of the next annual general shareholders meeting, which may then give its advice to the annual general shareholders meeting, at the latest on the day of publication of the convening notice of the annual general shareholders meeting. This advice is published on the website of the Company.

Also, any agreement, entered into or extended on or after 3 May 2010, between the Company and a non-executive director, which would provide for a variable remuneration, must be submitted for approval to the next annual shareholders' meeting.

In accordance with Article 520bis of the Belgian Company Code, the criteria for granting variable remuneration to leaders must, as of 1 January 2011, be included in the contractual or other provisions governing the relevant legal relationship. The variable remuneration can only be paid out if the milestones for the reference period have been met. If the aforementioned obligations are not complied with, the variable remuneration may not be taken into account for calculating the severance pay.

Furthermore, in accordance with Article 520ter of the Belgian Company Code, and unless provided otherwise in the articles of association or approved by the annual general shareholders' meeting, (a) variable remuneration for leaders must be based, at least for 25%, on performance criteria measured over a period of at least two years and for (another) 25% on performance criteria measured over a period of at least three years and (b) shares may only be definitively acquired by directors and leaders and stock options or other rights to acquire shares may only be exercised by leaders at the earliest three years after they have been granted to them. The rules set out under (a) above, do not apply if the variable remuneration represents 25% or less of the total annual remuneration of the leader. The Company's articles of association explicitly provide that Article 520ter of the Belgian Company Code does not apply to the Company.

#### 10.8.2 Directors

The remuneration of the directors is determined by the shareholders' meeting upon proposal of the Board of Directors on the basis of the recommendations made by the Nomination and Remuneration Committee.

The non-executive directors will receive a fixed remuneration in consideration for their membership of the Board of Directors and their attendance at the meetings of the Committees of which they are member, with the exception of Mr Jean-Jacques Verdickt, who will not receive any remuration in this respect..

Upon advice of the Nomination and Remuneration Committee, the Board of Directors may propose to the shareholders' meeting to grant stock options or warrants in order to attract or retain non-executive directors with the most relevant skills, knowledge and expertise. Insofar as this grant of stock options or warrants constitutes variable remuneration in accordance with Article 554 of the Belgian Company Code, this remuneration will be submitted for approval to the next annual general shareholders meeting.

The Nomination and Remuneration Committee recommends the level of remuneration for non-executive directors, subject to approval by the Board of Directors and, subsequently, by the shareholders' meeting. The Nomination and Remuneration Committee benchmarks directors' compensation against peer companies to ensure that it is competitive. Remuneration is linked to the time committed to the Board of Directors and its various Committees.

The remuneration package for the non-executive directors approved by the shareholders' meeting of the Company held on 16 January 2015 consists of a fixed annual fee of  $\in$  20,000 for the non-executive directors (with the exception of Mr. Jean-Jacques Verdickt), and  $\in$  30,000 for the chairman. Such fee is supplemented (i) with a fixed annual fee of  $\in$  5,000 for membership of the Audit Committee (with the exception of Mr. Jean-Jacques Verdickt), to be increased by  $\in$  2,500 in case the relevant director chairs the Committee and (ii) with a fixed annual fee of  $\in$  3,000 for membership of the Nomination and Remuneration Committee, to be increased by  $\in$  2,000 in case the relevant director chairs the Committee. Any changes to these fees will be submitted to the shareholders' meeting for approval. The executive directors will not receive any specific remuneration in consideration for their membership of the Board of Directors.

All directors will be entitled to a reimbursement of out-of-pocket expenses actually incurred as a result of participation in meetings of the Board of Directors.

For an overview of the warrants held by certain directors, reference is made to Section 10.9.1 "Securities held by directors".

There are no loans outstanding from the Company to the members of the Board of Directors. There are no employment or service agreements that provide for notice periods or indemnities between the Company and non-executive directors. In respect of the executive directors, reference is made to Section 10.8.3 "Management Team"

The total remuneration and benefits paid to the non-executive directors in 2012, 2013 and 2014 was approximately  $\in$  17,500,  $\in$  8,750 and  $\in$  125,025 respectively.

### 10.8.3 Management Team

The remuneration of the members of the Management Team is determined by the Board of Directors on the basis of the recommendations made by the Nomination and Remuneration Committee, after the recommendation of the CEO to such Committee (except with respect to his own remuneration and the remuneration of the CFO).

The remuneration of the members of the Management Team is designed to hire, retain and motivate high quality executive managers. The remuneration of the members of the Management Team currently consists of the following elements:

- The members of the Management Team receive a fixed compensation matching the volume, complexity and sophistication of the services delivered to the Company.
- Certain members of the Management Team are eligible to receive variable compensation, of which both the
  amount and receipt depend on the realisation of objectives determined by the Board of Directors at the start
  of each financial year.

Certain members of the Management Team participate in stock-based incentive schemes and have the possibility to participate in future stock-based incentive schemes in accordance with the recommendations of the Nomination and Remuneration Committee. Currently, the members of the Management Team are engaged with the Company on a self-employed basis in accordance with a management agreement, which can be terminated at any time, subject to notice given in accordance with the provisions of such management agreement. None of these agreements provide for notice periods or corresponding compensatory payments exceeding 18 months, except for Enrico Bastianelli SPRL, relating to a non-compete clause.

The total amount of remuneration and benefits paid to Enrico Bastianelli SPRL during the financial year ended on 31 December 2013 amounted to  $\in$  261,098, of which  $\in$  205,621 fixed remuneration,  $\in$  30,000 variable remuneration,  $\in$  12,000 royalties and  $\in$  13,478 benefits (car and insurance). The total amount of remuneration and benefits granted to the CEO during the financial year ended on 31 December 2014 amounted to  $\in$  343,591, of which  $\in$  231,113 fixed remuneration,  $\in$  87,000 variable remuneration,  $\in$  12,000 royalties and approximately  $\in$  13,478 benefits (car and insurance).

The total remuneration and benefits paid to the members of the Management Team other than Enrico Bastianelli SPRL during the financial year ended on December 31 2013 amounted to  $\in$  60,264, all of which was fixed remuneration. The total remuneration and benefits paid to the members of the Management Team other than the CEO during the financial year ended on December 31 2014 amounted to  $\in$  332,750, of which  $\in$  199,050 fixed remuneration,  $\in$  120,500 variable remuneration and approximately  $\in$  13,200 benefits (car and insurance).

The annual remuneration report of the Company will include a statement on the remuneration policy during the financial year reported on, as applied in respect of the members of the Management Team, other leaders and the persons in charge of daily management. In addition, such report will set forth the amounts of remuneration and other benefits granted directly or indirectly to the members of the Management Team.

## 10.9 Securities held by directors and members of the Management Team

## 10.9.1 Securities held by directors

The table below provides an overview (as of the date of this Prospectus) of the shares and convertible bonds held by the non-executive members of the Board of Directors. The overview must be read together with the notes referred to below.

	Shares		Convertible bonds	
Non-executive directors	Number	%	Number	
Roland Baron	-	-	-	
Chris Buyse	-	-	-	
Michel Helbig de Balzac	-	-	-	
Magenta Tree BVBA <sup>(1)</sup>	-	-	-	
Marc Nolet de Brauwere van Steeland <sup>(2)</sup>	-	-	1,000	
Paul Magrez	-	-	-	
Partigest-Garence SA <sup>(3)</sup>	538,382	15.57%	50	
SFPI SA <sup>(4)</sup>	-	-	2,500	
Jean-Jacques Verdickt <sup>(5)</sup>	175,107	5.06%	50	

Notes:

- (1): with as permanent representative Thierry François.
- (2): through Alegrecha SDC.
- (3): through Jacques Reymann, its permanent representative.
- (4): with as permanent representative François Fontaine.
- (5): through JJ Verdickt & Consorts.

None of the non-executive directors holds warrants<sup>80</sup>.

<sup>80</sup> Other than the anti-dilution warrants issued with the convertible bonds which will expire upon completion of the Offering.

## 10.9.2 Securities held by members of the Management Team

The table below provides an overview (as of the date of this Prospectus) of the shares and warrants held by the members of the Management Team. No member of the Management Team holds any convertible bonds.

	Shares		Warrants	
Managers	Number %		Number	%
Enrico Bastianelli SPRL	-	-	-	-
Enrico Bastianelli	110,820	3.20%	100,000	2.66%
Valérie Gangji	-	-	-	-
Wim Goemaere BVBA	-	-	-	-
Wim Goemaere	-	-	39,800	1.06%
Guy Heynen	-	-	20,000	0.53%

All the warrants mentioned above were granted on 18 December 2014.

#### 10.9.3 Existing stock option plans

The Company has established three warrant plans under which warrants can be granted.

Plan	Beneficiaries	Number of warrants issued	Number of warrants granted	Exercise price of warrants granted	Expiry
Warrant Plan A	Employees, consultants or directors	113,760	None	To be determined	February 2024
Warrant Plan B	CEO, CFO	46,000	14,800	€ 11	February 2019
Warrant Plan C	CEO, CFO, CCRO	145,000	145,000	€ 11	December 2019

## **10.10 Statutory Auditor**

Deloitte Réviseurs d'Entreprises SCCRL, a civil company having the form of a co-operative company with limited liability organised and existing under the laws of Belgium, with registered office at Berkenlaan 8B, 1831 Diegem, Belgium, represented by Mrs Julie Delforge (member of the Belgian *Institut des Réviseurs d'Entreprises/Instituut voor Bedrijfsrevisoren*) is appointed statutory auditor of the Company, for a term of three years ending immediately following the adjournment of the annual general shareholders' meeting of the Company to be held in 2016, resolving upon the financial statements for the fiscal year ended on 31 December 2015. Previously, Mr Laurent Weerts acted as representative of Deloitte Réviseurs d'Entreprises SCCRL, as of 20 June 2008 until 1 January 2013.

The remuneration of the statutory auditor for the performance of its three year mandate for the audit of the financial statements of the Company amounts to € 19,500 (excluding VAT adjustment to the cost of living index).

## 11 Shareholders' structure

The table in Section 5, "Dilution", sets out the shareholders of the Company who have an interest in the Company's capital which is notifiable under the Company's articles of association.

All shares have the same voting rights.

The Company is not aware of any existing shareholders' agreement or any shareholders' agreement that would be effective upon completion of the Offering and listing of the Offered Shares, other than the specific lock-up and standstill arrangement described in Section 15.10 "Lock-up and standstill arrangements" and the Overallotment Option described in Section 15.5 "Over-allotment and stabilisation".

The Company is not controlled by one or more shareholders. The Company is not aware of any arrangement the operation of which may at a subsequent date result in a change of control of the Company.

# 12 Related party transactions

## 12.1 General

Each directors and member of the Management Team is encouraged to arrange his personal and business affairs to avoid direct and indirect conflicts of interest with the Company. The Corporate Governance Charter contains specific procedures to deal with potential conflicts.

#### 12.2 Conflicts of interest of members of the Board of Directors

Article 523 of the Belgian Company Code provides for a special procedure within the Board of Directors in the event of a possible personal financial conflict of interest of one or more directors with one or more decisions or transactions to be adopted by the Board of Directors. In the event of 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 potential conflict of interest. The minutes of the meeting of the Board of Directors must contain the relevant statements made by the conflicted director, as well as a description by the Board of Directors of the conflicting interests and the nature of the relevant decision or transaction to be adopted. The minutes must also contain a justification by the Board of Directors for the decision or transaction adopted, and a description of the financial consequences thereof for the Company. The relevant minutes must be included in the (statutory) annual report of the Board of Directors.

The conflicted director must notify the Statutory Auditor of the conflict. The Statutory Auditor must describe in its statutory annual audit report the financial consequences of the decision or transaction that gave rise to the potential conflict.

In case of non-compliance with the foregoing, the Company may request the annulment of the decision or the transaction which has taken place in breach of these provisions 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 of the Company 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 voting financial instruments of the other, and transactions or decisions between companies whereby at least 95% of the voting financial instruments of both companies are (directly or indirectly) held by another company.

### 12.3 Transactions with affiliates

Article 524 of the Belgian Company Code, which will apply to the Company following completion of the Offering, provides for a special procedure that applies to intra-group or related party transactions with affiliates. The procedure will apply to decisions or transactions between the Company and affiliates of the Company that are not a subsidiary of the Company. It will also apply to decisions or transactions between any of the Company's subsidiaries and such subsidiaries' affiliates that are not a subsidiary of the Company.

Prior to any such decision or transaction, the Board of Directors of the Company must appoint a special committee consisting of three independent directors, assisted by one or more independent experts. This committee must assess the business advantages and disadvantages of the decision or transaction for the Company. It must quantify the financial consequences thereof and must determine whether or not the decision or transaction causes a disadvantage to the Company that is manifestly illegitimate in view of the Company's policy. If the committee determines that the decision or transaction is not manifestly illegitimate, but is of the opinion that it will prejudice the Company, it must clarify which advantages are taken into account in the decision or transaction to compensate the disadvantages. All these elements must be set out in the committee's advice.

The Board of Directors must then take a decision, taking into account the opinion of the committee. Any deviation from the committee's advice must be explained. Directors who have a conflict of interest are not entitled to participate in the deliberation and vote (as set out in Section 12.2 "Conflicts of interest of members of the Board of Directors" above). The committee's advice and the decision of the Board of Directors must be communicated to the Company's statutory auditor, who must render a separate opinion. The conclusion of the committee, an excerpt from the minutes of the Board of Directors and the opinion of the statutory auditor of the Company must be included in the (statutory) annual report of the Board of Directors. The procedure does not

apply to decisions or transactions in the ordinary course of business of the Company at customary market conditions, and transactions or decisions with a value of less than 1% of the consolidated net assets of the Company. On completion of the Offering and the listing of the shares of the Company, the Company will not have a controlling parent company.

## 12.4 Existing conflicts of interest of members of the Board of Directors and the Management Team

The BONE-011 patent family is co-owned by the Company and Enrico Bastianelli SPRL and the Company has entered into an agreement with Enrico Bastianelli SPRL regarding the use of BPBONE-001 and BPBONE-002 patent families (see Section 6.8.5, "License agreement between Enrico Bastianelli SPRL and the Company regarding the BPBONE-001 and BPBONE-002 patent families").

Two directors, Jacques Reymann and Jean-Jacques Verdickt, are holders of preference shares in SCTS and as such, parties to the SCTS shareholders' agreement to which the Company, as main shareholder of SCTS, is also a party. Among other provisions, this agreement contains a broad undertaking by the Company to use the services provided by SCTS in accordance with the invoicing policy included in the agreement, which results in undertaking by the Company to guarantee a minimum dividend payment of 6.5% to the holders of preference shares of SCTS. Also, the agreement contains a call option right pursuant to which the Company is entitled, until 31 December 2019, to acquire the shares held by the other shareholders (including the two directors mentioned above), for a price generating an internal rate of return of 8% for these shareholders (see Section 6.8.1 "Shareholders' agreement in relation to SCTS").

Currently, as far as the Company is aware, none of the other members of the Board of Directors have a conflict of interest within the meaning of Article 523 of the Belgian Company Code that has not been disclosed to the Board of Directors. Other than potential conflicts arising in respect of compensation-related matters, the Company does not foresee any other potential conflicts of interest in the near future.

#### 12.5 Related party transactions

#### 12.5.1 Transactions with SCTS

The Company has granted SCTS two personal, non-transferable royalty-free licenses to use, perform, research, develop and manufacture products in name of the Company. A first license is granted by the Company to SCTS over the technology claimed by the ULB-028 patent family, in the framework of the PROFAB agreement entered into by the Company and SCTS (i.e. a research and development agreement between the Company, SCTS and the Region). A second license is granted by the Company to SCTS over the technology claimed by the BPBONE-001 and 002 patent families in the framework of the JTA PROD agreement (i.e. also a research and development agreement between the Company, SCTS and the Region). For more detailed information on the Company's contractual arrangements with SCTS, see Sections 6.8.6 to 6.8.8.

#### 12.5.2 Transactions with SISE

SISE leases land to SCTS in the context of a long lease right (99 years) and performs certain infrastructure and maintenance services for the Company and SCTS.

#### 12.5.3 Transactions with the Walloon Region

As a result of the relationship of the Walloon Region with some shareholders of the Company and the extent of financing received, the Company judges that the government is a related party. The Company (and SCTS) have obtained a number of loan facilities through regional investment offices, such as Sambrinvest SA, Fond de Capital à Risque SA, Novallia SA and Sofipôle SA. Also, since its incorporation and until 30 September 2014, the Company has been awarded non-dilutive financial support from the Walloon Region, amounting to in aggregate € 20.4 million, in the form of both recoverable cash advances and subsidies. More information on the government grants, subsidies, and government agencies loans granted to the Company and SCTS are set out in Sections 6.10 "Financing Agreements" and 6.11 "Grants and subsidies".

#### 12.5.4 Transactions with the Management Team.

The Company has been granted a personal and non-transferable, exclusive, worldwide license over the technology claimed by the BPBONE-001 and 002 patent families, which are owned by Enrico Bastianelli SPRL. For more detailed information on the Company's license arrangements with Enrico Bastianelli SPRL, see

Section 6.8.5 "License agreement between Enrico Bastianelli SPRL and the Company regarding the BPBONE-001 and BPBONE-002 patent families".

For information on the Management Team remuneration, see Section 10.8 "Remuneration of directors and members of the Management Team".

## 13 Dividends and dividend policy

#### 13.1 Entitlement to dividends

The Offered Shares are entitled to dividends, if and when declared, for the financial year ended on 31 December 2014 and the following financial years.

Dividends can only be distributed if, following the declaration and payment of the dividends, the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory financial statements prepared in accordance with Belgian GAAP (i.e., the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities), decreased with the non-amortised activated costs of incorporation and extension and the non-amortised activated costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the called capital), increased with the amount of non-distributable reserves. In addition, pursuant to the Belgian Company Code and the articles of association, the Company must allocate at least 5% of its annual net profits under its statutory non-consolidated accounts to a legal reserve until the reserve equals 10% of the Company's share capital.

In accordance with Belgian law, the right to collect dividends declared on ordinary shares expires five years after the date the Board of Directors has declared the dividend payable, whereupon the Company is no longer under an obligation to pay such dividends.

#### 13.2 Dividend policy

The Company has never declared or paid any dividends on its shares.

Following the Offering, the Company's dividend policy will be determined by, and may change from time to time by determination of, the Company's Board of Directors. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the Board of Directors. The calculation of amounts available to be distributed as dividends or otherwise distributed to shareholders must be made on the basis of the Belgian statutory financial statements, taking into account the limits set out in the Belgian Company Code (see Section 13.1 "Entitlement to dividends").

Belgian law and the Company's articles of association do not require the Company to declare dividends. The Board of Directors expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the near future.

## 14 Taxation in Belgium and in France

#### **14.1** Taxation in Belgium

The following is a summary of the principal Belgian tax consequences for investors relating to the acquisition, the ownership and disposal of the Shares. This summary is based on the Company's understanding of the applicable laws, treaties and regulatory interpretations as in effect in Belgium on the date of this Prospectus, all of which are subject to change, including changes that could have a retroactive effect.

This summary does not purport to address all tax consequences associated with the acquisition, ownership and disposal of the Shares, and does not take into account the specific circumstances of any particular investor or the tax laws of any country other than Belgium. Moreover, it does not address specific rules, such as Belgian federal or regional estate and gift tax, nor the tax treatment of investors who are subject to special rules, such as financial institutions, insurance companies, collective investment undertakings, dealers in securities or currencies or persons who hold the shares as a position in a straddle, share-repurchase transactions, conversion transactions, a synthetic security or other integrated financial transaction. This summary does not address the local taxes that may be due in connection with an investment in Shares, other than Belgian local surcharges which generally vary from 0% to 10% of the investor's income tax liability.

For the purposes of this summary, a resident investor is:

- an individual subject to Belgian personal income tax, *i.e.* an individual having its domicile or seat of wealth in Belgium or assimilated individuals for purposes of Belgian tax law;
- a company (as defined by Belgian tax law) subject to Belgian corporate income tax, i.e. a company having
  its registered seat, principal establishment, administrative seat or effective place of management in
  Belgium; or
- a legal entity subject to the Belgian tax on legal entities, i.e. a legal entity other than a company subject to Belgian corporate income tax having its registered seat, principal establishment, administrative seat or effective place of management in Belgium.

A non-resident investor is any individual, company or legal entity that does not fall in any of the three previous classes.

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.

Investors should consult their own advisers regarding the tax consequences of an investment in the Shares in light of their particular situation, including the effect of any state, local or other national laws, treaties and regulatory interpretations thereof.

#### 14.1.1 Dividends

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 Companies Code is not treated as a dividend distribution to the extent that such repayment is imputed to fiscal capital. Generally, fiscal capital includes paid-up statutory capital and, subject to certain conditions, paid-up share premiums and the amounts subscribed to at the time of the issuance of profit participating certificates.

Belgian withholding tax of 25% is normally levied on dividends, subject to such relief as may be available under applicable domestic or tax treaty provisions.

In the case of a redemption of the Shares, the redemption distribution (after deduction of the part of the fiscal capital represented by the redeemed Shares) will be treated as a dividend subject to a Belgian withholding tax of 25%, subject to such relief as may be available under applicable domestic or tax treaty provisions. No withholding tax will be triggered if this redemption is carried out on a stock exchange and meets certain conditions.

#### 14.1.1.1 Resident individuals

For resident individuals who acquire and hold the Shares as a private investment, the Belgian withholding tax fully discharges their personal income tax liability. This means that they do not have to declare the dividends in

their personal income tax return and that the Belgian withholding tax constitutes a final tax. Nevertheless, these resident individuals may elect to declare the dividends in their personal income tax return. Dividends that are declared this way will in principle be taxed at a flat rate of 25% (or at the relevant progressive personal income tax rate(s) taking into account the taxpayer's other declared income, whichever is more beneficial) and no local surcharges will be due. In addition, if the dividends are declared, the Belgian withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent 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 Company's shares. This condition is not applicable if the investor demonstrates that he has held the Company's shares in full legal ownership during an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

For resident individuals who acquire and hold the Shares for professional purposes, the Belgian withholding tax does not fully discharge their income tax liability. Dividends received must be declared by the investor and will, in such a case, be taxable at the investor's progressive personal income tax rates (of up to 50%, plus local surcharges). The Belgian withholding tax levied at source may be credited against the personal income tax due and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the investor must have held full legal ownership of the Company's shares at the time of payment or attribution of the dividends and (ii) the dividend distribution may not result in a reduction in value of, or a capital loss on, the Company's shares. The latter condition is not applicable if the investor demonstrates that he has held full legal ownership of the Company's shares during an uninterrupted period of 12 months prior to the payment or attribution of the dividends.

#### 14.1.1.2 Resident companies

#### Corporate income tax

For resident companies, the gross dividend income (including the withholding tax levied) must be declared in the corporate income tax return and will generally be taxable at the standard corporate income tax rate of 33.99% (unless the reduced corporate income tax rates for small and medium sized enterprises apply).

However, resident companies can generally (although subject to certain limitations) deduct up to 95% of the gross dividends received from its taxable income (the "**Dividend Received Deduction**"), provided that at the time of attribution or payment of the dividends: (i) the Belgian resident company holds the Company's shares representing at least 10% of the share capital of the Company or a participation in the Company with an acquisition value of at least €2,500,000, (ii) the Company's shares have been held or will be held in full ownership for an uninterrupted period of at least one year, and (iii) the conditions relating to the taxation of the underlying distributed income, as described in Article 203 of the Belgian Income Tax Code (the "**BITC**") (the "**Article 203 BITC Taxation Conditions**") are met (together, the "**Conditions for the application of the Dividend Received Deduction regime**"). The Conditions for the application of the Dividend Received Deduction regime depend on a factual analysis and for this reason the availability of this regime should be verified upon each dividend distribution.

Any Belgian dividend withholding tax levied at source may, in principle, be credited against the corporate income tax due and is reimbursable to the extent that it exceeds the investor's corporate income tax due, subject to two conditions: (i) the investor must have held the full legal ownership of the shares at the time of payment or attribution of the dividends, and (ii) the dividend distribution may not result in a reduction in value of, or a capital loss on, the Company's shares. The latter condition is not applicable (A) if the investor demonstrates that it has held the Company's shares in full legal ownership during an uninterrupted period of 12 months prior to the payment or attribution of the dividends or (B) if, during that period, the Company's shares never belonged to a taxpayer other than a resident company or a non-resident company that held the Company's shares in an uninterrupted manner through a permanent establishment in Belgium.

#### Withholding tax

Dividends distributed to a 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 Company's share capital 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 investor must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the two required conditions. If the investor holds a minimum participation for less than one year, at the time the dividends are paid on or attributed, the Company will levy the withholding tax but will not transfer it to the Belgian Treasury provided that the investor certifies its qualifying status, the date from which it has held such minimum participation, its commitment to

hold the minimum participation for an uninterrupted period of at least one year and its commitment to immediately notify to the Company or its paying agent a reduction of its shareholding below such threshold prior to the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the levied dividend withholding tax will be passed on to the investor.

#### 14.1.1.3 Organisations for Financing Pensions

For organisations for financing of pensions ("**OFPs**"), i.e. Belgian pension funds incorporated under the form of an OFP (*organismen voor de financiering van pensioenen/organismes de financement de pensions*) within the meaning of Article 8 of the Belgian Law of 27 October 2006, dividend income is generally tax exempt. Subject to certain limitations, any Belgian withholding tax levied at source may be credited against the final income tax due and is reimbursable to the extent that it exceeds the investor's income tax due.

#### 14.1.1.4 Resident legal entities

For resident legal entities, the Belgian withholding tax levied at source generally constitutes their final tax liability.

#### 14.1.1.5 Non-residents

#### Withholding tax

For non-resident individuals, corporations or other legal entities the withholding tax levied at source will be the only tax on dividends in Belgium, unless the non-resident holds Company's shares in connection with a business conducted in Belgium through a fixed base in Belgium or a permanent establishment in Belgium.

If the Company's shares are acquired or held by a non-resident in connection with a business conducted in Belgium through a fixed base in Belgium or a permanent establishment in Belgium, the investor must report any dividends received in its Belgian income tax return and the dividends will be taxable at the applicable non-resident individual or corporate income tax rate, as appropriate. Withholding tax levied at source may then be credited against non-resident individual or corporate income tax and is reimbursable to the extent that it exceeds the income tax due, subject to two conditions: (i) the investor must have held full legal ownership of the shares at the time of payment or attribution of the dividends and (ii) the dividend distribution may not result in a reduction in value of, or a capital loss on, the Company's shares. The latter condition is not applicable if (i) the non-resident individual or the non-resident company demonstrates that the Company's shares were held in full legal ownership for an uninterrupted period of 12 months prior to the payment or attribution of the dividends or (ii) with regard to non-resident companies only, if, during the said period, the Company's shares have not belonged to a taxpayer other than a resident company or a non-resident company that held the Company's shares in an uninterrupted manner through a permanent establishment in Belgium.

Non-resident companies whose Company's shares are invested in a permanent establishment may deduct up to 95% of the gross dividends included in their taxable profits if, at the date dividends are paid or attributed, the Conditions for the application of the Dividend Received Deduction regime are met. 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 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 and qualifying as a parent company, will be exempt from Belgian withholding tax provided that Company's shares held by the non-resident company, upon payment or attribution of the dividends, amount to at least 10% of the Company's share capital and such minimum participation is held or will be held during an uninterrupted period of at least one year. A 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 EU Parent-Subsidiary Directive of July 23, 1990 (90/435/EC), as amended by Directive 2003/123/EC of December 22, 2003, 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 investor must provide the Company or its paying agent with a certificate confirming its qualifying status and the fact that it meets the three abovementioned conditions. If the

investor holds a minimum participation for less than one year, at the time the dividends are paid on or attributed to the Company's shares, the Company or the paying agent will levy the withholding tax but will not transfer it to the Belgian Treasury provided that the investor certifies its qualifying status, the date from which the investor has held such minimum participation, its commitment to hold the minimum participation for an uninterrupted period of at least one year and its commitment to immediately notify the Company of a reduction of its shareholding below such threshold prior to the end of the one-year holding period. Upon satisfying the one-year shareholding requirement, the levied dividend withholding tax will be passed on to the investor.

Under Belgian tax law, withholding tax is also not due on dividends paid to a non-resident pension fund which satisfies the following conditions: (i) to be a legal entity with fiscal residence outside of Belgium, (ii) whose corporate purpose consists solely in managing and investing funds collected in order to serve legal or complementary pension schemes, (iii) whose activity is limited to the investment of funds collected in the exercise of its statutory mission, without any profit making aim, (iv) which is exempt from income tax in its country of residence, and (v) provided that it is not contractually obligated to remit or transfer the dividends received to any ultimate beneficiary of such dividends for whom it would manage the Shares, nor obligated to pay a manufactured dividend with respect to the Shares under a securities borrowing transaction. The exemption will only apply if the non-resident pension fund provides a certificate confirming that it is the full legal owner or usufruct holder of the Company's shares and that the above conditions are satisfied.

If there is no exemption available under Belgian domestic law, the Belgian withholding tax can potentially be reduced for non-resident investors pursuant to the bilateral tax treaty concluded between Belgium and the state of residence of the investor. Belgium has concluded tax treaties with over 95 countries, reducing the dividend withholding tax rate to 20%, 15%, 10%, 5% or 0% for residents of such countries, subject to conditions relating, amongst others, 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 tax treaty rate.

Prospective investors should consult their own tax advisors as to whether they qualify for a reduction of, or exemption from, Belgian withholding tax upon payment or attribution of dividends, and as to the procedural requirements for obtaining such a reduction or exemption.

#### 14.1.2 Capital gains and losses

#### 14.1.2.1 Resident individuals

For resident individuals acquiring and holding the Company's shares as a private investment, capital gains realised upon the transfer of the shares are generally not subject to Belgian income tax. However, resident individuals may be subject to a 33% income tax (to be increased with local surcharges) if the capital gain on the shares is deemed to be speculative or realised outside the scope of the normal management of their private estate. Moreover, capital gains realised by Belgian resident individuals on the disposal of the Company's shares for consideration, outside the exercise of a professional activity, to a legal person that has its registered office, its principal establishment, or place of management outside the European Economic Area, 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/her spouse or with certain relatives, a substantial shareholding in the Company (*i.e.*, a shareholding of more than 25% in the Company). Capital losses arising from such transactions are, however, not tax deductible.

For resident individuals holding the Company's shares for professional purposes, capital gains realised upon transfer of shares shall be taxable at the normal progressive personal income tax rates (which are currently in the range of 25% to 50%, plus local surcharges), except for Company's shares held for more than five years, which are taxable at a separate rate of 16.5% (plus local surcharges). Capital losses on the Company's shares incurred by resident individuals holding the shares for professional purposes are in principle tax deductible.

Capital gains realised by resident individuals upon redemption of the Company's shares or upon liquidation of the Company will in principle be taxed as dividend income (see above).

#### 14.1.2.2 Resident companies

Resident companies (not being small or medium sized enterprises within the meaning of Article 15 of the Belgian Companies Code, SMEs) are subject to Belgian capital gains taxation at a separate rate of 0.412% on gains realised upon the disposal of Company's shares provided that (i) the Article 203 BITC Taxation Conditions are met and (ii) the Company's shares have been held in full legal ownership for an uninterrupted period of at least one year. The 0.412% separate capital gains tax rate cannot be off-set by any tax assets (such as e.g. tax losses) or any tax credits.

Resident corporations qualifying as SMEs are normally not subject to Belgian capital gains taxation on gains realised upon the disposal of Company's shares provided that (i) the Article 203 BITC Taxation Conditions are met and (ii) the Company's shares have been held in full legal ownership for an uninterrupted period of at least one year.

If the one-year minimum holding period condition is not met (but the Article 203 BITC Taxation Conditions are met), the capital gains realised upon the disposal of Company's shares by resident companies (both non-SMEs and SMEs) will be taxable at a separate corporate income tax rate of 25.75%.

Capital losses on shares incurred by resident companies (both non-SMEs and SMEs) are as a general rule not tax deductible.

Capital gains realised upon redemption of the shares or upon liquidation of the Company will in principle be taxed as dividend income (see above).

If the Company's shares form part of the trading portfolio (handelsportefeuille/portefeuille commercial) of companies which are subject to the Royal Decree of 23 September 1992 on the annual accounts of credit institutions, investment firms and management companies of collective investment institutions (jaarrekening van de kredietinstellingen, de beleggingsondernemingen en de beheervennootschappen van instellingen voor collectieve belegging/comptes annuels des établissements de crédit, des entreprises d'investissement et des sociétés de gestion d'organismes de placement collectif), the capital gains realised upon the disposal of shares will be subject to corporate income tax at the standard rates, and capital losses will be tax deductible.

#### 14.1.2.3 Organisation for Financing Pensions

OFPs are, in principle, not subject to Belgian capital gains taxation realised upon the disposal of the Company's shares, and capital losses are not tax deductible.

#### 14.1.2.4 Other resident legal entities

Capital gains realised upon transfer of the Company's shares by resident legal entities are generally not subject to income tax, safe in case of a sale of Company's shares which are directly or indirectly part of a stake representing more than 25% of the share capital in the Company which may, under certain conditions, give rise to a 16.5% tax (plus local surcharges). Capital losses on the Company's shares incurred by Belgian resident legal entities are not tax deductible.

Capital gains realised by Belgian resident legal entities upon the redemption of the Company's shares or upon the liquidation of the Company will in principle be taxed as dividends.

#### 14.1.2.5 Non-residents

#### Non-resident individuals

Capital gains realised on the Company's shares by a non-resident individual that has not acquired the shares in connection with a business conducted in Belgium through a fixed base in Belgium are in principle not subject to taxation, unless the gain is deemed to be realised outside the scope of the normal management of the individual's private estate (Article 90, 1° of the BITC or Article 90, 9°, first indent of the BITC). In such case, if the gain is taxable under Article 90, 1° of the BITC and Article 228, §2, 9°, a) of the ITC, it is subject to a final professional withholding tax of 30.28% (to the extent that Article 248 of the BITC is applicable). If the gain is taxable under Article 90, 9°, first indent of the BITC and Article 228, § 2, 9°, h) of the BITC, it must be reported in a non-resident tax return for the income year during which the gain has been realised, in which case the capital gain will be taxable at the rate of 35.31% (33% plus local surcharges of currently 7%). Moreover, non-resident individuals may be subject to the 16.5% income tax described above (resulting in a tax rate of 17.66%, *i.e.* 16.5% plus local surcharges of currently 7%) if they held a participation of more than 25% in the capital of the Company (see Section 14.1.2.1 "Resident individuals" above). However, Belgium has concluded tax treaties with more than 95 countries which generally provide for a full exemption from Belgian capital gains taxation on such gains realised by residents of those countries. Capital losses are generally not tax deductible.

Capital gains will be taxable at the ordinary progressive income tax rates and capital losses will be tax deductible, if those gains or losses are realised on Company's shares by a non-resident individual that holds the Company's shares in connection with a business conducted in Belgium through a fixed base in Belgium.

Capital gains realised by Belgian non-resident individuals upon the redemption of Company's shares or upon the liquidation of the Company will generally be taxable as a dividend (see above).

Non-resident companies

Non-resident companies that have not acquired the Company's shares in connection with a business conducted in Belgium through a Belgian establishment are generally not subject to taxation in Belgium on capital gains on those shares.

Non-resident companies that hold the shares in connection with a business conducted in Belgium through a Belgian establishment will generally be taxable in the same way as resident companies (see Section 14.1.2.2 "Resident companies" above).

Capital gains realised by non-resident companies upon redemption of the shares or upon liquidation of the Company will in principle be taxed as dividend income (see above).

#### 14.1.3 Tax on stock exchange transactions

The purchase and sale or any other acquisition or transfer for consideration of existing Company's shares (secondary market) in Belgium through a professional intermediary is subject to the tax on stock exchange transactions (*taks op de beursverrichtingen/taxe sur les opérations de bourse*) currently at a rate of 0.27%, capped at € 800 per taxable transaction. A separate tax is due from each party to the transaction, both collected by the professional intermediary.

Upon the issue of the New Shares (primary market), no tax on stock exchange transactions is due.

Furthermore, no tax on stock exchange transactions is due on transactions entered into by the following parties, provided they are acting for their own account:

- professional intermediaries described in Articles 2, 9° and 10° of the Belgian Law of 2 August 2002 on the supervision of the financial sector and financial services;
- insurance companies described in Article 2, §1 of the Belgian Act of 9 July 1975 on the supervision of insurance companies;
- pension institutions described in Article 2, 1° of the Belgian Act of 27 October 2006 on the supervision of pension institutions;
- collective investment undertakings; and
- non-residents (provided that they deliver a certificate to the professional intermediary in Belgium confirming their non-resident status).

As stated above, the EU Commission adopted on 14 February 2013 the Draft Directive on an FTT. 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 is still subject to negotiation between the Participating Member States and therefore may be changed at any time.

#### 14.2 Taxation in France

#### 14.2.1 Dividends

14.2.1.1 Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity

Income tax

Dividends received by individuals who are fiscally domiciled in France are taken into account for the computation of their taxable income. They are subject to personal income tax at the progressive rates and, subject to certain conditions, to the exceptional tax on high income (*contribution exceptionnelle sur les hauts revenus*). For taxpayers who are married or have entered into a civil partnership (*PACS*) and who are filing a joint tax return, the exceptional tax on high income applies at a rate of 3% on fiscal income (*revenu fiscal de référence*) of the fiscal household between  $\ensuremath{\epsilon} 500,000$  and  $\ensuremath{\epsilon} 1,000,000$  and at a rate of 4% on fiscal income above  $\ensuremath{\epsilon} 1,000,000$  and at a rate of 4% on fiscal income above  $\ensuremath{\epsilon} 250,000$  and at a rate of 4% on fiscal income above  $\ensuremath{\epsilon} 500,000$ .

Furthermore, dividends are generally subject to the 21% withholding tax set out under article 117 *quater* of the French Code *général des impôts* (the "**French Tax Code**") if paid by a paying agent located in France. The 21% withholding tax is applicable to the gross amount of the dividend paid and is deductible from their personal income tax liability in respect of the year in which the payment has been made. If the 21% withholding tax exceeds the amount of personal income tax due by the taxpayer, it may be reimbursed.

Persons belonging to a fiscal household with a fiscal income (revenu fiscal de référence) below  $\[ < \]$  55,000, for taxpayers filing a joint return, and below  $\[ < \]$  50,000, for other taxpayers, during the penultimate year preceding the payment of the dividends, can elect not to be subject to the 21% withholding tax. Furthermore, dividends paid on shares of the Company held in a personal equity plan (plan d'épargne en action") are exempt from the 21% withholding tax.

Pursuant to article 158 of the French Tax Code, a rebate of 40% (*abattement de* 40%) is applicable when the personal income tax liability is computed and certain costs and expenses may also be deducted.

Furthermore, in application of the tax treaty entered into between France and Belgium on 10 March 1964 (the "**Treaty**"), a French shareholder is entitled to claim a tax credit for the Belgian withholding tax applicable to the dividends. This foreign tax credit may be offset against his/her personal income tax, to the extent that the foreign tax credit does not exceed the amount of French tax attributable to the dividend payments (*règle du butoir*) and that the Belgian withholding tax has been levied at the rate provided in the Treaty.

#### Social levies

The following social levies are applicable to the gross amount of the dividends:

- contribution sociale généralisée (CSG) at the rate of 8.2% (5.1% being deductible from the taxable income subject to personal income tax);
- contribution au remboursement de la dette sociale (CRDS), at the rate of 0.5% (not deductible from the taxable income subject to personal income tax);
- prélèvement social at the rate of 4.5% (not deductible from the taxable income subject to personal income tax);
- contribution additionnelle au prélèvement social at the rate of 0.3% (not deductible from the taxable income subject to personal income tax); and
- prélèvement de solidarité at the rate of 2% (not deductible from the taxable income subject to personal income tax).

The aggregate rate of the social levies equals 15.5%

#### 14.2.1.2 Legal entities subject to French corporation tax

Shareholders not qualifying for the participation exemption (régime des sociétés mères et filiales)

Dividends received by shareholders who do not qualify for the participation exemption are subject to corporation tax at a rate of 33.33% to which is added a social surtax at a rate of 3.3% calculated on the amount of corporation tax due after a deduction of  $\epsilon$ 763,000. Besides, an additional contribution of 10.7% applies to companies having a turnover in excess of  $\epsilon$ 250,000,000.

Small and medium sized enterprises (i.e. enterprises whose turnover is lower than  $\[ \in \]$ 7,630,000) may benefit, if the conditions specified under articles 219 I b) and 235 ter ZC of the French Tax Code respectively, are met, from a 15% reduced rate of corporation tax on profits up to  $\[ \in \]$ 38,120 and from an exemption of the 3.3% social surtax.

By application of the Treaty, a French shareholder is entitled to claim a tax credit for the Belgian withholding tax applicable to the dividends. This foreign tax credit may be offset against the corporation tax due, to the extent that the foreign tax credit does not exceed the amount of French tax attributable to the dividend payments  $(r\grave{e}gle\ du\ butoir)$  and that the Belgian withholding tax has been levied at the rate provided in the Treaty.

Shareholders qualifying for the participation exemption

Pursuant to articles 145 and 216 of the French Tax Code, legal entities (i) subject to corporation tax and (ii) holding at least 5% of the share capital and voting rights of the Company (iii) for a continuing period of at least two years may benefit, upon election, from the participation exemption.

Under the participating exemption, dividends are exempt from corporation tax, except that 5% of the dividends received (including any foreign tax credit) must be added back to the shareholder's taxable income (*quote-part de frais et charges*).

#### 14.2.2 Capital gains and losses

14.2.2.1 Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity

Pursuant to the Treaty, any capital gains realised by a French resident shareholder upon the disposal of the shares of the Company will be taxable in France.

In accordance with article 150-0A of the French Tax Code, capital gains on the disposal of shares are subject to personal income tax at the progressive rates and to social levies at the aggregate rate of 15.5%, as mentioned under paragraph "Social levies", under "Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity" (see Section 14.2.1 "Dividends").

Pursuant to article 150-0 D-1 of the French Tax Code, capital gains realised upon the disposal of the shares are reduced by a rebate equal to (i) 50% if the shares have been held between two and less than eight years, and (ii) 65% if the shares have been held for at least eight years. The rebate does not apply for the computation of the 15.5% social levies.

According to article 150-0 D of the French Tax Code, capital losses incurred in a given year may be offset against capital gains of the same kind realised during that year and during the ten following years. However, the 50% / 65% rebates apply to capital losses too. Accordingly, the amount of capital losses which is deductible from capital gains of the same kind may be reduced by the application of such rebate.

The capital gains on the disposal of shares may also be subject to the exceptional tax on high income (contribution exceptionnelle sur les hauts revenus), as mentioned under paragraph "Income tax", under "Individuals who are fiscally domiciled in France, who hold the shares in their personal portfolio and who do not carry on a trading activity in conditions which are similar to those of a professional trading activity" (see Section 14.2.1 "Dividends").

#### 14.2.2.2 Legal entities subject to French corporation tax

Pursuant to the Treaty, any capital gains realised by a French resident shareholder upon the disposal of the shares of the Company will be taxable in France.

#### General regime

Capital gains realised upon the disposal of the shares are subject to corporation tax, to the social surtax and to the additional contribution at the rates mentioned under paragraph "Shareholders not qualifying for the participation exemption", under "Legal entities subject to French corporation tax" (see Section 14.2.1 "Dividends").

Capital losses are deductible from the taxable income.

Special rules applicable to long-term capital gains and losses

Pursuant to article 219 I a) *quinquies* of the French Tax Code, long-term capital gains realised upon the disposal of shares qualifying as non-portfolio shares (titres de participation) and which have been held for at least two years, are exempt from corporation tax, except that 12% of the gross capital gains must be added back to the shareholder's taxable income (*quote-part de frais et charges*).

Long-term capital losses are not deductible for corporation tax purposes and may not be imputed against long-term capital gains for the purposes of computation of the *quote-part de frais et charges*.

Prospective investors should consult their own tax advisor as to the qualification of the shares of the Company as non-portfolio shares (*titres de participation*).

Special rules applicable to a plan d'épargne en actions PEA (personal equity plan) and to a plan d'épargne en actions destiné au financement des petites et moyennes entreprises et des entreprises de taille intermédiaire PEA PME-ETI (personal plan for equity of small and medium sized companies)

Under certain conditions set out under article 163 *quinquies* D of the French Tax Code, the shares of the Company may be eligible to the PEA (personal equity plan) or PEA PME-ETI (personal plan for equity of small and medium sized companies).

Holders of a PEA and PEA PME-ETI are, subject to certain conditions, entitled to an exemption from personal income tax on net income and net capital gains derived from investments held in the PEA and PEA PME-ETI provided that no withdrawal occurs during the five-year period following the opening of the PEA and PEA PME-ETI. Special rates of personal income tax apply to closing and withdrawals occurring before two years and between two and five years following the opening of the PEA and PEA PME-ETI. Social levies are due upon withdrawal from the PEA and PEA PME-ETI.

Capital losses incurred on shares held in a PEA and PEA PME-ETI may in principle only be offset against capital gains realised on other shares held in the plan.

#### 14.2.3 French wealth tax

The shares of the Company held by individuals fiscally domiciled in France in their personal portfolio are included in the taxable basis for wealth tax purposes (however wealth tax and similar tax paid outside France on these shares may be deducted, to a certain extent, from the French wealth tax). French wealth tax is applicable at progressive rates to individuals whose net wealth exceeds €1,300,000 on 1 January of the relevant year.

Certain exemptions may be available depending on the specific situation of each holder of the shares of the Company. Prospective investors in the shares should therefore consult their own tax advisor in this respect.

#### 14.2.4 Stamp duties

The subscription of the shares does not give rise to stamp duties or other transfer taxes in France. The sale of the shares is not subject to stamp duties or other transfer taxes in France provided that the transfer is not evidenced by a written deed or agreement executed in France, unless a purchase agreement is voluntarily registered before the French tax authorities (in which case the 0.1% rate would apply).

#### 14.2.5 Other situations

Prospective investors who are subject to taxation regimes other than those described above should consult their own tax advisor in respect of their specific situation.

## 15 Information on the Offering

Certain key dates in connection with the Offering are summarised in the following table. These are all anticipated dates, which are subject to any unforeseen circumstance and to acceleration or suspension of the Offering Period.

Date	Event
22 January 2015	Expected start of the Offering Period
2 February 2015 (T-1)	Expected end of the Offering Period
3 February 2015 (T)	Expected Allocation Date
4 February 2015 (T+1)	Expected publication date of the Offer Price and results of the Offering
5 February 2015 (T+2)	Expected Closing Date (payment and delivery)
6 February 2015 (T+3)	Expected Listing Date and start of trading

#### 15.1 Information related to the capital increase

At the extraordinary shareholders' meeting of the Company held on 16 January 2015, it was decided to increase the Company's share capital through a cash contribution and the issuance of maximum 1,750,000 New Shares, subject to the completion of the Offering. The amount of New Shares may be increased by up to 15%, to an amount of 2,012,500 New Shares.

At the same shareholders' meeting, it has been decided to grant the Over-allotment Option to the Global Coordinator, acting on behalf of the Joint Bookrunners, in order to grant it with the right to subscribe in cash for a number of new shares equal to maximum 15% of the New Shares allocated in the Offering. The Over-allotment Option will be exercisable for a period of 30 calendar days from the Listing Date. The Over-allotment Option is issued for the sole purpose of allowing the Global Coordinator to cover over-allotments, if any. The new shares to be issued on the exercise of the Over-allotment Option will have the same issue price as the New Shares in the Offering.

The issue price (including share premium) of each New Share and of each new share issued upon the exercise of the Over-allotment Option will be the Offer Price and will be determined based on a book-building procedure during the Offering Period, in which only Institutional Investors can participate. The number of New Shares to be issued in the Offering will be determined by dividing the amount of the capital increase (including share premium) by the Offer Price.

In connection with the issuance of the New Shares, the preferential subscription rights of the existing shareholders of the Company have been cancelled. In connection with the grant of the Over-allotment Option, the preferential subscription rights of the existing shareholders of the Company have been cancelled.

Whether or not the Offering is fully subscribed, the Global Coordinator may proceed with over-allotments, covered by the Over-allotment Option, aiming at creating stabilisation after the start of the trading. See also Section 15.5 "Over-allotment and stabilisation".

#### 15.2 Terms and conditions of the Offering

#### 15.2.1 Conditions and nature of the Offering

The Offering is comprised of (i) a public offering in Belgium and France and (ii) private placements outside the United States in offshore transactions in accordance with Regulation S under the Securities Act ("**Regulation S**") to qualified investors, and, with respect to the EEA, pursuant to an exemption under the Prospectus Directive where implemented by the Relevant Member State.

The capital increase will consist of maximum 1,750,000 new ordinary shares. The number of New Shares may be increased by up to 15%, to 2,012,500 (the "**Increase Option**", the new shares initially offered and the new

shares offered as a result of the possible exercise of the Increase Option jointly being referred to as the "**New Shares**"). Any decision to exercise the Increase Option will be announced at the latest on the date the Offer Price is announced, which is currently expected to be on or about 4 February 2015.

The Global Coordinator has been granted an Over-allotment Option, exercisable for a period of 30 calendar days from the Listing Date, to subscribe for new shares at the final Offer Price for the sole purpose of allowing the Global Coordinator to cover over-allotments of Additional Shares, if any.

In accordance with Belgian and French regulations, no less than 10% of the Offered Shares will be reserved for Retail Investors. However, the proportion of Offered Shares allocated to Retail Investors may be higher or lower than 10% of the Offered Shares (possibly substantially) if Retail Investors have applied in aggregate for more or less, respectively, than this percentage. The subscription by the Anchor Investors will not be taken into account for the calculation of the above 10% tranches.

The Offer Price and the placement commission (*commission de placement*) will be the same for Institutional Investors and Retail Investors. See also the Section 15.2.2 "Offer price" below.

The Company has the right to proceed with a capital increase for a reduced number of shares. The actual number of Offered Shares subscribed for or sold in the Offering will be confirmed on the website of the Company and by press release together with the Offer Price. The minimum amount set for the Offering is  $\[mathebox{0.6}\]$  17.5 million, below which the Offering will not be completed.

The Offering is subject to (i) the Board of Directors concluding that the quantity and quality of the subscriptions received is such that the Offering can be closed in the interests of the Company, and (ii) the Company and the Joint Bookrunners reaching a final agreement on the terms of the Underwriting Agreement. For more information, see Section 16 "Underwriting Agreement".

The Offering is subject to Belgian law. Any person applying for Offered Shares shall be deemed to accept the terms and conditions of the Offering set out in this Prospectus. Any dispute in relation with the Offering shall be submitted to the exclusive jurisdiction of the courts of Brussels, Belgium.

#### 15.2.2 Offer price

The Offer Price will be a single price in Euro that will apply to all investors, whether Retail Investors or Institutional Investors.

The Offer Price will be determined by the Company on the basis of a book building procedure conducted during the Offering Period, in which only Institutional Investors can participate, and taking into account various relevant qualitative and quantitative elements, including, but not limited to, the number of shares applied for, the size of orders received, the quality of the investors submitting such orders and the prices at which the orders were made, as well as the market conditions at that time. The Offer Price is expected to be set within a price range of between  $\in$  14.5 and  $\in$  16.5 per share (the "Offer Price Range").

The Offer Price will be determined as soon as possible after the end of the Offering Period on the Allocation Date, which is expected to take place on 3 February 2015 and will be published on the website of the Company and by press release on the first business day following its determination, which is expected to be 4 February 2015. Both dates are subject to the acceleration or suspension of the Offering Period.

Retail Investors in Belgium and France can only acquire the Offered Shares at the Offer Price and are legally bound to purchase the number of shares indicated in their share application at the Offer Price.

The applicable Offer Price will in no event exceed the upper end of the price range, although it may be set below the lower end of the price range. If the Offer Price is set below the Offer Price Range, a supplement to this Prospectus will be published. In such event, investors will have the right to withdraw their share applications made prior to the publication of the supplement within the time limits set out in the supplement (which shall not be shorter than two Business Days after publication of the supplement).

#### 15.2.3 Offering period

The Offering Period will begin on 22 January 2015 and is expected to close at 5.00 p.m. Brussels time on 2 February 2015, unless it is closed or suspended earlier, provided that the Offering Period will in any event be open for at least six Business Days as from the availability of this Prospectus. Any acceleration or suspension of the Offering Period will be announced on the website of the Company and by press release, and the dates for pricing, allocation, publication of the Offer Price and results of the Offering, listing and trading and completion of the Offering will be adjusted accordingly. The Offering Period for Retail Investors and Institutional Investors

will be the same. In the event that the Offering Period is extended, a supplement to this Prospectus will be published on the website of the Company.

Prospective investors may submit their 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.

In accordance with Article 34, §3 of the Prospectus Act, in the event that a supplement to this Prospectus is published prior to the Listing Date and in that event only, investors will have the right to withdraw their share applications made prior to the publication of the supplement within the time limits set out in the supplement (which shall not be shorter than two Business Days after publication of the supplement).

#### **15.3** Application procedure

#### **15.3.1** *General*

The Joint Bookrunners are investment service providers registered with their respective national securities regulatory authority and are authorised to operate and participate in public offerings in Belgium and in France.

To be valid, share orders from Retail Investors and Institutional Investors must be submitted at the earliest on the first day of the Offering Period which will begin on 22 January 2015, and at the latest on 2 February 2015, by 5.00 p.m. Brussels time, unless the Offering Period is closed earlier or suspended.

Share applications are not binding on the Company or the Joint Bookrunners as long as they have not been accepted in accordance with the allocation rules described below in the Section 15.3.4 "Allocation of the Offered Shares".

#### 15.3.2 Retail investors

Retail Investors must place their share order with their own financial intermediary in Belgium or France in accordance with the procedure of such intermediary. Retail Investors should request details of the costs which their financial intermediary may charge and which they will have to pay themselves.

A single order per Retail Investor will be accepted. If the Joint Bookrunners determine, or have reason to believe, that a single Retail Investor has submitted several orders through one or more intermediaries, such orders may be disregarded.

There is no minimum or maximum amount that may be subscribed for in one order. Every order must be expressed in number of shares with no indication of price and shall be deemed placed at the Offer Price (which will be determined after the end of the Offering Period on the Allocation Date). Orders are subject to a possible reduction as described below in the Section 15.3.4 "Allocation of the Offered Shares".

Orders will be irrevocable (even in the case of reduction) after the end of the Offering Period. However, in the event that a supplement to this Prospectus is published prior to the Listing Date and in that event only, Retail Investors shall have the right to withdraw their share applications made prior to the publication of the supplement within the time limits set out in the supplement (which shall not be shorter than two Business Days after publication of the supplement).

No later than 10 a.m. CET on 3 February 2015, all orders collected by financial intermediaries from Retail Investors must be transferred as follows:

- For market members of Euronext Brussels and/or Euronext Paris: orders will be sent to Euronext in accordance with the calendar and the procedure described in the notices of Euronext Brussels and Euronext Paris which will be published on 22 January 2015. In its capacity of market operator, Euronext Paris will be the centralisation agent in France for the retail demand in France. Upon the Company's request, Euronext will also centralise the retail demand in Belgium in accordance with the aforementioned conditions. Euronext will not charge additional fees to Euronext market members in respect of centralisation services as stated in the 2015 Euronext fee brochure.
- For financial intermediaries based in Belgium and having no membership to Euronext Brussels or Euronext Paris, or no agreement with a market member of Euronext Brussels or Euronext Paris, retail orders can be passed to Bryan Garnier & Co, Equity Capital Market Department either by email (ecm@bryangarnier.com) or by facsimile to the following number (+33 1 56 68 75 21) in accordance with the calendar and the procedure described in the notices of Euronext Brussels and Euronext Paris which wil be published on 22 January 2015.

- The Euronext corporate event notices and a Q&A will be available on the website of Euronext at the following link: https://www.euronext.com/fr/listings.ipo-showcase.

#### 15.3.3 Institutional investors

Institutional Investors must indicate on their orders the number of Offered Shares they are committing to subscribe for, and the prices at which they are making such orders during the book-building period.

Only Institutional Investors may participate in the book-building procedure during the Offering Period.

Institutional Investors are invited to submit their orders, after the start of the Offering Period, as soon as possible with any of the Joint Bookrunners.

#### 15.3.4 Allocation of the Offered Shares

The exact number of Offered Shares allocated to the investors will be determined at the end of the Offering Period by the Company and the Joint Bookrunners 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, and in accordance with Belgian and French regulations relating to allocation to Retail Investors and Institutional Investors (see Section 15.2.1 "Conditions and nature of the Offering"), but without prejudice to the rules set out below.

The orders placed by the Retail Investors located in Belgium and France will be equally treated irrespective of the financial intermediary selected by them.

In the event of over-subscription of the Offered Shares reserved for Retail Investors, reductions will be made on a pro rata basis. In cases where the reduction would lead to a non-whole number of shares, this number will be rounded down to the nearest whole number.

The Company has committed to fully allocate the amount of Offered Shares subscribed by the Anchor Investors in the Offering, even in case of over-subscription of the Offering. For further information about the commitment of Anchor Investors to participate in the Offering, see Section 15.7 "Intentions of the shareholders, bondholders, directors and managers".

The results of the Offering, the allocation of Offered Shares to the Retail Investors and the Offer Price will be published on the website of the Company and by press release, which is expected to occur on or about 4 February 2015, subject to any acceleration or suspension of the Offering Period. Such notice will specify any reduction rate applied to the orders as the case may be.

The acquisition of Additional Shares will give rise to a tax on stock exchange transactions (*taxe sur les opérations de bourse*) at a rate of 0.27% of the purchase price capped at €800 per transaction and per party. Exemptions apply for certain categories of Institutional Investors and Belgian non-residents. The subscription for New Shares will not give rise to a tax on stock exchange transactions. See also Section 14 "Taxation in Belgium and in France".

#### 15.3.5 Payment, settlement and delivery of the Shares

The Offer Price must be paid up in full, in Euro, together with any applicable stock exchange tax. For further information about applicable taxes, see Section 14 "Taxation in Belgium and in France".

The settlement date, which is also the Closing Date, will be the second Business Day after the Allocation Date, and is expected to occur on or about 5 February 2015, unless the Offering Period is closed or suspended earlier. The Offer Price must be paid by investors upon submission of their share applications or, alternatively, by authorising their financial institutions to debit their bank account with such amount for value on the Closing Date.

All Offered Shares will be delivered against payment in dematerialized form through Euroclear Belgium, the Belgian central securities depository.

#### 15.3.6 Form of the Shares

All Offered Shares will have the same rights and benefits attached to them as the Company's other ordinary shares and will be issued with coupons 1 and following attached. The Offered Shares will have ISIN (International Security Identification Number) BE0974280126. For a further description of the Company's shares and the rights and benefits attached thereto, see Section 9 "Description of the issuer, the share capital and shares".

As described above, all Offered Shares will be delivered in dematerialized form only, through Euroclear Belgium.

Investors who, after delivery, wish to have their shares in registered form in the share register of the Company, should ask the Company to do this, and the Company will thereupon within a reasonable period of time record the shares in its share register which is held at the registered office of the Company. Any costs incurred in connection with the conversion of shares in dematerialized form into registered form will be borne by the converting shareholder (see Section 9.5 "Form and transferability of the shares").

All of the Offered Shares will be fully paid up on delivery, and freely transferable, subject to what is set out under Section 15.10 "Lock-up and standstill arrangements".

#### 15.4 Listing and first trading

An application has been made by the Company for the listing and admission to trading on the regulated market of Euronext Brussels and Euronext Paris of all existing and new shares of the Company, including all shares to be issued (if any) upon the exercise of the Over-allotment Option. The shares are expected to be listed under the symbol "BOTHE".

Trading is expected to commence on or about 6 February 2015 (unless the Offering Period is accelerated or suspended), being one Business Day following the Closing Date when the Offered Shares are delivered to the investors. See also Section 16 "Underwriting Agreement". Prior to the listing of the Shares, no public market existed for the Shares issued by the Company.

#### 15.5 Over-allotment and stabilisation

In connection with the Offering, the Joint Bookrunners will be able to, for a period of 30 days from the Listing Date (the "Stabilisation Period") effect transactions that stabilise or maintain the market price of the Company's shares at levels above those that might otherwise prevail in the open market. For this purpose, the Global Coordinator, acting on behalf of the Joint Bookrunners, will act as stabilisation agent. Such transactions, if any, will be performed in compliance with the applicable laws and regulations, including Chapter III of Commission Regulation (EC) No 2273/2003 and the Belgian Royal Decree of 17 May 2007 on primary market practices, and may be effected on Euronext Brussels and Euronext Paris, on the over-the-counter market, or otherwise. There is no assurance that such stabilisation will be undertaken and, if it is, it may be discontinued at any time and will, in any event, be discontinued 30 days after the Listing Date.

The Company has granted the Global Coordinator, acting on behalf of the Joint Bookrunners, an Over-allotment Option which allows the Global Coordinator to subscribe for additional new shares at the Offer Price up to maximum 15% of the number of New Shares allocated in the Offering (the "**Additional Shares**"). The Over-allotment Option corresponds to a maximum number of 301,875 Additional Shares.

If the Global Coordinator creates a short position in the shares in connection with the Offering (i.e., over-allot Additional Shares), it may reduce that short position by purchasing shares or, as referred to below, by exercising all or part of the Over-allotment Option. Purchases of shares to stabilise 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 Company nor the Global Coordinator makes 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.

The stabilisation, if any, will not occur at a price higher than the Offer Price.

The Global Coordinator may elect to reduce any short position by exercising all or part of the Over-allotment Option. The Over-allotment Option will be exercisable for a period of 30 calendar days from the Listing Date. The Over-allotment Option will be exercisable in whole or in part, and in one or in several times, only to cover over-allotments of Additional Shares, if any. The possibility to over-allot shares in the Offering and to exercise the Over-allotment Option will exist whether or not the Offering is fully subscribed.

Within five Business Days of the end of the Stabilisation Period, the following information will be published on the website of the Company in accordance with Article 5, § 2 of the Royal Decree of 17 May 2007 on primary markets practices: (i) whether or not stabilisation was undertaken, (ii) the period during which the stabilisation has been performed, (iii) the price range within which stabilisation was carried out, for each of the dates on which stabilisation transactions were carried out, and (iv) the final size of the Offering, including the result of the stabilisation and the exercise of the Over-allotment Option, if any.

In order to cover any over-allotments prior to the exercise of the Over-allotment Option, it is expected that the Global Coordinator will enter into a stock lending agreement with existing shareholders. These Additional Shares which may be allocated to investors by way of over-allotment are existing shares.

#### 15.6 Costs and remuneration of intermediaries

The aggregate costs of the Offering are estimated to be approximately 9.50% of the gross proceeds of the Offering (assuming the mid-range of the Offer Price Range and assuming the Increase Option and the Overallotment Option are exercised in full). These costs include legal, consulting, administrative, audit and other costs ( $\epsilon$ 786,000), remuneration of the Belgian Financial Services and Markets Authority ( $\epsilon$ 20,000), legal publications, printing of this Prospectus ( $\epsilon$ 35,000), advisors, management, placing and selling fees ( $\epsilon$ 70,000), and the fees payable to Euronext Brussels and Euronext Paris ( $\epsilon$ 70,000).

All costs will be borne by the Company.

#### 15.7 Intentions of the shareholders, bondholders, directors and managers

Certain shareholders and bondholders of the Company have committed to subscribe to Offered Shares in the Offering (the "Anchor Investors") for a total amount of €10,350,000.

Certain shareholders of the Company, including Jacques Reymann, Christian Boon Falleur and JJ Verdickt & Consorts, have committed to apply for Offered Shares in the Offering for a minimum amount of €1,175,000.

Certain holders of convertible bonds issued by the Company, including Sofipôle SA and SFPI SA, have committed to apply for Offered Shares in the Offering for a minimum amount of  $\in$  9,175,000.

#### 15.8 Interest of natural and legal persons involved in the Offering

Save for (i) the fees payable to the Joint Bookrunners (upon entering into the Underwriting Agreement with the Company, which is expected to occur prior to completion of the Offering, and subject to the terms and conditions thereof) (see Section 15.6, "Costs and remuneration of intermediaries"), (ii) the conversion of the Bonds upon completion of the Offering (see Section 9.4.3, "Automatically convertible bonds") and (iii) a bonus payment (at the occasion of the successful completion of the Offering) to and the vesting or exercisability of certain warrants held by members of the Management Team (see Section, 10.9.2, "Securities held by members of the Management Team"), so far as the Company is aware, no person involved in the Offering has an interest that could be material to the Offering .

#### 15.9 Financial service

From the Listing Date, the financial service for the shares of the Company will be provided by Banque Degroof SA. Should the Company alter its policy in this respect, this will be announced in accordance with applicable law.

#### 15.10 Lock-up and standstill arrangements

#### 15.10.1 Lock-up arrangements

Certain shareholders of the Company are expected to agree not to transfer during a period of 365 days from the Closing Date any shares held prior to the Offering, except for a limited number of shares (maximum 5,000 shares per shareholder) which may be freely transferred following a shortened lock-up period of 90 days. The shares covered by the 365 days lock-up agreement represent in total 94.83% of the Company's shares on the date of this Prospectus.

The holders of Bonds are also expected to agree not to transfer any shares issued upon conversion of the Bonds (i.e. on completion of the Offering) during a period of 365 days from the Closing Date, except for a limited number of shares (maximum 5,000 shares per shareholder) which may be freely transferred following a shortened lock-up period of 90 days.

In addition thereto, the above mentioned shareholders and bond holders are expected to enter into a soft lock-up undertaking vis-à-vis Joint Bookrunners, whereby they undertake not to transfer the above mentioned shares for a period of 180 days following the above-mentioned 365 days lock-up period without prior approval by the Joint Bookrunners.

None of the restrictions referred to above are expected to apply to (i) the existing shares borrowed under the stock lending agreement(s) referred to under Section 15.5 "Over-allotment and stabilisation", (ii) transfers to legal successors or other transferees in case of death of a natural person or in case of liquidation, merger, demerger, transfer or contribution of a branch of activity or transfer or contribution of a universality of or by a legal person (provided, however, that the legal successor or transferee of such person assumes the relevant transfer restriction obligations for the remaining term thereof), (iii) intra-group transfers, including to and from controlling natural persons (provided, however, that the transferee assumes the relevant transfer restriction obligations for the remaining term thereof), (iv) transfers between the shareholders subject to the lock-up agreement (provided, however, that the transferee assumes the relevant transfer restriction obligations for the remaining term thereof), (v) acceptance of a public takeover bid, or (vi) an order from a court or as otherwise mandatorily required under the applicable law.

#### 15.10.2 Standstill arrangements

The Company has agreed that during a term ending 365 days following the Closing Date it shall not, except with the prior consent of the Joint Bookrunners, issue any new shares, warrants or other securities that give a right to acquire shares or enter into any contract or commitment with similar effects, irrespective of whether these are or are not listed on a stock exchange or a regulated market, except for (i) the issue of the New Shares, (ii) the issue of the Over-allotment Option, (iii) the issue of new shares following any exercise of the Over-allotment Option, (iv) the issue of new shares following the exercise of existing Warrants, (v) the issue of up to 1% new warrants in the aggregate (and the issue of new shares following the exercise of such warrants) that would be granted to executives, employees or consultants of the Company, and (vi) any issue in the context of a merger, de-merger, transfer of a universality or branch of activity or other corporate restructuring, acquisition, or strategic partnership provided, in the case of such corporate restructuring, acquisition or strategic partnership, that any shares issued do not represent more than 10% of the Company's share capital immediately after the Closing Date.

## 16 Underwriting Agreement

The Company and the Joint Bookrunners (the "**Underwriters**") expect (but have no obligation) to enter into an Underwriting Agreement upon the determination of the Offer Price, which is expected to take place on or about 3 February 2015. The entering into the Underwriting Agreement may depend on various factors including, but not limited to, market conditions and the result of the book building process. If the Company or the Underwriters do not sign the Underwriting Agreement, the Offering will not be completed.

Subject to the terms and conditions to be set forth in the Underwriting Agreement, the Underwriters will severally agree to subscribe at completion of the Offering the following percentage of the total number of Offered Shares in their own name but for the account of the (retail and other) investors to whom those Offered Shares have been allocated:

Underwriters	Percentage of Offered Shares
Bryan, Garnier & Co Ltd. 26, avenue des Champs-Elysées 75008 Paris France	40.00%
Kepler Capital Markets 112 avenue Kleber 75116 Paris France	40.00%
Bank Degroof Rue de l'Industrie 44 1040 Brussels Belgium	20.00%
Total	100.00%

Following the enactment of the issue of the New Shares by notarial deed, the Underwriters will deliver the Shares subscribed by them to the investors.

The Underwriters will be under no obligation to purchase any Offered Shares prior to the execution of the Underwriting Agreement (and then only on the terms and subject to the conditions set out therein).

In the Underwriting Agreement, the Company will make certain representations and warranties and agree to indemnify the Underwriters against certain liabilities.

Bryan Garnier will act as Global Coordinator, and Kepler and Bank Degroof will act as joint lead managers and Joint Bookrunners.

The Underwriting Agreement will provide that the Joint Bookrunners will have the right to terminate, on behalf of the Underwriters, collectively but not individually, the Underwriting Agreement and their several obligations thereunder to purchase and deliver the Offered Shares (i) upon the occurrence of certain events, such as (i) a suspension or limitation in trading of financial instruments on certain markets, (ii) a general moratorium on commercial banking activities declared by the relevant authorities, a disruption in commercial banking or securities settlement or clearance services, (iii) the outbreak or escalation of hostilities, terrorist attacks or another emergency or crisis involving or having an effect on any of the United States, Canada, or on any country of the EEA, or (iv) any significant adverse change in any political, financial, economical, monetary or social conditions or in taxation or currency exchange rates or exchange controls in Belgium, France, the United Kingdom or the United States, if with respect to (iii) and (iv) the effect of any such event or change would be likely to prejudice the success of the Offering, the enforcement of contracts for the subscription and sale of the Offer Shares, or dealings in the Shares in the secondary markets, and (ii) if the conditions contained in the Underwriting Agreement, such as delivery of a certificate from the Company and legal opinions, are not satisfied or waived. If the Underwriting Agreement is terminated, which can happen at any time up to the date of closing and settlement, the Offering will not close, allocations of the Offered Shares to investors will be cancelled and investors will not have any claim to delivery of the Offered Shares.

## **ANNEX A – Definitions**

Additional Shares	The existing shares in the Company covered by the Over-allotment Option.
Advanced therapy medicinal product	Medicine for human use that are based on gene therapy, somatic cell therapy or tissue engineering (EMA classification 1394/2007).
Allocation Date	The date on which the Offer Price will be determined and the Offered Shares will be allocated to investors who have duly applied for them.
Allogeneic	Said for tissues or cells when the donor is different from the recipient (i.e., the patient)
Anchor investors	Shareholders and bondholders of the Company that have committed to subscribe to Offered Shares in the Offering.
Atrophic	For a non-union, characterized by an absence of a callus, deficiency in bone vascularity and poor healing potential
Audit Committee	The audit committee installed by the Board of Directors.
Autologous	Said for tissues or cells when the donor is the same as the recipient (i.e., the patient).
Belgian Company Code	The Belgian Act of 7 May 1999 containing the companies code ( <i>Code des sociétés</i> )
Belgian Generally Accepted Accounting Principles	The applicable legal framework in Belgium.
Biovigilance (MCH)	The process of monitoring, reporting and preventing all risks associated with the therapeutic use of products derived from human biological materials, in accordance with the Belgium law (as issued on 12 December 2003 and as amended on 17 July 2017).
Board of Directors	The board of directors of the Company.
Business Day	Any day, other than a Saturday or Sunday, on which banks are generally open for general business in Brussels.
Callus	Unorganized bony and cartilaginous tissue that forms around the ends of a broken bone during healing. It is absorbed as repair is completed and ultimately replaced by true bone.
СНИ	Centre Hospitalier Universitaire de Liège
Cost of goods sold	Direct costs attributable to the production of the goods sold by a company. This amount includes the cost of the materials, the direct labor costs and infrastructure costs used to produce the good. It excludes indirect expenses such as distribution costs and sales force costs.
Competent Authority (Regulatory Agency)	National organization that regulates medicinal products for human use in accordance with the European directives and national law. Clinical trials of medicinal products in human subjects require authorisation by the competent authority.
Core Decompression	Surgical procedure for the treatment of osteonecrosis of the femoral head, that consists in drilling a small hole into the femoral neck and through the necrotic bone area. This is intended to reduce internal bone pressure and increased blood flow.
Belgian Corporate Governance Code	The Belgian code as issued on 9 December 2004 by the Belgian Corporate Governance Committee and as amended on 12 March 2009.
Closing Date	The date of the completion of the Offering.
Company	Bone Therapeutics SA.
Corporate Governance Charter	The corporate governance charter of the Company.
·	

D&O policy	Provides cover for the personal liability of directors and officers of a company arising due to wrongful acts in their managerial capacity. Indemnification (reimbursement) for losses and defence costs are covered.
Dividend Received Reduction	Dividend Received Reduction regime.
Delayed-union fracture	A medical condition defined as a fracture that has not united within a period of time that would be considered adequate for bone healing.
Ectopic	Occurring in a location other than its normal location
ERP platform	An ERP platform is a software program that can be used to manage data about financial data, business assets, and personnel.
Ethics Committee	Established committee that ensures that research conducted within a hospital complies with moral and ethical principles. Clinical trials of medicinal products in human subjects require positive opinion by the ethic committee.
Euronext Brussels	The regulated market operated by Euronext Brussels SA/NV.
Euronext Paris	The regulated market operated by Euronext Paris SA.
Ex vivo	Taking place outside the organism.
Executive Directors	Directors entrusted with the day-to-day management of the Company.
GCP (Good clinical practise)	An international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects.
Global Coordinator	Bryan, Garnier & Co Ltd.
GMP (Good manufacturing practise)	Tart of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use.
Group	The Company and SCTS.
GIE BOCEGO	Groupement d'Intérêt Economique BOCEGO, consisting of the Company and SCTS.
HCTS (Hepatic Cell Therapy Support SA)	A limited liability company incorporated under the laws of Belgium with registered office at avenue Georges Lemaitre 62, 6041 Gosselies and
Homeostasis	registered with the register of legal entities under number 0841.727.891.
	Self-regulating process by which biological systems tend to maintain internal stability.
Hospital Exemption	Self-regulating process by which biological systems tend to maintain
Hospital Exemption  Hypotrophic	Self-regulating process by which biological systems tend to maintain internal stability.  Allows hospitals and medical practitioners to provide ATMP-classified products to patients, e.g., in case of high unmet medical need because there is no authorized ATMP alternative available. Said products are custom-made for an individual patient, prepared on a non-routine basis, and used within the same Member State in a hospital under the exclusive
	Self-regulating process by which biological systems tend to maintain internal stability.  Allows hospitals and medical practitioners to provide ATMP-classified products to patients, e.g., in case of high unmet medical need because there is no authorized ATMP alternative available. Said products are custom-made for an individual patient, prepared on a non-routine basis, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner.  For a non-union, characterized by the absence of callus formation and a
Hypotrophic	Self-regulating process by which biological systems tend to maintain internal stability.  Allows hospitals and medical practitioners to provide ATMP-classified products to patients, e.g., in case of high unmet medical need because there is no authorized ATMP alternative available. Said products are custom-made for an individual patient, prepared on a non-routine basis, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner.  For a non-union, characterized by the absence of callus formation and a poor healing response due to low biological activity.  The option to increase the amount of new shares by up to 15%, as
Hypotrophic Increase Option	Self-regulating process by which biological systems tend to maintain internal stability.  Allows hospitals and medical practitioners to provide ATMP-classified products to patients, e.g., in case of high unmet medical need because there is no authorized ATMP alternative available. Said products are custom-made for an individual patient, prepared on a non-routine basis, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner.  For a non-union, characterized by the absence of callus formation and a poor healing response due to low biological activity.  The option to increase the amount of new shares by up to 15%, as described in Section 15.2 "Terms and conditions of the Offering".  Autoimmune diseases characterized by inflammation and loss of function of muscles, joints, bones and other tissues producing symptoms such as pain, swelling and stiffness (e.g., osteoarthritis, rheumatoid arthritis,
Hypotrophic Increase Option Inflammatory Rheumatic Diseases	Self-regulating process by which biological systems tend to maintain internal stability.  Allows hospitals and medical practitioners to provide ATMP-classified products to patients, e.g., in case of high unmet medical need because there is no authorized ATMP alternative available. Said products are custom-made for an individual patient, prepared on a non-routine basis, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner.  For a non-union, characterized by the absence of callus formation and a poor healing response due to low biological activity.  The option to increase the amount of new shares by up to 15%, as described in Section 15.2 "Terms and conditions of the Offering".  Autoimmune diseases characterized by inflammation and loss of function of muscles, joints, bones and other tissues producing symptoms such as pain, swelling and stiffness (e.g., osteoarthritis, rheumatoid arthritis, ankylosing spondylitis)  Qualified and/or institutional investors under applicable laws of the

Listing Date	The date on which the Company's shares shall be admitted to trading of Euronext Brussels and Euronext Paris.
Management Team	The team consisting of the CEO, CFO, CCRO and CMO.
M-ERA.net	A EU funded network which has been established to support and increase the coordination of European research programmes and related funding in materials science and engineering.
Mesenchymal stem cells	Multipotent stem cells that can convert into cell types such as bone cells, cartilage cells, fat cells, etc.
MXB	A combined cell-matrix product of Bone Therapeutics for large bone defects and maxillofacial applications.
New Contracts	RCAs governed by the currently applicable Walloon regulations.
New Shares	The new shares initially offered in the Offering, including the new shares offered as a result of the possible exercise of the Increase Option.
Nomination and Remuneration Committee	The nomination and remuneration committee of the Company installed by the Board of Directors.
Non-union fracture	A medical condition characterised by a failure to achieve bone union within 6-9 months as, all reparative processes have ceased, hence requiring additional surgical intervention.
Orphan Drug Designation	A special status to a drug developed for the treatment of a rare disease or medical condition. This enables the product to gain exclusivity when reaching market and creates additional value (e.g., easier marketing approval, extended exclusivity periods, fee reduction etc.) This status was received for PREOB® and ALLOB® in osteonecrosis of the femoral head by the EMA and the FDA.
Offer Price	The single price in euro at which the Offered Shares shall be purchased as set out in Section 15.1 "Information related to the capital increase".
Offer Price Range	The price range of the shares as disclosed in this Prospectus.
Offered share	The New Shares and the shares of the Company covered by the Overallotment Option.
Offering	A public offering in Belgium and France to Retail Investor and a private placement to certain Institutional Investors in certain jurisdictions outside the United States in accordance with Regulation S under the Securities Act.
Offering Period	The period during which the Offering will be open for subscription as described in Section 15.2 "Terms and conditions of the Offering".
Old Contracts	RCAs governed by the previously applicable Walloon regulations.
Osteoarthritis	A degenerative joint disease.
Osteoblast	Bone-forming cell.
Osteoclast	Bone-resorbing cell.
Osteoconduction	The capacity (of a material) to provide a "physical" scaffold favourable to cell colonization, growth and vascularization in order to support bone formation.
Osteocyte	A terminal bone forming cell embedded in mineralized bone matrix.
Osteogenesis	The capacity to produce new bone
Osteoinduction	The capability to induce bone formation via the recruitment, proliferation and differentiation of MSC and progenitor cells.
Osteonecrosis (of the hip)	A medical condition characterized by the death of bone cells and loss of the associated marrow elements. It is a painful condition in which the joint degenerates progressively, ultimately leading to collapse of the femoral head.

A medical condition characterized by an excessive loss of bone mass leading to bone fragility and increased risk of fracture.
A surgical procedure performed to stabilize a fracture by mechanical devices such as metal plates, pins, rods, wires or screws.
The option granted to Bryan, Garnier & Co Ltd., acting both for itself and Kepler Capital Markets and Banque Degroof, as described in Section 15.5 "Over-allotment and stabilisation".
Substances (e.g., growth factors) naturally found in human body, which are used as a drug (in higher concentrations) to improve bone healing.
A first-in-man proof-of-concept pilot study in which the product will be administered to humans for the first time and in which efficacy parameters will be assessed. This is the case for ALLOB® in delayed-union.
A proof-of-concept pilot study in which the product has already been administered to human – in general in another indication - and in which efficacy parameters will be assessed. This is the case for PREOB® in osteoporosis and for ALLOB® in spine fusion.
A pivotal study in which the product has already been shown to be safe and efficacious in the indication, and in which the safety and efficacy will be further confirmed in a larger groups of patients. This is the case for PREOB® in osteonecrosis and non-union.
Studies done after the product has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.
The process of collecting, monitoring and evaluating adverse events in clinical trials for safety purpose.
Consultation meeting with FDA, which precedes and helps shape the preparation of the IND (Investigational New Drug Application) that must be submitted to FDA prior to initiation of a clinical trial.
A differentiated mesenchymal cell that is already committed to the osteoblastic lineage (to transform into an osteoblast).
The Belgian Royal Decree as issued on 17 May 2007.
This document, as well as any supplement thereto.
The Belgian Act of June 16, 2006 on the public offering of securities and the admission of securities to trading on a regulated market ( <i>Loi relative aux offres publiques d'instruments de placement et aux admissions d'instruments de placement à la négociation sur des marchés réglementés</i> ).
Directive 2003/71/EC together with any relevant implementing measure in each Relevant Member Share (as amended from time to time).
Regulation 809/2004/EG of the European Commission, implementing the Prospectus Directive.
Resistant to a certain process or treatment.
Regulation S under the Securities Act.
Each Member State of the EEA which has implemented the Prospectus Directive.
A chronic systemic inflammatory disease affecting the joints.
71 chrome systemic inflammatory disease affecting the joints.
A medical condition that causes abnormal curvature of the spine.

Securities Act	The United States Securities Act of 1933, as amended.			
Significant shareholder	A shareholder holding at least 5% of the share capital.			
SME Agreement	The agreement dated 24 April 2014 between the Walloon Region and Groupement d'Intérêt Economique BOCEGO (consisting of the Company and SCTS) (BOCEGO).			
Société d'Infrastructures, de Services et d'Energies SA	A limited liability company incorporated under the laws of Belgium with registered office at avenue Georges Lemaitre 62, 6041 Gosselies and registered with the register of legal entities under number 0841.727.101.			
Spinal fusion	A surgical procedure that consists of bridging two or more vertebrae to obtain fusion of an unstable portion of the spine or to immobilize a painful vertebral motion segment.			
Spondylolisthesis	A condition in which one or more vertebrae slips out of place onto the vertebra above and below it/them			
Stenosis	A narrowing of a channel or a vessel In this document, spinal stenosis is the narrowing of spaces in the spine (backbone) which causes pressure on the spinal cord and nerves.			
THA	Total hip arthroplasty.			
Third party payer	An institution or company that provides reimbursement to health care providers for services rendered to a third party (i.e., the patient).			
Tissue Bank	An entity that is licensed, accredited or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human biological materials. The Company has obtained a license as a tissue bank for handling autologous human biological materials and a license as a tissue bank for handling in collaboration with hospital tissue banks allogeneic human biological materials.			
Underwriters	The Joint Bookrunners.			
Underwriting Agreement	The Agreement to be entered into between the Issuer and the Underwriters on or around 3 February 2015.			
Viscosupplementation	A treatment using intra-articular injection of hyaluronan-based preparations which absorb shocks and provide lubrication in order to decrease pain and improve mobility.			
Warrants	Warrants issued by the Company as described in Section 9.4.1, "Securities issued by the Company".			

## **ANNEX B – Abbreviation**

AMF	Autorité des Marchés Financiers (Financial Markets Authority)		
ATMP	Advanced Therapy Medicinal Product		
BCC	Belgian Company Code		
BCGC	Belgian Corporate Governance Code		
β-ТСР	β-tricalcium phosphate		
BITC	Belgian Income Tax Code		
BLA	Biologics License Application		
СВМР	Cell-Based Medicinal Product		
CCRO	Chief Clinical and Regulatory Officer		
CEO	Chief Executive Officer		
CFO	Chief Financial Officer		
CGC	(Belgian) Corporate Governance Code		
СНИ	Centre Hospitalier Universitaire		
СМО	Chief Medical Officer		
COGS	Cost Of Goods Sold		
CRA	Clinical Research Associate		
CRO	Contract Research Organization		
CTA	Clinical Trial Authorisation (in the EU)		
DMARD	Disease-Modifying Anti-Rheumatic Drugs		
D&O	Director and Officer		
DU	Delayed Union (fracture)		
EFDR/FEDER	European Regional Development Fund (Fonds Européen de Développement Régional)		
EEA	European Economic Area		
EMA	European Medicines Agency		
ERP (platform)	Enterprise Resource Planning (platform)		
EU	European Union		
FDA	Food and Drug Administration (in the US)		
FIEL	Financial Instruments and Exchange Law		
FSMA	Financial Services and Markets Authority in Belgium (Autorité des services et marchés financiers)		
FTT	Financial Transaction Tax		
GAAP	(Belgian) Generally Accepted Accounting Principles		
GCP	Good Clinical Practice		
GMP	Good Manufacturing Practice		
GIE	Groupement d'Intérêt Economique (Economic Interest Grouping)		
HCTS	Hepatic Cell Therapy Support SA		
IBGE	Institut Bruxellois pour la Gestion de l'Environnement		
IFRS	International Financial Reporting Standards		
IND	Investigational New Drug application (in the US)		
IRD	Inflammatory Rheumatic Disease		

MAA	Marketing Authorization Application
MSC	Mesenchymal Stem Cells
MTF	Multilateral Trading Facility
NU	Non-Union (fracture)
NSAID	Non-Steroidal Anti-Inflammatory Drugs
ODD	Orphan Drug Designation
OECD	The Organization for Economic Co-operation and Development
OFP	Organisations for Financing of Pensions
ON	Osteonecrosis
PEA	Personal Equity Plan
PEA PME-ETI	Plan d'Épargne en Actions destiné au financement des PME et ETI (Personal plan for equity of small and medium sized companies)
PPP	Public-Private Partnership
Pre-IND	Pre-Investigational New Drug
PWTC	Plateforme Wallonne de la Thérapie Cellulaire (Walloon Platform for cell therapy)
RCA(s)	Recoverable Cash Advance(s)
RA	Rheumatoid Arthritis
SCTS	Skeletal Cell Therapy Support SA
SISE	Société d'Infrastructures, de Services et d'Energies SA
SME	Small and Medium Enterprise
SF	Spinal Fusion
SIX	SIX Swiss Exchange
THA	Total Hip Arthroplasty
ULB	Université Libre de Bruxelles
ULg	Université de Liège
VAS	Visual Analogue Scale

## **ANNEX C – Financial information**

#### **Deloitte**

## **Bone Therapeutics SA**

# Auditor's report on the consolidated financial statements for the years ended 31 December 2012 and 31 December 2013

To the Board of Directors

We report on the financial information set out in Annex C of the prospectus of Bone Therapeutics SA (the "Company") and, together with its subsidiary, the "Group" (the "Investment Circular"). This financial information has been prepared for inclusion in the Investment Circular on the basis of the accounting policies set out in note 2 to the financial information. This report is required by Annex XXV item 20.1 of Commission Regulation (EC) No 809/2004 (the "Prospectus Directive Regulation") and is given for the purpose of complying with that requirement and for no other purpose.

#### Report on the consolidated financial statements – Unqualified opinion

We have audited the consolidated financial statements of Bone Therapeutics SA (the "Company") and together with its subsidiary, the "Group" for the years ended 31 December 2012 and 31 December 2013 prepared in accordance with International Financial Reporting Standards as adopted by the European Union.

The consolidated statement of financial position shows total assets of 12,811 (000) EUR for the year ended 31 December 2013 and 14,418 (000) EUR for the year ended 31 December 2012 and the consolidated statement of comprehensive income shows a consolidated loss (group share) of 4,079 (000) EUR for the year ended 31 December 2013 and 3,689 (000) EUR for the year ended 31 December 2012.

Board of directors' responsibility for the preparation of the consolidated financial statements

The board of directors is responsible for the preparation and fair presentation of consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and, for such internal control as the 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.

Auditor's responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit for the purposes of the Investment Circular. We conducted our audit in accordance with International Standards on Auditing (ISA). Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the Auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the Auditor considers internal control relevant to the group's preparation and fair presentation of consolidated financial statements 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the board of directors, as well as evaluating the overall presentation of the consolidated financial statements. We have obtained from the group's officials and the board of directors 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.

Our work has been carried out in accordance with ISA and not with other auditing or standards and practices generally accepted in jurisdictions outside Belgium, including the United States of America, and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

#### Unqualified opinion

In our opinion, the consolidated financial statements of Bone Therapeutics SA give a true and fair view, for the purposes of the Investment Circular, of the Group's net equity and financial position as of 31 December 2012 and 2013, and of its results and its cash flows for the years then ended, in accordance with International Financial Reporting Standards as adopted by the European Union.

#### Declaration

For the purposes of art. 61 of the Law of 16 June 2006, we are responsible for this report as part of the Investment Circular and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Investment Circular in compliance with Annex XXV item 1.2 and Annex III item 1.2 of the Prospectus Directive Regulation.

Liège, 20 January 2015

The Auditor

**DELOITTE Bedrijfsrevisoren / Reviseurs d'Entreprises** BV o.v.v.e. CVBA / SC s.f.d. SCRL Represented by Julie Delforge

## **Bone Therapeutics**

# Consolidated Financial Statements For the years ended 31 December 2012 and 2013

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## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS	Note	31/12/2013	31/12/2012	1/01/2012
(in thousands of euros)				
Non-current assets		4,724	2,650	2,004
Intangible assets	5.1.	60	19	4
Property, plant and equipment	5.2.	2,869	1,277	1,137
Investments in associates	5.3.	282	263	280
Financial assets	5.6.	180	163	59
Deferred tax assets	5.4.	1,333	927	523
Current assets		8,087	11,767	13,049
Trade and other receivables	5.5.	5,513	6,834	7,220
Other financial assets	5.6.	0	0	203
Other current assets		134	112	67
Cash and cash equivalents	5.7.	2,440	4,822	5,559
TOTAL ASSETS		12,811	14,418	15,053
			,	
EQUITY AND LIABILITIES	Note	31/12/2013	31/12/2012	1/01/2012
(in thousands of euros)	Note	31/12/2013	31/12/2012	1/01/2012
Equity	5.8.			
Equity attributable to owners of the Company		63	2,637	3,812
Share capital		9,288	8,417	6,943
Share premium		6,635	6,014	4,966
Retained earnings		(15,860)	(11,794)	(8,097)
Non-controlling interests		0	0	0
Total equity		63	2,637	3,812
				•
Non-current liabilities		6,502	5,926	4,840
Financial liabilities	5.9.	5,052	4,115	3,090
Deferred tax liabilities	5.4.	0	0	0
Other non-current liabilities	5.10.	1,450	1,811	1,750
Current liabilities		6,246	5,854	6,400
Financial liabilities	5.9.	509	192	152
Trade and other payables	5.11.	1,458	1,116	789
Current tax liabilities		0	0	0
Other current liabilities	5.12.	4,279	4,546	5,459
Total liabilities		12,748	11,780	11,241
TOTAL FOLLOW AND VALDY YOUR		·		
TOTAL EQUITY AND LIABILITIES		12,811	14,418	15,053

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

	_	Year ended 31 December	
(in thousands of euros)	Note	2013	2012
Revenue		0	0
Other operating income	6.1	3,394	3,057
Total operating income		3,394	3,057
Research and development expenses	6.2	(6,816)	(6,371)
General and administrative expenses	6.3	(621)	(348)
Operating profit/(loss)		(4,043)	(3,662)
Interest income	6.5	150	172
Financial expenses	6.5	(190)	(189)
Exchange gains/(losses)	6.5	(1)	(3)
Share of profit/(loss) of associates	6.5.	19	(17)
Profit/(loss) before taxes		(4,066)	(3,698)
Income taxes	6.4	0	0
PROFIT/(LOSS) FOR THE PERIOD		(4,066)	(3,698)
Other comprehensive income		0	0
TOTAL COMPREHENSIVE INCOME OF THE PERIOD		(4,066)	(3,698)
Basic and diluted loss per share (in euros)	6.6	(13.38)	(19.21)
Profit/(loss) for period attributable to the owners of the Company		(4,079)	(3,689)
Profit/(loss) for period attributable to the non-controlling interests		13	(9)
Total comprehensive income for the period attributable to the owners of the Company		(4,079)	(3,689)
Total comprehensive income for the period attributable to the non- controlling interests		13	(9)

## CONSOLIDATED STATEMENT OF CASH FLOWS

(in thousands of euros)	Note	Year ended 31 December 2013	Year ended 31 December 2012
CASH FLOW FROM OPERATING ACTIVITIES			
Operating profit/(loss)		(4,043)	(3,662)
Adjustments for:		, , ,	,
Depreciation, Amortisation and Impairments	5.1. & 5.2.	407	402
Grants income related to forgivable loans	6.1.	(2,383)	(1,939)
Grants income related to patents	6.1.	(87)	(113)
Grants income related to tax credit	6.1.	(405)	(404)
Other		83	1
Movements in working capital:			
Trade and other receivables (excluding government			
grants)		(170)	(136)
Trade and Other Payables		337	324
Cash generated from operations		(6,261)	(5,528)
Cash received from grants related to forgivable loans		2,913	1,395
Cash received from grants related to patents		75	83
Cash received from grants related to tax credit		0	0
Income taxes paid		0	0
Discontinued operations		0	0
Net cash used in operating activities		(3,274)	(4,050)
CASH FLOW FROM INVESTING ACTIVITIES			
Interests received		39	78
Purchases of property, plant and equipment		(1,710)	(533)
Purchases of intangible assets		(61)	(24)
Proceeds from other current financial assets		Ó	203
Payments to acquire financial investments		(17)	(104)
Discontinued operations		0	0
Net cash used in investing activities		(1,748)	(380)
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from government loans		1.248	598
Repayment of government loans		(135)	(125)
Reimbursements of other non-current liabilities		(375)	0
Proceeds from loans from related parties		500	750
Reimbursements of financial lease liabilities		(37)	(35)
Proceeds from financial loans		0	0
Proceeds from government grants		0	0
Interests paid		(52)	(18)
Proceeds from issue of equity instruments of the Company			
(net of issue costs)		1,491	2,522
Net cash provided by financing activities		2,641	3,692
NET INCOEASE (DECDEASE) IN CASH AND CASH			
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(2,381)	(737)
CASH AND CASH FOLLOWAL ENTER of hosinging of you		4 922	£ 550
CASH AND CASH EQUIVALENTS at beginning of yea CASH AND CASH EQUIVALENTS at end of year	1	4,822 2,440	5,559 4,822
order in the original and original orig		2,770	7,022

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

		Attributable to owners of the parent				
(in thousands of euros)	Share capital	Share premium	Retained earnings	Total equity attributable to owners of the Company	Non-controlling interests	TOTAL EQUITY
Balance at 1 January 2012	6,943	4,966	(8,097)	3,812	0	3,812
Total comprehensive income of the period	0	0	(3,689)	(3,689)	(9)	(3,698)
Issue of share capital	1,474	1,065	Ó	2,539	Ó	2,539
Transaction costs for equity issue	0	(17)	0	(17)	0	(17)
Mouvement non-controlling interests	0	0	(9)	(9)	9	0
Balance at 31 December 2012	8,417	6,014	(11,795)	2,636	0	2,637
Total comprehensive income of the period	0	0	(4,079)	(4,079)	13	(4,066)
Issue of share capital	871	629	0	1,500	0	1,500
Transaction costs for equity issue	0	(9)	0	(9)	0	(9)
Mouvement non-controlling interests	0	0	13	13	(13)	0
Other	0	0	1	1	0	1
Balance at 31 December 2013	9,288	6,635	(15,860)	63	0	63

#### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

#### 1. General information

Bone Therapeutics SA (the "**Company**") is a limited liability company governed by Belgian law. The address of its registered office is Rue Adrienne Bolland 8, 6041 Gosselies, Belgium.

The Company and its affiliate Skeletal Cell Therapy Support SA ("SCTS", together with the Company referred as the "Group") are active in regenerative therapy specialising in addressing unmet medical needs in the field of bone diseases and orthopaedics. The Company was incorporated by professionals from both the pharmaceutical industry and the hospital community. They share an in-depth knowledge of bone diseases and stem cell science, a strong expertise in cell manufacturing for human use, in cell therapy clinical trials and regulatory development.

The consolidated financial statements were authorised for issue by the Board of Directors on 8 January 2015.

### 2. Summary of significant accounting policies

The principal accounting policies applied in the preparation of the consolidated financial statements are set out below.

### Statement of compliance

The Group's consolidated financial statements for the year ended 31 December 2013 have been prepared for the first time in accordance with International Financial Reporting Standards as endorsed the European Union ("IFRS").

The impacts of the transition from Belgian GAAP to IFRS on the Group's reported financial position and financial performance are detailed in note 4 below in accordance with IFRS 1 – *First-time Adoption of IFRS*.

The Group has consistently applied the accounting policies used in the preparation of its opening IFRS statement of financial position on 1 January 2012 throughout all periods presented, unless stated otherwise.

# Applicable IFRS standards and interpretations

The Group has applied IFRS standards and interpretations that are effective at the closing date of these first IFRS financial statements. In addition, the following standards and amendments that otherwise become effective as from 1 January 2014, have been early applied in the preparation of these first IFRS financial statements closed on 31 December 2013:

- IFRS 10 Consolidated Financial Statements
- IFRS 11 Joint Arrangements
- IFRS 12 Disclosures of Interests in Other Entities
- IAS 28 Investments in Associates and Joint Ventures
- Amendments to IFRS 10, IFRS 12 and IAS 27 Consolidated Financial Statements and Disclosure of Interests in Other Entities: Investment Entities

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 2013:

- IFRS 9 *Financial Instruments* and subsequent amendments (normally applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in EU)
- IFRS 15 *Revenue from Contracts with Customers* (applicable for annual periods beginning on or after 1 January 2017)
- Improvements to IFRS (2010-2012) (normally applicable for annual periods beginning on or after 1 January 2015, but not yet endorsed in EU)

- Improvements to IFRS (2011-2013) (normally applicable for annual periods beginning on or after 1 January 2015, but not yet endorsed in EU)
- Improvements to IFRS (2012-2014) (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IAS 19 *Employee Benefits* Employee Contributions (applicable for annual periods beginning on or after 1 January 2015, but not yet endorsed in EU)
- Amendments to IAS 36 *Impairment of Assets* Recoverable Amount Disclosures for Non-Financial Asset (applicable for annual periods beginning on or after 1 January 2014)
- IFRIC 21 *Levies* (applicable for annual periods beginning on or after 17 June 2014)
- Amendments to IAS 16 and IAS 38 Clarification of Acceptable Methods of Depreciation and Amortisation (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IFRS 11 Accounting for Acquisitions of Interests in Joint Operations (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IFRS 10 and IAS 28 Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)

It is not expected that the initial application of the above mentioned IFRS standards, interpretations and amendments will have a significant impact on the consolidated financial statements.

# Basis of preparation

The consolidated financial statements are presented in thousands of euros, unless otherwise stated. Euro is also the functional currency of both the Company and SCTS. The functional currency is the currency of the economic environment in which an entity operates. The consolidated financial statements have been prepared on a historical basis, unless otherwise stated.

# Basis of consolidation

The consolidated financial statements incorporate the financial statements of the Company and entities directly or indirectly controlled by the Company.

Control is achieved when the Company:

- has power over the investee;
- is exposed, or has rights, to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

The Company reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. When the Company has less than a majority of the voting rights of an investee, it has power over the investee when the voting rights are sufficient to give it the practical ability to direct the relevant activities of the investee unilaterally. The Company considers all relevant facts and circumstances in assessing whether or not the Company's voting rights in an investee are sufficient to give it power, including:

- the size of the Company's holding of voting rights relative to the size and dispersion of holdings of the other vote holders;
- potential voting rights held by the Company, other vote holders or other parties;
- rights arising from other contractual arrangements; and
- any additional facts and circumstances that indicate that the Company has, or does not have, the current ability to direct the relevant activities at the time that decisions need to be made.

Consolidation of a subsidiary begins when the Company obtains control over the subsidiary and ceases when the Company loses control of the subsidiary. Specifically, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated statement of profit or loss and other comprehensive income from the date the Company gains control until the date when the Company ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the owners of the Company and to the non-controlling interests.

All intragroup assets and liabilities, income, expenses and cash flows relating to transactions between members of the Group are eliminated in full on consolidation.

Changes in the Group's ownership interests in subsidiaries that do not result in the Group losing control over the subsidiaries are accounted for as equity transactions. The carrying amounts of the Group's interests and the non-controlling interests are adjusted to reflect the changes in their relative interests in the subsidiaries. Any difference between the amount by which the non-controlling interests are adjusted and the fair value of the consideration paid or received is recognised directly in equity and attributed to owners of the Company.

When the Group loses control of a subsidiary, the Group derecognises the assets and liabilities of the former subsidiary from the consolidated statement of financial position. The gain or loss associated with the loss of control attributable to the former controlling interest is recognised in profit or loss. The Group recognises any investment retained in the former subsidiary when control is lost and subsequently accounts for it under the equity method if the former subsidiary qualifies as an associate or a joint venture (see section on investments in associates and joint ventures below), or at fair value if the investment in the former subsidiary qualifies as a financial asset in the scope of IAS 39.

# Investments in associates and joint ventures

An associate is an entity over which the Group has significant influence and that is neither a subsidiary nor an interest in a joint arrangement. Significant influence is the power to participate in the financial and operating policy decisions of the investee but is not control or joint control over those policies.

A joint arrangement is an arrangement of which two or more parties have joint control, which exists only when the decisions about the relevant activities require the unanimous consent of the parties sharing control. Amongst joint arrangements, a distinction is made between joint operations and joint ventures. In a joint operation, parties have rights to the assets, and obligations for the liabilities relating to the joint arrangement. In a joint venture, parties have rights to the net assets of the arrangement.

In its consolidated financial statements, the Group uses the equity method of accounting for investments in associates and joint ventures. Under the equity method, the investment is initially recognised at cost in the consolidated statement of financial position and adjusted thereafter to recognise the Group's share of the profit or loss and other comprehensive income of the associate or joint venture.

An investment in an associate or joint venture is accounted for using the equity method from the date on which the investee becomes an associate or joint venture. On acquisition of the investment, any excess of the cost of the investment over the Group's share of the net fair value of the identifiable assets and liabilities of the investee is recognised as goodwill, which is included in the carrying amount of the investment. Any excess of the Group's share of the net fair value of the identifiable assets and liabilities over the cost of the investment, after reassessment, is recognised immediately in profit or loss in the period in which the investment is acquired.

The Group discontinues the use of the equity method from the date when the investment ceases to be an associate or a joint venture or when the investment is classified as held for sale.

### Intangible assets

Intangible assets acquired separately or in the context of a business combination

Intangible assets are recognised if and only if it is probable that future economic benefits associated with the asset will flow to the Group and the cost of that asset can be measured reliably. Intangible assets with finite useful lives that are acquired separately are measured at cost less accumulated amortisation 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. Amortisation is recognised on a straight-line basis over the estimated useful lives. The estimated useful life and amortisation 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. Recognition of costs in the carrying amount of an intangible asset ceases when the asset is in the condition necessary for it to be capable of operating in the manner intended by the Group.

Intangible assets acquired in a business combination are measured at fair value at the date of acquisition. Subsequent to initial recognition, intangible assets acquired in a business combination are subject to amortisation and impairment test, on the same basis as intangible assets that are acquired separately.

Intangible assets	Estimated useful life
Software	3 years

An intangible asset is derecognised 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 recognised in profit or loss when the asset is derecognised.

*Internally-generated intangible assets* 

To assess whether an internally generated intangible asset meets the criteria for recognition, the Group classifies the internal generation of assets into a research phase and a development phase.

No intangible asset arising from research is recognised. Expenditure on research is recognised as an expense when it is incurred.

An intangible asset arising from development is recognised if, and only if, the Group 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.

Management uses its judgement to assess whether the above conditions are met. With respect to the technical feasibility condition, a strong evidence is achieved only when Phase III of the related development project is successfully completed.

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).

After initial recognition, intangible assets are measured at cost less accumulated amortisation and any accumulated impairment losses. Intangible assets are amortised on a straight-line basis over their estimated useful life. Amortisation begins when the asset is capable of operating in the manner intended by management.

#### Property, plant and equipment

Property, plant and equipment are recognised as assets at acquisition or production cost if and only if it is probable that future economic benefits associated with the asset will flow to the Group and the cost of the asset can be measured reliably. The cost of an item of property, plant and equipment comprises its purchase or production price and any costs directly attributable to bringing the asset to the location and condition necessary for it to be capable of operating in the manner intended by management, together with the initial estimation of the costs of dismantling and removing the asset and restoring the site on which it is located, if applicable.

After initial recognition at historical cost, property, plant and equipment owned by the Group are depreciated using the straight-line method and are carried on the balance sheet at cost less accumulated depreciation and impairment. Depreciation begins when the asset is capable of operating in the manner intended by management and is charged to profit or loss, unless it is included in the carrying amount of another asset. The components of an item of property, plant and equipment with a significant cost and different useful lives are recognised separately. Lands are not depreciated. The residual value and the useful life of property, plant and equipment are reviewed at least at the end of each reporting period. The depreciation method is also reviewed annually.

Property, plant and equipment	Estimated useful life
Office furniture	4 years
Lab equipment	3 to 5 years
IT equipment	3 years

An item of property, plant and equipment is derecognised upon disposal or when no future economic benefits are expected to arise from the continued use of the asset. Any gain or loss arising on the disposal or retirement of an item of property, plant and equipment is determined as the difference between the sales proceeds and the carrying amount of the asset and is recognised in profit or loss.

# Leases

The Group classifies leases as finance leases whenever the terms of the lease transfer substantially all the risks and rewards of ownership to the lessee. All other leases are classified as operating leases. Classification is made at the inception of the lease.

#### Finance leases

Assets held under finance leases by the Group are recognised as assets at their fair value or, if lower, at the present value of the minimum lease payments. The corresponding liability is included in the consolidated statement of financial position as a finance lease obligation. Assets held under finance leases are depreciated over their estimated useful live on a systematic basis consistent with the depreciation policy for depreciable assets that are owned by the Group or, if shorter, over the lease term. Lease payments are apportioned between finance expenses and the reduction of the lease obligation.

Assets owned by the Group and leased to third parties under finance leases are derecognised and a receivable is recognised as an asset in the consolidated statement of financial position for an amount equal to the net investment in the lease contract. The recognition of financial income is made based on pattern reflecting a constant periodic rate of return on the lessor's net investment in the finance lease.

# Operating leases

Assets held by the Group under operating leases are not recognised in the statement of financial position. Operating lease payments are recognised as expenses in the period in which they are incurred on a straight-line basis over the lease term.

Assets owned by the Group and leased to third parties under operating leases are not derecognised from the statement of financial position. Rental income from operating lease is recognised as income on a straight-line

basis over the lease term. The depreciation method used for the assets leased under operating leases is consistent with the method used for similar assets that are not subject to a lease agreement.

### <u>Impairment of tangible and intangible assets</u>

At the end of each reporting period, the Group assess whether there is any indications that an asset may be impaired. If any such indication exists, the recoverable amount of the asset is estimated in order to determine the extent of the impairment loss, if any. Recoverable amounts of intangible assets with an indefinite useful life and intangible assets not yet available for use are tested for impairment at least annually, and whenever there is an indication that the asset may be impaired. Where it is not possible to estimate the recoverable amount of an individual asset, the Group estimates the recoverable amount of the cash-generating unit to which the asset belongs.

Recoverable amount is the higher of an asset's fair value less costs of disposal and its value in use. The value in use is the present value of the future cash flows expected to be derived from an asset or cash-generating unit. In assessing the value in use, the estimated 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 for which the estimates of future cash flows have not been adjusted.

An impairment loss is recognised whenever recoverable amount is below carrying amount. If the recoverable amount of an asset (or cash-generating unit) is estimated to be less than its carrying amount, the carrying amount of the asset (or cash-generating unit) is reduced to its recoverable amount. An impairment loss is recognised immediately in profit or loss.

Where an impairment loss subsequently reverses, the carrying amount of the asset (or a cash-generating unit) 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 recognised for the asset (or cash-generating unit) in prior years. A reversal of an impairment loss is recognised immediately in profit or loss. An impairment loss on goodwill can never be reversed.

# Financial assets

Financial assets are classified in one of the following categories: financial assets at fair value through profit or loss (FVTPL), loans and receivables, available-for-sale financial assets (AFS) and held-to-maturity investments.

### Loans and receivables

Loans and receivables (trade and other receivables) are financial assets with fixed or determinable payments that are not quoted in an active market. They are initially recognised at their fair value, plus transaction costs. After their initial recognition, these financial assets are measured at amortised cost using the effective interest method, less any impairment. Interest income is recognised by applying the effective interest rate. An impairment loss is recognised if there is any indication that the Group might not recover all the amounts due. Gains or losses are recognised in the statement of profit and loss when the financial asset recognised at amortised cost is derecognised or impaired.

The effective interest method is a method of calculating the amortised cost of a financial asset (or a financial liability) and of allocating interest income or expenses over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash inflows (or outflows) through the expected life of the financial instrument or, where appropriate, a shorter period so as to determine the net carrying amount for the financial asset (or the financial liability).

Receivables related to government grants, including forgivable loans ("avances récupérables"), are recognised when there is reasonable assurance that the Group will comply with the conditions attaching to them and the grant will be received, which generally corresponds to the date at which the Group obtains a confirmation letter from the authorities (see "government grants" below).

Available-for-sale financial assets (AFS)

AFS financial assets include investments in entities that are neither consolidated nor recognised using the equity method. They are measured at fair value and the changes are recognised directly in other comprehensive income (equity). Once it has been determined that an AFS financial asset is impaired, the cumulative loss that had been

recognised directly in other comprehensive income is recycled in profit or loss. AFS financial assets whose fair value cannot be reliably determinable are measured at cost.

### Held-to-maturity investments

Held-to-maturity investments are non-derivative financial assets with fixed or determinable payments that the Group intends and is able to hold to maturity and that do not meet the definition of loans and receivables and are not designated on initial recognition as assets at fair value through profit or loss or as available for sale. Held-to-maturity investments are measured at amortised cost.

Financial assets at fair value through profit or loss

This category has two subcategories:

- Financial assets designated as at fair value through profit or loss: financial asset that is designated on initial recognition as one to be measured at fair value with fair value changes in profit or loss.
- Financial assets held for trading: all derivative financial assets (except those designated hedging instruments) and financial assets acquired or held for the purpose of selling in the short term or for which there is a recent pattern of short-term profit taking are held for trading.

# Cash and cash equivalents

Cash and cash equivalents include cash on hand and in banks, as well as short-term deposits with a maturity of three months or less.

### Financial liabilities

Financial liabilities are classified as either financial liabilities at fair value through profit or loss or as other financial liabilities.

Financial liabilities classified as other liabilities include borrowings contracted by the Group and trade and other payables, including the portion of forgivable loans ("avances récupérables") that is expected to be reimbursed. They are initially measured at their fair value less transaction costs, which corresponds to the present value of amounts expected to be reimbursed for forgivable loans recognised as financial liabilities to the extent no interest is charged on these loans. Subsequently, financial liabilities are measured at amortised cost using the effective interest method less repayments of principal. Interest expense is recognised using the effective interest rate.

Financial liabilities at fair value through profit or loss include all derivative financial liabilities, except those designated as hedging instruments.

# Income tax

The tax currently payable is based on taxable profit for the year, which differs from profit as reported in the consolidated statement of profit and loss because of items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible. Income tax for the current and prior periods is recognised as a liability to the extent that it has not yet been settled, and as an asset to the extent that the amounts already paid, exceeds the amount due. The Group's current tax is calculated using tax rates that have been enacted or substantively enacted by the end of the reporting period.

Deferred taxes are recognised on temporary differences between the carrying amounts of assets and liabilities in the financial statements and the corresponding tax bases used in the computation of taxable profit.

Deferred tax liabilities are recognised for all taxable temporary differences. Deferred tax assets are recognised for all deductible temporary differences and tax losses carried-forward to the extent that it is probable that taxable profits will be available against which those deductible temporary differences and tax losses carried-forward can be utilised. Such deferred tax assets and liabilities are not recognised if the temporary difference arises from the initial recognition (other than in a business combination) of assets and liabilities in a transaction that affects neither the taxable profit nor the accounting profit.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rates/laws that have been enacted or substantively enacted by the end of the reporting period. The measurement reflects the Group's expectations, at the end of the reporting period, as to the manner in which the carrying amount of its assets and liabilities will be recovered or settled.

# 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 Group in return for past or future compliance with certain conditions.

The Group recognises a government grant only when there is reasonable assurance that the Group will comply with the conditions attached to the grant and the grant will be received. As such, a receivable is recognised in the statement of financial position and measured in accordance with the accounting policy mentioned above (see "loans and receivables").

With respect to forgivable loans ("avances récupérables"), only the portion of the loan for which there is a reasonable assurance that the Group will meet the terms for forgiveness is recognised as government grant. The Group recognises the portion of forgivable loans that is expected to be reimbursed as a liability. This liability is initially measured at fair value, which corresponds to the present value of the amounts expected to be reimbursed as forgivable loans do not bear interests (see "financial liabilities" above).

In addition, the benefit of a government loan without interest or at a below market rate of interest is treated as a government grant and measured as the difference between the initial discounted value of the loan and the proceeds received or to be received.

Government grants are recognised in profit or loss on a systematic basis over the periods in which the Group recognises as expenses the related costs which the grants are intended to compensate. As a result, grants relating to costs that are recognised 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 recognised in the profit or loss statement consistently with the amortisation or depreciation expense of the related assets. Grants that intend to compensate costs that are expensed as incurred are released as income when the subsidised costs are incurred, which is the case for grants relating to research and development costs expensed as incurred.

Government grants that become receivable as compensation for expenses or losses already incurred are recognised in profit or loss of the period in which they become receivable.

The portion of grants not yet released as income is presented as deferred income in the statement of financial position. 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.

# **Share-based payments**

A share-based payment is a transaction in which the Group receives goods or services either as consideration for its equity instruments or by incurring liabilities for amounts based on the price of the Group's shares or other equity instruments of the Group. The accounting for share-based payment transactions depends on how the transaction will be settled, that is, by the issuance of equity, cash, or both 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 Group's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognised in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled employee benefits reserve.

For cash-settled share-based payments, a liability is recognised for the goods or services acquired, measured initially at the fair value of the liability. At the end of each reporting period until the liability is settled, and at

the date of settlement, the fair value of the liability is re-measured, with any changes in fair value recognised in profit or loss for the year.

### **Provisions**

A provision is recognised when the Group has a present obligation (legal or constructive), at the end of the reporting period, as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligations and a reliable estimate can be made of the amount of the obligation. The amount recognised as a provision is the best estimate of the consideration required to settle the present obligation at the end of the reporting period. When a provision is measured using the cash flows estimated to settle the present obligation, its carrying amount is the present value of those cash flows when the effect of time value of money is material.

### **Employee benefits**

The Company offers post-employment, death, disability and healthcare benefit schemes to certain categories of employees.

Disability, death and healthcare benefits granted to employees of the Company are covered by an external insurance company, where premiums are paid annually and expensed as they were incurred.

Some employees of the Group were granted a post-employment pension plan for which the fixed contributions made to an external insurance company are subject to a minimum return guaranteed by the Belgian legislation. The related contributions are expensed when they are incurred and a post-employment provision is recognised only to the extent the benefits accumulated by the employees taking into account the minimum guaranteed return exceed the actual plan assets at closing date.

#### Revenue recognition

The Group is currently not generating revenue from contracts with customers. Most income recognised by the Group is resulting from government grants.

An accounting policy will be developed in accordance with relevant IFRS requirements when revenue generating arrangements will be entered into by the Group.

# Events after the reporting period

Events after the reporting period which provide additional information about the Group's position at the closing date (adjusting events) are reflected in the financial statements. Events after the reporting period which are not adjusting events are disclosed in the notes if material.

# 3. Critical accounting judgements and key sources of estimation uncertainty

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 years:

### Going-concern

The 2013 consolidated results of the Company show a loss of  $\in$  4,066,000, and the consolidated statement of financial position includes a loss carried forward of  $\in$  15,860,000. These consolidated financial statements have been prepared assuming that the Group will continue as a going concern considering:

- the cash balance as per the beginning of January 2015 amounting to € 10.4 million (mainly resulting from the issue of convertible bonds on 18 December 2014 for a gross amount of € 10.0 million);
- In case of a successful IPO, the amount of funds raised in this context; and
- In case of no IPO taking place, the firm commitment of the bond holders to invest a further amount of € 10.0 million on 30 September 2015 (unconditional); and
- the support from the region through non-dilutive financing instruments to support on-going and new research projects.

Considering all these elements, management is of the opinion that the Group's financial future is guaranteed in the near future.

#### **Investment in SCTS**

Despite a holding of 49.9% in SCTS, management concluded that the Company controls SCTS considering the combination of the following elements:

- The purpose and design of SCTS are specific to the Company's needs with respect to R&D and production activities, including the construction of a building specific to the production needs of the Company;
- The Company reached the majority on all general assemblies of SCTS since its incorporation; and
- The Company has the option to buy (call option) the SCTS shares held by other shareholders as from 1 January 2014.

# Put and call on non-controlling interests in SCTS

The Company has granted to the 50.1% non-controlling interests in SCTS an option to sell (put option) their SCTS shares to the Company. This put option is exercisable as from 1 January 2020 at a strike price amounting to the net assets of SCTS multiplied by the percentage held, with a minimum price floored at 90% of the share subscription value. This put option on non-controlling interests (own equity instrument) gives rise to a gross liability that is initially recognised against equity and measured at the present value of the redemption amount (strike price). This gross liability is subsequently measured at fair value with changes in fair value recognized in profit or loss.

In this context, management made estimations in measuring the expected net assets of SCTS on 1 January 2020 taking into account that the SCTS shareholders' agreement prescribes in substance that a minimum return of 6.5% shall be reached on the investment as from the fourth year of SCTS incorporation. The expected net assets value has been discounted to the reporting date using a rate of 3.5% (see also note 4.2.2).

In the statement of financial position on 31 December 2013, the fair value of the gross liability for the put option on non-controlling interests in SCTS amounts to  $\in$  1,450,000.

In addition, the Company holds an option to buy (call option) the 50.1% non-controlling interests in SCTS. This call option is exercisable from 1 January 2014 until 31 December 2019 at such a strike price that non-controlling interests realize an internal rate of return reaching 8% on capital contributed to SCTS. This call option is a derivative financial asset of the Company. Considering however that the strike price is based on a return of 8% whereas the minimum agreed return is limited to 6.5% as from the fourth year of SCTS incorporation, management concluded that this call option will always be out of the money. As a result, the fair value of this derivative financial asset is negligible.

#### Recognition of development costs as intangible assets

Consistently with industry practices, management concluded that development costs incurred by the Group do not meet the recognition conditions before Phase III of the related development project is finalised.

### Forgivable loans

Management uses its judgement to estimate the portion of forgivable loans for which there is reasonable assurance that the terms for forgiveness will be met. Consistently with past practices, management expects that it will decide to exploit the results of the R&D project, which triggers the repayment of a portion of the loan (typically 30% in nominal terms) that is recognised as a liability and measured at the present value of the amounts expected to be reimbursed using a market-based discount factor as the loans do not bear interests. Similarly, management expects that revenue potentially generated from the R&D project within 10 years after the exploitation date is insignificant considering the length of the products' development cycle, and consequently that there is reasonable assurance that the remaining part (typically 70% in nominal terms) of the loan will be forgiven. Note 8.4 on contingent liabilities provides additional information on that portion of forgivable loans that might become partially reimbursable.

# Recognition of deferred tax assets

Deferred tax assets are recognised 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 recognised as of 31 December 2012 and 2013, except for the deferred tax asset related to the R&D tax credit as this is independent from future taxable profit

#### 4. Transition to IFRS

The consolidated financial statements for the period ended 31 December 2013 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 2012. Therefore, an audited opening IFRS statement of financial position has been prepared as per 1 January 2012, which is the date of transition to IFRS. On this date, the impacts of changes in accounting policies from BeGAAP to IFRS are recognised against equity ( $retained\ earnings$ ) in accordance with IFRS 1 – First-time  $Adoption\ of\ IFRS$ .

The objective of this note is to provide a reconciliation of the effects of both the first consolidation and the first-time adoption of IFRS on the Company's financial statements, including:

- A reconciliation of the individual financial statements of the Company (parent) and SCTS (subsidiary) prepared and filed under BeGAAP, to the consolidated financial statements of the Group prepared under BeGAAP for the year 2012 (see note 4.1.);
- A reconciliation of the consolidated equity under BeGAAP at 1 January 2012 (i.e. date of transition to IFRS) and 31 December 2012 to the consolidated equity under IFRS at the same dates (see note 4.2);
- A reconciliation of the consolidated result under BeGAAP to the consolidated result under IFRS for the year 2012 (see note 4.2);

The source of each adjustment is explained in the note below.

The Company did not prepare a cash flow statement in its individual financial statements under BeGAAP.

# 4.1. Consolidated financial statements

The Company owns 49.9% of the share capital of SCTS, whereas the remaining 50.1% are owned by the Walloon Region (23.5%), Sambrinvest (12.7%) and seven other parties individually holding between 1.2% and 3.9% (13.9% in total). SCTS is a service company dedicated to the specific needs of the Company and whose purpose is to provide logistic support with respect to the R&D and production activities, including the construction of a building specific to the production needs of the Company.

Considering the specific purpose and design of SCTS as described above together with the fact that the Company always reached the majority on the general assembly of SCTS with 49.9% of its share capital, and the fact that the Company has the option to buy (call option)<sup>81</sup> the SCTS shares held by other shareholders as from 1 January 2014, it has been concluded that the Company controls SCTS in accordance with IFRS 10 – *Consolidated Financial Statements*. As a result, the IFRS financial statements of the Company shall be prepared on a consolidated basis.

As the Company did not prepare consolidated financial statements in accordance with BeGAAP, the table below reconciles the preparation of the consolidated statement of financial position and consolidated statement of comprehensive income on the basis of the individual financial statements of the Company (parent) and SCTS (subsidiary) prepared under BeGAAP and publicly filed for the year 2012.

Those consolidated statements prepared in accordance with BeGAAP recognition and measurement principles are already presented in a format that is compliant with the IFRS presentation requirements.

Consolidated statement of financial position at 1 January 2012 under BeGAAP (IFRS format)

1/01/2012 **ASSETS** Consolidation **BoneTherapeutics SCTS** Total adjustments (in thousands of euros) 7,355 Non-current assets 8,350 280 (1,275)Intangible assets 5,878 0 5,878 0 Property, plant and equipment 1,137 0 0 1,137 Investments in associates 1,275 280 (1,275)280 Financial assets 59 0 59 Deferred tax assets 0 0 0 9.039 **Current assets** 6,389 2,650 0 Trade and other receivables 3,209 0 3,209 0 Other financial assets 0 0 203 203 0 Other current assets 67 0 67 Cash and cash equivalents 2,909 2,650 0 5,559 TOTAL ASSETS 14,738 2,930 (1,275)16,393

<sup>&</sup>lt;sup>81</sup> According to the SCTS shareholders' agreement, Bone has also granted a put option to the other shareholders of SCTS. This put option triggers an IFRS adjustment that is addressed under note 4.2.2. (put on non-controlling interests).

1/01/2012

EQUITY AND LIABILITIES (in thousands of euros)	BoneTherapeutics	SCTS	Consolidation adjustments	Total
Equity				
Equity attributable to owners of the				
Company	7,194	2,930	(2,930)	7,194
Share capital	6,943	2,930	(2,930)	6,943
Share premium	5,017	0	0	5,017
Retained earnings	(4,767)	0	0	(4,767)
Non-controlling interests	0	0	1,655	1,655
Total equity	7,194	2,930	(1,275)	8,849
Non-current liabilities	1,134	0	0	1,134
Financial liabilities	1,134	0	0	1,134
Deferred tax liabilities	0	0	0	0
Current liabilities	6,411	0	0	6,411
Financial liabilities	99	0	0	99
Trade and other payables	789	0	0	789
Other current liabilities	5,522	0	0	5,522
Total liabilities	7,545	0	0	7,545
TOTAL EQUITY AND LIABILITIES	14,738	2,930	(1,275)	16,393

Consolidated statement of comprehensive income for the year 2012 under BeGAAP (IFRS format)

		31/12/20	)12	
(in thousands of euros)	Bone Therapeutics	SCTS	Consolidation adjustments	Total
Revenue	0	0	0	0
Other operating income	7,819	425	(231)	8,013
Total operating income	7,819	425	(231)	8,013
Research and development expenses	(9,584)	(465)	182	(9,867)
General and administrative expenses	(344)	(4)	0	(348)
Other operating expenses	(433)	0	0	(433)
Operating profit/(loss)	(2,542)	(44)	(49)	(2,634)
Interest income	35	28	0	63
Financial expenses	(19)	0	0	(19)
Exchange gains/(losses)	(10)	0	0	(10)
Share of profit/(loss) of associates	0	0	(17)	(17)
Result Profit/(loss) before taxes	(2,534)	(15)	(65)	(2,615)
Income taxes	0	0	0	0
PROFIT/(LOSS) FOR THE PERIOD	(2,534)	(15)	(65)	(2,615)
Other comprehensive income	0	0	0	0
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	(2,534)	(15)	(65)	(2,615)

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ASSETS (in thousands of euros)	Bone Therapeutics	SCTS	Consolidation adjustments	Total			
Non-current assets	9,990	707	(1,292)	9,405			
Intangible assets	7,697	4	0	7,701			
Property, plant and equipment	855	422	0	1,277			
Investments in associates	1,275	280	(1,292)	263			
Financial assets	163	0	0	163			
Deferred tax assets	0	0	0	0			
Current assets	7,728	2,501	(231)	9,999			
Trade and other receivables	4,707	589	(231)	5,066			
Other financial assets	0	0	0	0			
Other current assets	110	2	0	112			
Cash and cash equivalents	2,912	1,910	0	4,822			
TOTAL ASSETS	17,718	3,208	(1,522)	19,404			

# 31/12/2012

EQUITY AND LIABILITIES (in thousands of euros)	BoneTherapeutics	SCTS	Consolidation adjustments	Total			
Equity							
Equity attributable to owners of the Company	7,198	2,915	(2,987)	7,126			
Share capital	8,417	2,930	(2,930)	8,417			
Share premium	6,083	0	0	6,083			
Retained earnings	(7,301)	(15)	(57)	(7,373)			
Non-controlling interests	0	0	1,646	1,646			
Total equity	7,198	2,915	(1,340)	8,772			
Non-current liabilities	2,074	0	0	2,074			
Financial liabilities	2,074	0	0	2,074			
Deferred tax liabilities	0	0	0	0			
Current liabilities	8,446	293	(182)	8,558			
Financial liabilities	189	0	0	189			
Trade and other payables	1,190	108	(182)	1,116			
Other current liabilities	7,068	185	0	7,253			
Total liabilities	10,520	293	(182)	10,632			
TOTAL EQUITY AND LIABILITIES	17,718	3,208	(1,522)	19,404			

#### 4.2. IFRS adjustments on the consolidated equity and result 2012

#### 4.2.1. Overview

(in thousands of euros)	Reference	Equity per 01/01/20 12	Result 2012	Other comprehensi ve income 2012	Other moveme nts 2012	Equity per 31/12/201 2
Consolidated BeGAAP		8,849	(2,615)	0	2,539	8,772
Put on non-controlling interests	(1)	(1,750)	(61)	0	0	(1,811)
R&D	(2)	(5,470)	(1,664)	0	0	(7,134)
Patents	(3)	(356)	(139)	0	0	(495)
Costs related to capital increases	(4)	(48)	11	0	(17)	(54)
Government grants - Forgivable loans	(5)	1,905	609	0	0	2,514
Government grants - Patents	(6)	252	41	0	0	293
Government grants - Other	(7)	32	(20)	0	0	12
Government grants - Tax credit	(8)	399	142	0	0	540
Deferred Taxes	(9)	0	0	0	0	0
Total IFRS adjustments		(5,036)	(1,083)	0	(17)	(6,136)
Consolidated IFRS		3,812	(3,698)	0	2,522	2,637

The application of IFRS on the consolidated financial statements resulted to a decrease of equity for an amount  $\in 5,036,000$  as per 1 January 2012 and  $\in 6,136,000$  as per 31 December 2012, whereas the result of the year 2012 decreased by  $\in 1,083,000$ .

The nature of each IFRS adjustment is further explained below.

# 4.2.2. IFRS adjustments

For the preparation of the opening consolidated statement of financial position as per 1 January 2012 the Company did not retain any specific exemptions that are available to first-time adopters of IFRS in accordance with IFRS 1.

The consolidated statement of financial position prepared under BeGAAP as per 1 January 2012 has been adjusted for the preparation of the opening statement of financial position in accordance with IFRS effective on 31 December 2013, which is the closing date of the first IFRS financial statements. In accordance with IFRS, the impacts resulting from the application of the new accounting framework have been recognized against the opening equity (*retained earnings*) as per 1 January 2012. However, certain adjustments did not have an impact on equity. These are also disclosed in below.

# (1) Put on non-controlling interests

As mentioned under section 4.1 above, the Company controls SCTS in accordance with IFRS 10 – Consolidated Financial Statements. According to the SCTS shareholders' agreement, the Company has granted to the 50.1% non-controlling interests in SCTS an option to sell (put option) their SCTS shares to the Company. This put option is exercisable as from 1 January 2020 at a strike price amounting to the net assets of SCTS multiplied by the percentage held, with a minimum price floored at 90% of the share subscription value. In accordance with IAS 32 – Financial Instruments: Presentation, this put option on non-controlling interests (own equity instrument) gives rise to a gross liability that shall initially be recognised against equity and measured at the

present value of the redemption amount (strike price), even if the obligation to purchase is conditional on the counterparties exercising the put option. In accordance with IAS 39 – *Financial Instruments: Recognition and Measurement*, this gross liability is subsequently measured at fair value with changes in fair value recognized in profit or loss.

Based on the above IFRS requirements, a gross liability is recognised against equity in the opening statement of financial position and the increase in the fair value of this liability negatively impacts the 2012 result of the Group compared to BeGAAP.

#### (2) R&D

In accordance with IAS 38 – *Intangible Assets*, research costs should always be expensed as incurred, whereas an intangible asset arising from the development phase of an internal project should be recognised if and only if the Group can demonstrate all of the following:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- its intention to complete the intangible asset and use or sell it;
- its 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
- its ability to measure reliably the expenditure attributable to the intangible asset during its development.

The Group is currently developing two first-in-class products that are in clinical development:

- PREOB<sup>®</sup>, an autologous osteoblastic cell product currently in Phase III clinical trials for the treatment of osteonecrosis and non-union fractures, and in a Phase I/IIa for severe osteoporosis.
- ALLOB<sup>®</sup>, an allogeneic ("off-the-shelf") osteoblastic cell product currently in a Phase I/IIa for the treatment of delayed union

Since the clinical phases for both products have not yet been completed, the Group cannot demonstrate yet that they will generate probable future economic benefits. Accordingly, the Group has not recognised any intangible assets arising from the research and development phases of its products. Under BeGAAP, both research and development costs are capitalised and amortised on a straight line basis over 3 years. Consequently, the adoption of IFRS led to the reversal of all capitalised R&D costs in the opening statement of financial position. In addition, the 2012 amortisation of capitalised R&D under BeGAAP has been reversed and the R&D costs incurred in 2012 have been immediately expensed in accordance with IFRS, which combined effect had a negative impact on the 2012 result of the Group.

# (3) Patents

As part of its activity, the Group frequently seeks to obtain patents in order to protect its R&D results and related intellectual property. In accordance with IAS 38 – *Intangible Assets*, 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. Directly attributable costs include fees to register a legal right. Since an internally generated intangible asset cannot be recognised for development costs incurred (see adjustment (2) above), the fees linked to the related patent registration are also expensed as incurred. Under BeGAAP, these costs are capitalised as intangible assets and amortised over a period of 5 years. The adoption of IFRS led thus to the reversal of the patent costs capitalised under BeGAAP in the opening statement of financial position, as well as the reversal of related patent amortisation expenses in the 2012 result of the Group.

### (4) Costs related to capital increases

In accordance with IAS 32 – Financial Instruments: Presentation, transactions costs relating to an equity transactions, such as a capital increase, are immediately accounted for as a deduction from equity, whereas such costs can be capitalised as formation expenses in accordance with BeGAAP. Therefore, the adoption of IFRS

led to the reversal of all capitalised formation expenses in the opening statement of financial position, as well as the reversal of related amortisation expenses in the 2012 result of the Group

#### (5) Forgivable loans

The Group obtained several forgivable loans from the Walloon Region. These loans become refundable under certain conditions, including the fact that the Group decides to exploit the R&D results of the project. In such case, part of the loan (typically 30%) becomes refundable within an agreed schedule, whereas the remaining part (typically 70%) only becomes refundable to the extent of revenue generated within 10 years after the date at which exploitation has been decided. Accordingly, if no revenue is generated within that period of 10 years, any non-refunded part of the loan is forgiven. In addition, no interest is charged on the loan.

Under IAS 20 – Accounting for Government Grants and Disclosures of Government Assistance, a forgivable loan from government should be treated as a government grant when there is a reasonable assurance that the Group will meet the terms for forgiveness of the loan. Consistently with the length of the products' development cycle, it is expected that no significant revenue will be generated within a period of 10 years starting from the exploitation date of the R&D project. Consequently, there is a reasonable assurance that related part of the loan (typically 70%) will be forgiven. Conversely, past practice demonstrates that the Group decides to exploit R&D projects, which triggers the repayment of the related part of the loan (typically 30%) under an agreed schedule.

On this basis, a liability is recognised for the discounted value of the minimum refundable amount in case of exploitation, and any difference with the amount receivable from the government is accounted for as a grant and presented as deferred income in accordance with IAS 20. The deferred income is released as other operating income as the R&D costs compensated by the grant are incurred, whereas the part of the grant representing the discount effect on the minimum refundable amount is released as interest income over the period of interest free loan.

Under BeGAAP, the entire amount of forgivable loans is initially accounted for as a government grant and it is only when the Group decides to exploit the R&D project that a liability is recognised for the minimum amount to be repaid. In addition, the grant is released in the profit and loss statement consistently with the amortisation expense of the R&D costs that are capitalised according to BeGAAP (see adjustment (2) above).

The combined effect of these adjustments from BeGAAP to IFRS with respect to forgivable loans is positive on the 2012 equity and result of the Group.

## (6) Patents and other grants

The Group receives government grants related to patents. On average, the grants received cover 70% of the fees incurred in the process of obtaining patents.

Considering that patent costs are expensed as incurred under IAS 38 (see adjustment (3) above), related patent grants are immediately recognised as other operating income when the patent fees are incurred in accordance with IAS 20.

As patent costs are capitalised in accordance with BeGAAP, related grants are released as income over the amortisation period. A positive IFRS adjustment is thus recognised on the 2012 equity and result of the Group.

# (7) Tax credit

The Company has applied for an income tax credit that corresponds to a percentage of qualifying R&D costs to which the income tax rate (33.99%) is applied. In case of insufficient current tax payable against which to set off the tax credit, the latter is carried-forward to the following four years. At the end of this period, the balance of the unused tax credit is paid by the tax authorities. Considering that R&D tax credits are ultimately paid by the authorities, the related benefit is treated as a government grant in accordance with IAS 20 and released as other operating income when the R&D costs compensated by the grant are expensed.

As the tax credit has been carried-forward in the absence of taxable profit generated by the Company, an asset is recognised for the amount to be ultimately received from the tax authorities. In accordance with IAS 12 – *Income Taxes*, this amount is presented as a deferred tax asset.

Under Belgian GAAP, a receivable is recognised immediately against a deferred income, which is recognised in profit or loss over a period of 3 years, consistently with the amortisation period of the R&D costs that are capitalised under BeGAAP.

# (8) Deferred taxes

On the contrary to BeGAAP, deferred taxes are recognised on temporary differences between the carrying amount of assets and liabilities, and their tax base according to IAS 12 – *Income taxes*. For deductible temporary differences and tax losses carried forward, a deferred tax asset is recognised only to the extent that it is probable that future taxable profit will be available.

Considering that Group entities do not expect to generate a taxable profit in the foreseeable future, no deferred tax assets are recognised on tax losses carried-forward and deductible temporary differences triggered by the above detailed IFRS adjustments, except with respect to the tax credit carried-forward as it is ultimately paid by the authorities (see adjustment (7) above).

# 5. Notes relating to the statement of financial position

# 5.1. Intangible assets

The intangible assets consist only of purchased software.

(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Acquisition cost	96	35	11
Accumulated amortisation and impairment	(36)	(16)	(7)
Intangible assets	60	19	4

Cost (in thousands of euros)	Software
Balance at 01 January 2012	11
Additions	24
Balance at 31 December 2012	35
Additions	61
Balance at 31 December 2013	96

Accumulated amortisation and impairment (in thousands of euros)	Software		
Balance at 01 January 2012	(7)		
Amortisation expense	(9)		
Balance at 31 December 2012	(16)		
Amortisation expense	(20)		
Balance at 31 December 2013	(36)		

No pledges exist relating to intangible assets.

# 5.2. Property, plant and equipment

Property, plant and equipment consist mainly of laboratory equipment and a property under construction:

(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Acquisition cost	4,184	2,215	1,683
Accumulated depreciation and impairment	(1,315)	(939)	(546)

(in thousands of euros)			31/12/2013	31/1	12/2012	01/01/2012
Property, plant and equipment			2,869		1,276	1,137
of which:						
Laboratory equipment			584		804	1,061
IT material			18		25	36
Office furniture			13		29	41
Land			232		0	0
Properties under construction			2,022		418	0
Cost (in thousands of euros)	Laborator y equipmen t	IT material	Office furnitur e	Land	Properties under construction	Total
Balance at 01 January 2012	1,548	68	67	0		1,683
Additions	94	11	9		418	<b>532</b>
Additions through business						0
combinations						
Disposals						0
Reclassification as held for sale						0
Other						0
Balance at 31 December 2012	1,643	79	76	0	418	3 2,215
Additions	133	12	0	233	1.604	1,982
Additions through business combinations						0
Disposals	(9)	(4)				(13)
Reclassification as held for sale						0
Other						0
Balance at 31 December 2013	1,.766	87	76	233	2,022	2 4,184

Accumulated depreciation and impairment (in thousands of euros)	Laborator y equipmen t	IT material	Office furnitur e	Land	Properties under construction	Total
Balance at 01 January 2012	(488)	(32)	(26)	0	0	(546)
Depreciation expense	(351)	(22)	(20)			(393)
Disposals						0
Reclassification as held for sale						0
Impairment losses						0
Reversals of impairment losses						0
Other						0
Balance at 31 December 2012	(839)	(54)	(47)	0	0	(939)
Amortisation expense	(349)	(19)	(16)	(1)		(386)
Disposals	7	4				10
Reclassification as held for sale						0
Impairment losses						0
Reversals of impairment losses						0
Other						0
Balance at 31 December 2013	(1,182)	(69)	(63)	(1)	0	(1,315)

Carrying amount (in thousands of euros)	Laboratory equipment	IT material	Office furnitur e	Land	Properties under construction	Total
Balance at 01 January 2012	1,061	36	41	0	0	1,137
Balance at 31 December 2012	804	25	29	0	418	1,276
Balance at 31 December 2013	584	18	13	232	2,022	2,869

Property under construction relates to the new facilities of SCTS at Gosselies. The completion of the facility is planned in different phases. Different parts of the building will be occupied at different points in time. Depreciation will start for the different parts in line with the start of the occupation and for the production zones following GMP approval of the zones. The Company plans to occupy the first phase (administration and R&D facilities) in the second quarter of 2015. The commissioning of the two first production zones is foreseen in the second half of 2016. Committed expenditure on 31 December 2013 amounts to  $\mathfrak E$  4.188,000. For the financing of this project, see Section 6.7 "Investments".

Included in the carrying amount of laboratory equipment, an amount of  $\in$  100,000 is related to assets under finance lease (2012:  $\in$  81,000). The land represents a long lease right of 99 years on which the new facilities of SCTS are being constructed.

No pledges exist relating to property, plant and equipment. The pledge in respect of the long term investment credit facility provided by BNP Paribas Fortis SA/NV and ING Belgique SA/NV for the construction of the new facilities of SCTS at Gosselies has not been activated as the credit facility has not been used as per 31 December 2013.

#### 5.3. Investments in associates

The investment in associates relates solely to the investment in "Société d'Infrastructures, de Services et d'Energies" ('SISE'). The Group holds 30.94% in SISE (2012: 29.78%) and has significant influence over this entity since its incorporation. SISE is responsible for rendering infrastructure and maintenance services. The associate is accounted for using the equity method in the consolidated financial statements.

The investment in associates recognised in the consolidated statement of financial position can be reconciled as follows:

(in thousands of euros)	2013	2012
Balance at 1 January	263	280
Acquisition of investment	0	0
Capital increase/decrease	0	0
Net income from associates	19	(17)
Dividend received from associates	0	0
Impairment losses	0	0
Disposal of investment	0	0
Balance at 31 December	282	263
Goodwill included in carrying amount of investments in associates	0	0

Summarised financial information in respect of the Group's associate is set out below. The summarised financial information below represents amounts shown in the associate's financial statements prepared in accordance with IFRSs adjusted by the Group for equity accounting purposes.

(in thousands of euros)	31/12/2013	31/12/2012
Sales and other operating revenues		
Profit (loss) before interest and taxation	68	(61)
Finance costs and other finance expenses	(7)	5
Taxation	0	0
Profit (loss) for the year	61	(56)
Profit (loss) attributable to owners of the company	19	(17)

(in thousands of euros)	31/12/2013	31/12/2012
Non-current assets	690	589
Current Assets	1,947	315
Total Assets	2,637	904
Current liabilities	1,525	20
Non-current liabilities	200	0
Total Liabilities	1,725	20
Net assets	912	884
Group's share of net assets	282	263

The Group granted no loans to associates.

# 5.4. Income taxes

As Group entities did not realise a taxable profit in 2012 and 2013, there is no current income tax expense recognised in the consolidated financial statements.

The following tables detail the amounts recognised in the consolidated statement of financial position with respect to deferred taxes.

Deferred taxes by source of temporary differences

	Assets				Liabilities	
(in thousands of euros)	31/12/2013	31/12/2012	0101/2012	31/12/2013	31/12/2012	01/01/2012
Property, plant and equipment	0	0	0	5	0	0
In tangible assets	2,858	2,611	1,997	0	0	0
Trade and other receivables	0	3	0	450	601	1,363
Financial liabilities	861	695	683	0	0	0
Other non-current liabilities	493	616	595	0	0	0
Other current liabilities	0	0	0	1,032	920	22
Total temporary differences	4,212	3,922	3,274	1,486	1,521	1,385

Tax credits and tax losses carried forward and temporary differences

(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Tax credits	3,920	2,726	1,538
Tax credits related to notional interest deduction	415	415	415
Tax losses	11,079	7,558	4,836
Temporary differences	8,018	7,063	5,559
Total	23,432	17,762	12,348

Deferred tax assets and liabilities recognised

		Assets			Liabilities	
(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012	31/12/2013	31/12/2012	01/01/2012
Deferred tax assets/(liabilities)	9,451	7,559	5,582	1,486	1,521	1,385
Unrecognised deferred tax assets	(6,632)	(5,111)	(3,674)			
Total recognised deferred taxes	2,819	2,449	1,908	1,486	1,521	1,385
Offsetting	(1,486)	(1,521)	(1,385)	(1,486)	(1,521)	(1,385)
Total, net	1,333	927	523	0	0	0

The following table presents an overview of the deductible temporary differences, unused tax losses and unused tax credits for which no deferred tax asset has been recognised:

(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Tax credits	0	0	0
Tax credits related to notional interest deduction	415	415	415
Tax losses	11,079	7,558	4,836
Temporary differences	8,018	7,063	5,559
Total	19,512	15,036	10,810

The unrecognised tax credits related to notional interest deduction expire in 2019. There is no expiry date on the other sources of deferred tax assets.

Furthermore, the deferred tax asset on the tax credit has been treated as a government grant and presented as other operating income in the consolidated statement of comprehensive income (see note 6.1).

At closing 2013, there are no unrecognised deferred tax liabilities related to temporary differences associated with investments in subsidiaries and associates.

#### 5.5. Trade and other receivables

The trade and other receivables can be detailed as follows:

(in thousands of euros)	ands of euros) 31/12/2013		01/01/2012	
Trade receivables				
Trade receivables	19	5	1	
Write-downs on trade receivables	0	0	0	
Total trade receivables	19	5	1	
Other receivables				
Receivable related to taxes	226	184	133	
Receivable related to tax credit	0	0	0	
Receivable related to Forgivable loans	5,063	6,362	6,761	
Receivable related to Patents	192	261	316	
Receivable related to other grants	13	22	8	
Write-downs on other receivables	0	0	0	
Total other receivables	5,494	6,829	7,218	
Total trade and other receivables	5,513	6,834	7,220	

The other receivables mainly relate to government grants to receive. The receivables related to forgivable loans are reconciled in note 6.1.

Taxes relate mainly to VAT receivables.

#### 5.6. Financial assets

Non-current financial assets relate to restricted amounts representing a warranty for operating lease commitments.

Current financial assets in 2011 represent short-term deposits with fixed interest rates (€ 203,000).

#### 5.7. Cash and cash equivalents

Cash and cash equivalents include following components:

(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Cash at bank and in hand	898	3,471	5,559
Short-term bank deposits	1,542	1,350	0
Total	2,440	4,822	5,559

The short-term bank deposits have an original maturity date not exceeding 3 months.

#### 5.8. Equity

Share capital and share premium

On 10 June 2013, the share capital was increased by a contribution in cash for an amount of  $\in$  871,000 with the issuance of 22,800 shares. The aggregate share premium amounted to  $\in$  629,000. Following the capital increase, the share capital of the Company amounted to  $\in$  9,288,000 and was represented by 314,960 shares. Transaction costs were incurred for a total amount of  $\in$  17,000.

On 27 November 2012, the share capital was increased by a contribution in cash for an amount of  $\in$  1,474,000 with the issuance of 38,591 shares. The aggregate issuance premium amounted to  $\in$  1,065,000. Following an agreement between the existing shareholders, 32 shareholders were allowed to exercise an anti-dilution warrant (at a price of 1 euro cent each) to realign their number of shares obtained for their investments versus the investment made per share held by the other shareholders whereby as a result all parties had shares at an equivalent price (for investments made as of a particular point in the past). This resulted in a capital increase of  $\in$  0.32 (or thirty two euro cents) and the issuance of 71,772 shares. Following the capital increase, the share capital of the Company amounted to  $\in$  8,417,000 and was represented by 292,160 shares. Transaction costs were incurred for a total amount of  $\in$  9.000.

On 18 December 2014, the extraordinary general shareholders' meeting of the Company resolved to abolish the second anti-dilution warrants issued on 27 November 2012, further to a waiver of the holders thereof.

The shares have no nominal value.

Non-controlling interests

The gross liability relating to the put option on non-controlling interest in SCTS (see note 7.1) has been recognised against equity, as a reduction of non-controlling interests. Considering however that this gross liability exceeds the amount of non-controlling interests, the balance has been recognised as deduction of group equity (retained earnings) and the amount reported as non-controlling interest is nil.

# 5.9. Financial liabilities

Financial liabilities are detailed as follows:

		Non-current			current			Total	
(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012	31/12/2013	31/12/2012	01/01/2012	31/12/2013	31/12/2012	01/01/2012
Finance lease liabilities	100	60	105	229	37	27	329	97	132
Government loans	3,774	3,305	2,985	208	155	125	3,982	3,460	3,110
Loans form related									
parties	1,178	750	0	72	0	0	1,250	750	0
Total financial	5,052	4,115	3,090	509	192	152	5,561	4,307	3,242

liabilities

The finance lease liabilities relates to the leases of laboratory equipment (lease term of 5 years) and the long lease right on the land (lease term of 99 years).

The Group has options to purchase the equipment for a fixed amount at the end of the lease term. The Group's obligations under finance leases are secured by the lessors' title to the leased assets. Interest rates underlying the obligations under finance leases related to laboratory equipment are fixed at respective contract dates ranging from 2.2% to 3.3% per annum.

The future minimum lease payments related to these finance leases can be reconciled as follows to the liabilities recognised in the consolidated statement of financial position:

Future minimum lease payments	31/12/2013	31/12/2012	01/01/2012
(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Not later than 1 year	229	37	27
Later than 1 year and not later than 5 years	86	62	105
Later than 5 years	282	0	0
Less: future finance charges	(269)	(2)	
Present value of minimum lease payments	329	97	132

Present value of minimum lease payments (in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Not later than 1 year	229	37	36
Later than 1 year and not later than 5 years	80	60	96
Later than 5 years	20	0	0
Present value of minimum lease payments	329	97	132

The government loans relate to the forgivable loans are detailed in note 6.1. These loans are not bearing any interest.

The loans from related parties were granted by shareholders and other related parties (see note 8.1) and bear a fixed interest rate ranging from 2.5% to 6.5%. The loans have a maturity of 7 to 15 years.

Liquidity risk is further discussed in note 7.

# 5.10. Other non-current liabilities

According to the SCTS shareholders' agreement, the Company has granted to the 50.1% non-controlling interests in SCTS an option to sell (put option) their SCTS shares to the Company. This put option is exercisable as from 1 January 2020 at a strike price amounting to the net assets of SCTS multiplied by the percentage held, with a minimum price floored at 90% of the share subscription value. This put option on non-controlling interests (own equity instrument) gives rise to a gross liability that is initially measured at the present value of the redemption amount (strike price). This gross liability is subsequently measured at fair value with changes in fair value recognized in profit or loss. For additional information on the fair value, see also note 7.1 "Overview of financial instruments".

# 5.11. Trade and other payables

(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Trade payables	1,136	844	517
Other payables	323	272	272
Total trade and other payables	1,458	1,116	789

Trade payables (composed of supplier's invoices and accruals for supplier's invoices to receive at reporting date) are non-interest bearing and are in general settled 30 days from the date of invoice.

Other payables include solely short-term employee benefits liabilities.

### 5.12. Other current liabilities

Other current liabilities consist of the deferred income related to the government grants as detailed in the following table:

(in thousands of euros)	31/12/2013	31/12/2012	01/01/2012
Deferred income on grants related to forgivable loans	3,905	4,083	4,903
Deferred income on grants related to patents	374	462	556
Total	4,279	4,546	5,459

The deferred income related to the grants on the forgivable loans is detailed further in note 6.1.

# 6. Notes relating to the statement of comprehensive income

### 6.1. Other operating income

The other operating income relate to the different grants received by the Group:

(in thousands of euros)	31/12/2013	31/12/2012
Grants income related to forgivable loans	2,383	1,939
Grants income related to exemption on withholding taxes	430	501
Grants income related to tax credit	405	404
Grants income related to patents	87	113
Other grants income	88	100
Total	3,394	3,057

### Forgivable loans

The forgivable loans ("Avances récupérables") are granted to support specific research and development programs. After the approval of these loans by the government (i.e. Walloon Region), a receivable is recognised for the loan to be received and presented as other receivables (see note 5.5). These loans become refundable under certain conditions, including the fact that the Group decides to exploit the R&D results of the project. In such case, part of the loan (typically 30%) becomes refundable within an agreed schedule, whereas the remaining part (typically 70%) only becomes refundable to the extent of revenue generated within 10 years after the date at which exploitation has been decided. Accordingly, if no revenue is generated within that period of 10 years, any non-refunded part of the loan is forgiven. In addition, no interest is charged on the loan.

In accordance with IFRS, a forgivable loan from government should be treated as a government grant when there is a reasonable assurance that the Group will meet the terms for forgiveness of the loan. Consistently with the length of the products' development cycle, it is expected that no significant revenue will be generated within a period of 10 years starting from the exploitation date of the R&D project. Consequently, there is a reasonable assurance that related part of the loan (typically 70%) will be forgiven. Till date, the Group decided to exploit all R&D projects which were supported by the Walloon Region under the scheme of "Avances récupérables". These decisions have triggered the repayments of the related part of the loans (typically 30%) as per the agreed terms.

On this basis, a financial liability is recognised for the discounted value of the minimum refundable amount in case of exploitation (presented as government loans in note 5.9 above), and any difference with the amount receivable from the government is accounted for as a grant and presented as deferred income within other current liabilities in the consolidated statement of financial position (see note 5.12). The deferred income is released as other operating income as the R&D costs compensated by the grant are incurred, whereas the part of

the grant representing the discount effect on the minimum refundable amount is released as interest income over the period of interest free loan.

The receivable related to the forgivable loans is reconciled as follows:

(in thousands of euros)	31/12/2013	31/12/2012
Opening balance	6,362	6,761
New grants	2,325	1,228
New loans	537	366
Cash received	(4,161)	(1,993)
Closing balance	5,063	6,362

The movements related to the government loans are detailed in the following table:

(in thousands of euros)	31/12/2013	31/12/2012
Opening balance	3,459	3,109
New loans	537	366
Repayment	(135)	(125)
Unwind of discount	121	109
Closing balance	3,982	3,459

The deferred income related to the forgivable loans recognised in the consolidated statement of financial position can be reconciled as follows:

(in thousands of euros)	31/12/2013	31/12/2012
Opening balance	4,084	4,904
Released as operating income	(2,383)	(1,939)
Released as finance income	(121)	(109)
Increase on new grants	2,325	1,228
Closing balance	3,904	4,084

#### Grants related to tax credit

The Company has applied for an income tax credit that corresponds to a percentage of qualifying R&D costs to which the income tax rate (33.99%) is applied. In case of insufficient current tax payable against which to set off the tax credit, the latter is carried-forward to the following four years. At the end of this period, the balance of the unused tax credit is paid by the tax authorities. Considering that R&D tax credits are ultimately paid by the authorities, the related benefit is treated as a government grant and released as other operating income when the R&D costs compensated by the grant are expensed.

Grants related to the exemption of withholding taxes for researchers

Companies that employ scientific researchers benefit from a partial exemption from payment of withholding tax on their salaries. They must transfer to the tax authorities only 20% of the withholding tax due on the salary of these researchers while the remaining amount is considered to be a government grant. These grants are recognised in the consolidated statement of comprehensive income at the same moment the related personnel expenses are incurred.

# Grants related to patents

The Group receives government grants related to patents. On average, the grants received cover 70% of the fees incurred in the process of obtaining patents.

Considering that patent costs are expensed as incurred, related patent grants are immediately recognised as other operating income when the patent fees are incurred.

#### 6.2. Research and development expenses

	Year ended	Year ended
(in thousands of euros)	31/12/2013	31/12/2012
Lab fees and other operating expenses	3,283	2,777
Employee benefits expenses	2,975	2,973
Depreciations, amortisations and impairment losses	349	351
Patents costs	208	270
Total	6,816	6,371

The main movement compared to previous period relates to increased expenses incurred in the context of clinical trials.

# 6.3. General and administrative expenses

	Year ended	Year ended
(in thousands of euros)	31/12/2013	31/12/2012
Employee benefits expenses	224	166
Depreciation and amortisation expense	58	51
Other expenses	339	131
Total	621	348

The increase in employee benefits expenses is mainly related to the strengthening of the management team.

Other expenses have increased as a result of infrastructure services performed by the associate, increased public relation services and other outsourced activities.

# 6.4. Employee benefits expenses

Employee benefits expenses can be detailed as follows:

	Year ended	Year ended
(in thousands of euros)	31/12/2013	31/12/2012
Short term benefits	2,522	2,456
Social security cost	556	625
Post-employment benefits and other benefits	107	40
Share-based compensation	0	
Other expenses	15	18
Total	3,200	3,139

The Group has implemented a post-employment benefit plan as from 2013 for members of the management with an employee status. The post-employment benefit plan is by law subject to minimum guaranteed rates of return, currently 3.25% on employer contributions and 3.75% on employee contributions. These rates, which apply as an average over the entire career, may be modified by Belgian Royal Decree in which case the new rate(s) apply to both the accumulated past contributions and the future contributions as from the date of modification.

At 31 December 2013, no liability was recognized in the consolidated statement of financial position as there was no difference between the minimum guaranteed reserves and the actual accumulated reserves (2012: nil).

The contributions paid during 2013 for those plans amounted to € 35,000 by the employer (no employee contributions).

The plan assets at 31 December 2013 consisted of  $\in$  30,000 individual insurance reserves in benefit of still 'active' employees, which benefit from a weighted average guaranteed interest rate of 2.25%, and  $\in$  3,000 reserves in a related (collective) financing fund.

Additionally, the insurer has contractually agreed upon an average total net return of at least 3.25%.

The following table details the number of employees by department (in full time equivalents):

Number of employees	Year ended	Year ended
	31/12/2013	31/12/2012
Research and development	47	45
General and administrative	2	2
Total	49	47

# 6.5. Financial result

(in thousands of euros)	Year ended 31/12/2013	Year ended 31/12/2012
Interest income on bank deposits	29	63
Interest income in relation to government loans	121	109
Total interest income	150	172
Interest on borrowings	(31)	(13)
Interest on government loans	(121)	(109)
Interest on obligations under finance leases	(20)	(5)
Fair value gain or losses	(14)	(61)
Other	(4)	(1)
Total financial expenses	(190)	(189)
Exchange gains/(losses)	(1)	(3)
Share of profit/(loss) of associates	19	(17)
Total financial result	(41)	(20)

Financial income amounts to  $\in$  0.15 million in line with last year's income of  $\in$  0.17 million and relates mainly to income recognition on non-interest bearing government loans and more in particular the minimum refundable amount of the forgivable loans referred to in note 6.1.

Financial expenses amount to  $\in$  0.20 million compared to  $\in$  0.19 million for the full year 2012 and consist mainly of the unwinding of the discount on government loans (presented as interest on government loans).

The fair value gains or losses relate to the changes in fair value of the put option on non-controlling interests recognised as other non-current financial liabilities (see note 5.10).

### 6.6. Earnings per share

The earnings and weighted average number of ordinary shares used in the calculation of basic earnings per share are as follows:

	Year ended	Year ended
	31/12/2013	31/12/2012
Profit/loss for the period attributable to the owners of the Company (in		
thousands of euros)	(4,079)	(3,689)
Weighted average number of ordinary shares for basic loss per share (in number		
of shares)	304,903	192,049
Basic loss per share (in euros)	-13.38	-19.21

As the Company does not hold any dilutive instruments at 31 December 2013, the diluted earnings per share are equal to the basic earnings per share.

# 7. Financial instruments and financial risk management

# 7.1. Overview of financial instruments

The following table provides the category in which financial assets and financial liabilities are classified in accordance with IAS 39 – *Financial Instruments: Recognition and Measurement.* 

(in thousands of euros)	IAS 39 Category	31/12/2013	31/12/2012	01/01/2012
Other non-current financial assets				
Non-current receivables	Loans and receivables	180	163	59
Trade and other receivables	Loans and receivables	5,287	6,650	7,087
Other financial assets	Loans and receivables	0	0	203
Cash and cash equivalents	Loans and receivables	2,440	4,822	5,559
Total financial assets	-	7,907	11,635	12,908
Non-current financial liabilities				
Finance lease liabilities	At amortised cost	100	60	105
Government Loans	At amortised cost	3,774	3,305	2,985
Loans from related parties	At amortised cost	1,178	750	0
Other non-current liabilities		,		
	At fair value through profit			
Put on non-controlling interests	or loss	1,450	1,811	1,750
Current financial liabilities				
Finance lease liabilities	At amortised cost	229	37	27
Government loans	At amortised cost	208	155	125
Loans from related parties	At amortised cost	72	0	0
Trade and other payables				
Trade payables	At amortised cost	1,136	844	517
Total financial liabilities		8,147	6,963	5,509

The carrying amounts of financial assets recognised in the consolidated financial statements approximate their fair values. The same situation is applicable for financial liabilities, except as detailed in the following tables.

		31/12/2013			
(in thousands of euros)	Carrying amount	Fair value	Fair value level		
Non-current financial liabilities					
Finance lease liabilities	100	100	Level 2		
Government loans	3,774	3,655	Level 2		
Loans from related parties	1,178	1,159	Level 2		
Other non-current liabilities					
Put on non-controlling interests	1,450	1,450	Level 3		
Current financial liabilities					
Finance lease liabilities	229	229	Level 2		
Government loans	208	208	Level 2		
Loans from related parties	72	72	Level 2		
Trade and other payables					
Trade payables	1,136	1,136			
Total	7,011	6,873			

	31/12/2012			
(in thousands of euros)	Carrying amount	Fair value	Fair value level	
Non-current financial liabilities				
Finance lease liabilities	60	60	Level 2	
Government loans	3,305	3,397	Level 2	
Loans from related parties	750	755	Level 2	
Other non-current liabilities				
Put on non-controlling interests	1,811	1,811	Level 3	

	31/12/2012		
(in thousands of euros)	Carrying amount	Fair value	Fair value level
Current financial liabilities			
Finance lease liabilities	37	37	Level 2
Government loans	155	155	Level 2
Total	6,118	6,216	

		01/01/2012		
(in thousands of euros)	Carrying amount	Fair value	Fair value level	
Non-current financial liabilities				
Finance lease liabilities	105	105	Level 2	
Government loans	2,985	2,812	Level 2	
Loans from related parties	0	0	Level 2	
Other non-current liabilities				
Put on non-controlling interests	1,750	1,750	Level 3	
Current financial liabilities				
Finance lease liabilities	27	27	Level 2	
Government loans	125	125	Level 2	
Total	4,992	4,819		

The fair values of the financial assets and financial liabilities included in the level 2 and level 3 categories above have been determined in accordance with generally accepted pricing models based on a discounted cash flow analysis, with the most significant input being the discount rate that reflects the credit risk of counterparties.

The only financial liability subsequently measured at fair value on Level 3 fair value measurement is the put option granted by the Group to non-controlling interests in SCTS, which has been fully consolidated. These commitments to purchase equity instruments have been recognized under other non-current liabilities and concern 50.1% of SCTS (2012: 56.48%).

The following table includes a reconciliation of the level 3 fair value measurements:

in thousands of euros	31/12/2013	31/12/2012
Opening balance	1,811	1,750
Total gains or losses in profit or loss	14	61
Decrease of capital	(375)	0
Closing balance	1,450	1,811

The put option has been measured using a discounted cash flow analysis based on significant unobservable inputs, such as expected rate of return (6.5%) and discount rate (3.5%). See also section 3 of these consolidated financial statements on significant judgements.

If the above unobservable input linked to the expected rate of return was 10% higher/lower while all the other variables were held constant, the carrying amount of the put option would increase/decrease by  $\in$  47,000 (2012: increase/decrease by  $\in$  58,000; 2011: increase/decrease by  $\in$  56,000).

# 7.2. Capital risk

The Company manages its capital to ensure that it will be able to continue as a going concern. The capital structure of the Company consists of financial debt, cash and cash equivalents and short-term investments and equity attributed to the holders of equity instruments of the Company, such as capital, reserves and retained earnings as mentioned in the consolidated statement of changes in equity. The Company makes the necessary adjustments in the light of changes in the economic circumstances, risks associated to the different assets and the projected cash needs of the current and projected activities. The current cash situation and the anticipated cash generation and cash burn are the most important parameters in assessing the capital structure. The Company objective is to maintain the capital structure at a level to be able to finance its activities for at least twelve months. Cash income from existing and new non-dilutive funding sources (subsidies, grants and government loans) and cash income from possible future partnerships are taken into account and, if needed and possible, the Company can issue new shares or enter into financing agreements.

### 7.3. Credit risk

The Company believes that its credit risk, relating to receivables, is limited because currently almost all of its receivables are with public institutions.

Cash and cash equivalent and short-term deposits are invested with highly reputable banks and financial institutions.

The maximum credit risk, to which the Group is theoretically exposed as at the balance sheet date, is the carrying amount of the financial assets.

At the end of the reporting period no financial assets were past due, consequently no financial assets were subject to impairment.

# 7.4. Liquidity risk

The Group manages liquidity risk by maintaining adequate reserves and borrowing facilities, by continuously monitoring forecast and actual cash flows, and by matching the maturity profiles of financial assets and liabilities.

The Group's main sources of cash inflows are currently obtained through capital increases, subsidies and government loans.

The following table details the Group's remaining contractual maturity of its non-derivative 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 Group can be required to pay. The tables include both interest and principal cash flows. The contractual maturity is based on the earliest date on which the Group may be required to pay.

31/12/2013	Financial lease liabilities	Government	Loans from	Total
in thousands of euros		loans	related parties	<b>5</b> 46
Within one year	229	208	109	546
>1 and <5 years	86	2,486	930	3,503
>5 and <10 years	15	2,055	374	2,444
>10 and <15 years	15	148	0	163
>15 years	252	0	0	252
31/12/2012	Financial lease	Government	Loans from	Total
in thousands of euros	liabilities	loans	related parties	Total
Within one year	37	155	25	217
>1 and <5 years	62	1,635	605	2,303
>5 and <10 years	0	1,620	237	1,857
>10 and <15 years	0	158	0	158
>15 years	0	8	0	8
31/12/2011	Financial lease	Government	Loans from	m 1
in thousands of euros	liabilities	loans	related parties	Total
Within one year	27	125	0	152
>1 and <5 years	105	1,156	0	1,261
>5 and <10 years	0	1,445	0	1,445
>10 and <15 years	0	199	0	199
>15 years	0	16	0	16

All liabilities mentioned in the tables above are secured liabilities.

There are no covenants applicable to financial liabilities.

### 7.5. Interest rate risk

The Company has limited interest rate risk. The company has next to forgivable loans (non-interest bearing on a cash basis) a number of medium term loans provided by regional investments bodies at fixed market interest rates. SCTS has concluded on 15 July 2014 long term loans with two commercial banks with an interest rate linked to the Euribor 3M and short term loans to pre-finance subsidies to be received in respect of the building under construction (until the management of the subsidies) at similar short term rates. For the long-term loan the Company is permanently monitoring the short-term interest rates versus options to swap these rates versus a long term interest rate (IRS) in function of the remaining term of the loan.

### 7.6. Foreign exchange risk

The company is currently not exposed to any significant foreign currency risk. However should the company enter into long term collaboration agreements with third parties for which revenues would be expressed in a foreign currency which should compensate for expenses to be done by the Company, the Company might in such case consider to enter into a hedging arrangement to cover such currency exposure.

#### 8. Other disclosures

# 8.1. Related party transactions

Balances and transactions between the Company and its subsidiary, which is a related party 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.

SISE, which is an associate of the Group, performed certain services for the Company, for which an amount of  $\in 146,000$  (2012: nil) was charged, being an appropriate allocation of costs incurred by the associate. Furthermore, a liability is recognised in the consolidated statement of financial position for an amount of  $\in 357,000$ , consisting of trade payables ( $\in 146,000$ ) and a finance lease liability for the long lease right on the land ( $\in 211,000$ , of which  $\in 31,000$  as a non-current liability).

As a result of the relationship of the government (i.e. Walloon Region) with some shareholders of the Company and the extent of financing received, the Company judges that the government is a related party. However, the principal amounts recognised in the financial statements relate to government grants (see note 6.1). Next to the government grants, government agencies granted loans (see note 5.9) to the Group for a total amount of  $\{0.250,000,000,000\}$  (2012:  $\{0.250,000,000\}$ ).

The remuneration of directors and other members of key management personnel during the year was as follows:

(in thousands of euros)	31/12/2013	31/12/2012
Short-term benefits	330	252
Post-employment benefits	0	0
Other long-term benefits	0	0
Share-based payments	0	0
Termination benefits	0	0
Total	330	252

# 8.2. Consolidation scope

The Company has an affiliate, SCTS, of which 50.1% is held by non-controlling interests (2012: 56.48%). Although the Group holds less than 50% of SCTS, the Company concluded that it has control as mentioned in section 3 above on critical accounting judgements and key sources of estimation uncertainty.

The change in ownership interest is related to a capital decrease in the affiliate.

Summarised financial information in respect of the Group's affiliate is set out below. The summarised financial information below represents amounts before intragroup eliminations.

(in thousands of euros)	31/12/2013	31/12/2012
Current assets	1,728	2,172
Non-current assets	2,475	707
Total assets	4,203	2,879
Current liabilities	1,078	108
Non-current liabilities	706	0
Total liability	1,784	108
Total equity	2,419	2,771
Revenue	1,019	453
Expenses	(994)	(468)
Result for the period	26	(15)
Dividends paid to non-controlling interests	0	0

There are no significant restrictions on the ability of subsidiaries to transfer funds to the parent in the form of cash dividends or repayments of loans and recoverable cash advances.

### 8.3. Operating Segments

The Group does not make the distinction between different operating segments, neither business or geographical basis in accordance with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker is the board of directors of the Company.

All non-current assets are located in Belgium.

# 8.4. Contingent liabilities

Management uses its judgement to estimate the portion of forgivable loans for which there is reasonable assurance that the terms for forgiveness will be met. Consistently with past practices, management expects that it will decide to exploit the results of the R&D project, which triggers the repayment of a portion of the loan (typically 30%). Similarly, management expects that revenue potentially generated from the R&D project within 10 years after the exploitation date is insignificant considering the length of the products' development cycle, and consequently that there is reasonable assurance that the remaining part (typically 70%) of the loan will be forgiven. This latter part treated as government grants contains a contingent liability as there might be scenarios under which the Company will have to repay a portion of it.

As of 31 December 2013, the total amount of forgivable loans released in income amounts to  $\in$  7,938,000. This amount corresponds to the maximum contingent liability. For part of this amount, repayment will indeed occur only if the Company generates revenue for such an amount and in such a timing that the probability associated with this scenario is assessed to be remote. For further information regarding the expiring dates of the period of 10 years together with details on the amounts for each forgivable loans, we refer to Sections 6.11.1.1 and 6.11.2.1 of the Prospectus.

# 8.5. Commitments

Operating leases relate to leases of offices (lease term of 3 years) and company cars (lease term of 4 years). The Group does not have an option to purchase the leased assets at the expiry of the lease periods. For the period ended 31 December 2013 minimum lease payments for a total amount of  $\in$  425,000 have been recognised in the consolidated statement of comprehensive income (2012:  $\in$  549,000).

The following table presents the non-cancellable operating lease commitments:

(in thousands of euros)	31/12/2013	31/12/2012
Not later than 1 year	496	453
Later than 1 year and not later than 5 years	549	166
Later than 5 years	0	0
Total	1,046	619

#### 8.6. Events after the reporting period

The annual consolidated financial statements on 31 December 2013 were authorised for issue by the Board of Directors of the Company on 8 January 2015. Accordingly, events after the reporting period are those events that occurred between 1 January 2014 and 8 January 2015.

For those events after the reporting period until 30 September 2014, we also refer to the condensed consolidated financial statements for the 9 month period ended on 30 September 2014 that are included in the following section.

# Issue of share capital

On 24 February 2014, the shareholders of the Company resolved upon a share split, dividing the 314,960 shares, without nominal value, each representing 1/314,960th of the share capital of the Company by 1,000, creating 3,149,600 shares, without nominal value, each representing 1/3,149,600th of the share capital of the Company. On the same day, the share capital was increased by a contribution in cash in the amount of  $\in$  580,000 with issuance of 152,000 shares. The aggregate share premium amounted to  $\in$  420,000. Following the capital increase, the share capital of the Company amounted to  $\in$  9,868,000 and was represented by 3,301,600 shares.

On 10 July 2014, the share capital was increased by a contribution in cash in the amount of  $\in$  598,000 with issuance of 156,640 shares. The aggregate share premium amounted to  $\in$  432,000. Following the capital increase, the share capital of the Company amounted to  $\in$  10,466,000 and was represented by 3,458,240 shares.

# Straight loan facility

On 18 August 2014, a straight loan facility was provided by BNP Paribas Fortis for a total amount up to € 1,500,000 and is running until 30 June 2015. This facility allows to pre-finance amounts due by the Walloon Region on recoverable cash advances ("avances récuperables" referred to as "forgivable loans" under IFRS) and subsidies (see Section 6.11 "Grants and subsidies") granted by the Walloon Region. In respect of this arrangement the Company has pledged the amounts to be received from the Walloon Region during the term of this credit facility as well as granted a business pledge mandate ("mandat de fonds de commerce") in respect of the Company for as long the Company wants to use this credit facility.

This facility bears a Euribor-based interest rate that amounts to 2.76% per year for the last drawing made early December 2014. Consistently with accounting policies, this straight loan facility is recognised as a financial liability and measured at amortised cost using the effective interest rate method.

The Company has repaid in full the outstanding amount of  $\in$  1.50 million on 31 December 2014. Post Offering, the Company will discontinue the facility.

On 27 May 2014 SCTS obtained a straight loan facility from BNP Paribas Fortis SA/NV and ING Belgique SA/NV each for an amount of  $\in$  1,450,000 to pre-finance the investment premium granted by the Walloon Region (see also Section 6.7 "Investments" and Section 6.17 "Properties and facilities"). For these straight loan facility interest rates and terms are decided based on what is appropriate for the chosen term. On the date of this Prospectus, these facilities are fully used for the total amount of  $\in$  2,900,000.

Government grant related to the construction of the new facilities

The Group received in 2014 a government grant for a total amount of € 2,908,000 for the new facilities under construction at Gosselies. The grant is payable in three tranches (after 40% of the investment, after 70% of the

investment and after finalisation of the investment). The grant is based on 32% of the total estimated investment. The grant is subject to specific conditions, such as employment, location and innovation. If conditions are not met, the Group has to reimburse the grant partially or entirely.

Consistently with accounting policies, this grant is deducted from the carrying amount of the related asset and will be recognised in the statement of profit or loss consistently with the depreciation expense of the related asset.

## Automatically convertible bonds

On 18 December 2014 and 8 January 2015, the Company issued automatically convertible bonds for an aggregate amount of  $\in$  10,350,000 (the "Bonds"). The Bonds are issued in registered form. Each Bond has a nominal value of  $\in$  1,000. The Bonds bear interest as from their issue date, at the rate of 7% per annum. Transactions costs amounting  $\in$  470,000 have been incurred on the issuance of the Bonds.

The Bonds will automatically be converted into Shares at the earliest date between (i) the Closing Date and (ii) and 30 September 2015.

If the conversion occurs on the Closing Date, the number of Shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 166.5% of the nominal value of the Bonds, and the denominator is equal to the Offer Price. The exact number of shares to be issued upon conversion of the Bonds is unknown at the date of this Prospectus. On the basis of hypothetical offer prices, the potential dilution can be calculated as follows:

- if the Offer Price is set at the low end of the Offer Price Range, i.e. € 14.5, 1,188,465 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the mid-point of the Offer Price Range, i.e. € 15.5, 1,111,790 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the high end of the Offer Price Range, i.e. € 16.5, 1,044,409 Shares will be issued upon conversion of the Bonds.

If the conversion occurs on 30 September 2015, 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  $\in$  11.

The Bonds were subscribed to as follows:

- 35.5% of the Bonds were subscribed by existing shareholders (and their affiliates) of the Company; and
- 64.5% of the Bonds were subscribed by certain new investors, including SFPI SA.

Each investors subscribing to the Bonds have 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 case the conversion occurs on the Closing Date. As a result, the Bonds will not be classified as equity instruments of the Company before the Bonds are converted into Shares, including in the annual financial statements ended 31 December 2014.

# Offering related costs

After the reporting period, the Company has incurred several costs in connection with the Offering. The commitments of the Company in that include legal, consulting, administrative, audit, and other costs ( $\in$  786,000), remuneration of the Belgian Financial Services and Market Authority ( $\in$  20,000), legal publications, printing of the prospectus ( $\in$  35,000), advisors, management, placing and selling fees (estimated at 6.7% of the gross proceeds of the offering) and the fees payable to Euronext Brussels and Euronext Paris ( $\in$  70,000).

Considering that the Offering is also expected to result in the issuance of new shares, a rationale allocation of the above mentioned costs will be determined between (i) costs linked to equity transactions that are

immediately deducted from the equity of the Company, and (ii) and other costs relating to the Offering that are expensed in the statement of profit or loss.

#### Share-based payments

After the reporting period, the Company has created the following three warrant plans:

- Warrant Plan A for employees, directors or consultants: 113,760 warrants available for issuance but no warrants were proposed to designated beneficiaries after the reporting period.
- Warrant Plan B for two members of the Management Team: 46,000 warrants available for issuance with 14,800 warrants proposed to designated beneficiaries after the reporting period on 18 December 2014. These warrants are exercisable at a strike price of € 11 and are subject to a vesting period starting on the grant date and ending at the earliest of the Offering date and the first anniversary of the grant. These warrants expire in February 2019.
- Warrant Plan C for three members of the Management Team: 145,000 warrants issued and proposed to designated beneficiaries after the reporting period. These warrants are exercisable at a strike price of € 11 and are subject to the following graded vesting: 25% at Offering date (or 1 January 2016 if no Offering), 25% on 1 January 2016, 25% on 1 July 2016 and 25% on 1 January 2017. These warrants expire in December 2019.

Consistently with accounting policies, above warrants are equity settled share-based payment transactions. As a result, the fair value of warrants will be measured at grant date and recognised as an expense against equity over the related vesting period.

#### 8.7. Statutory auditors

The annual fees for the statutory audit mandate under BeGAAP amount to € 6,500 for the year 2013 (excl. VAT).

#### **Deloitte**

## **Bone Therapeutics SA**

# Limited review report on the condensed interim consolidated financial information for the nine months period ended 30 September 2014 and 30 September 2013

To the Board of Directors

We report on the interim financial information set out in Annex C, as from page 216 of the prospectus of Bone Therapeutics SA (the "Company") and, together with its subsidiary, the "Group, (the "Investment Circular"). This interim financial information has been prepared for inclusion in the Investment Circular on the basis of the accounting policies set out in note 2 to the interim financial information. This report is required by Annex XXV item 20.1 of Commission Regulation (EC) No 809/2004 (the "Prospectus Directive Regulation) and is given for the purpose of complying with that requirement and for no other purpose.

#### Report on the condensed interim consolidated financial information

We have reviewed the condensed interim consolidated financial information of Bone Therapeutics SA (the "Company") and together with its subsidiary (the "Group"), prepared in accordance with International Financial Reporting Standard IAS 34 – *Interim Financial Reporting* as adopted by the European Union.

The condensed interim consolidated statement of financial position shows total assets of 12,971 (000) EUR as of 30 September 2014 and of 12,811 (000) EUR as of 31 December 2013 and the condensed interim consolidated statement of comprehensive income shows a consolidated loss (group share) for the nine months period ended 30 September 2014 of 3,853 (000) EUR and for the nine months period ended 30 September 2013 of 2,730 (000) EUR.

The board of directors of the company is responsible for the preparation and fair presentation of the condensed interim consolidated 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 interim consolidated financial information based on our review.

#### Scope of review

We conducted our review of the condensed interim consolidated financial information in accordance with International Standard on Review Engagements (ISRE) 2410 – Review of interim financial information performed by the independent auditor of the entity for the purpose of the Investment Circular. 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 performed in accordance with the International Standards on Auditing (ISA) 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 on the condensed interim consolidated financial information.

Our work has been carried out in accordance with ISRE and not with other auditing or standards and practices generally accepted in jurisdictions outside Belgium, including the United States of America, and accordingly should not be relied upon as if it had been carried out in accordance with those standards and practices.

#### Conclusion

Based on our review, for the purposes of the Investment Circular, nothing has come to our attention that causes us to believe that the condensed interim consolidated financial information of Bone Therapeutics SA has not

been prepared, in all material respects, in accordance with IAS  $34 - Interim\ Financial\ Reporting$  as adopted by the European Union for the purposes of the Investment Circular.

#### Declaration

For the purposes of art. 61 of the Law of 16 June 2006, we are responsible for this report as part of the Investment Circular and declare that we have taken all reasonable care to ensure that the information contained in this report is, to the best of our knowledge, in accordance with the facts and contains no omission likely to affect its import. This declaration is included in the Investment Circular in compliance with Annex XXV item 1.2 and Annex III item 1.2 of the Prospectus Directive Regulation.

Liège, 20 January 2015

The Auditor

DELOITTE Bedrijfsrevisoren / Reviseurs d'Entreprises BV o.v.v.e. CVBA / SC s.f.d. SCRL Represented by Julie Delforge

## **Bone Therapeutics**

## **Condensed Consolidated Financial Statements For the 9-month period ended 30 September 2014**

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## CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS (in thousands of euros)	Note	30/09/2014	31/12/2013
Non-current assets		4,230	4,724
Intangible assets		42	60
Property, plant and equipment	1	2,074	2,869
Investments in associates		282	282
Financial assets		181	180
Deferred tax assets		1,652	1,333
Current assets		8,741	8,087
Trade and other receivables	4	6,861	5,513
Other financial assets		0	0
Other current assets		145	134
Cash and cash equivalents		1,735	2,440
TOTAL ASSETS		12,971	12,811
<b>EQUITY AND LIABILITIES</b> (in thousands of euros)	Note	30/09/2014	31/12/2013
Equity			
Equity attributable to owners of the Company		(1,810)	63
Share capital		10,466	9,288
Share premium		7,480	6,635
Retained earnings		(19,757)	(15,860)
Non-controlling interests		0	0
Total equity	2	(1,810)	63
Non-current liabilities		6,570	6,502
Financial liabilities	3	5,082	5,052
Deferred tax liabilities		0	0
Other non-current liabilities		1,488	1,450
Current liabilities		8,212	6,246
Financial liabilities	3	3,340	509
Trade and other payables		1,852	1,458
Current tax liabilities		0	0
Other current liabilities		3,020	4,279
Total liabilities		14,782	12,748
TOTAL EQUITY AND LIABILITIES		12,971	12,811

## CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

(in thousands of euros)	Note	9 month per	riod ended
		30/09/2014	30/09/2013
Revenue			
Other operating income	5	2,644	2,418
Total operating income		2,644	2,418
Research and development expenses	6	(5,523)	(4,647)
General and administrative expenses		(865)	(502)
Operating profit/(loss)		(3,743)	(2,731)
Interest income		110	96
Financial expenses		(201)	(115)
Exchange gains/(losses)		(63)	()
Share of profit/(loss) of associates		0	31
Result Profit/(loss) before taxes		(3,897)	(2,720)
Income taxes		0	0
PROFIT/(LOSS) FOR THE PERIOD		(3,897)	(2,720)
Other comprehensive income		0	0
TOTAL COMPREHENSIVE INCOME OF THE PERIOD		(3,897)	(2,720)
Basic and diluted loss per share (in euros)		(1.16)	(0.91)
Profit/(loss) for the period attributable to the owners of the Company		(3,853)	(2,730)
Profit/(loss) for the period attributable to the non-controlling interests		(44)	10
Total comprehensive income for the period attributable to the owners of the			
Company		(3,853)	(2,730)
Total comprehensive income for the period attributable to the non-controlling interests	g	(44)	10

## CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

(in the count of count) 9 month period end	led
(in thousands of euros) 30/09/2014 30/09/2	2013
CASH FLOW FROM OPERATING ACTIVITIES	
	,731)
Adjustments for:	
Depreciation, Amortisation and Impairments 305	296
Grants income related to forgivable loans (1,733)	,681)
Grants income related to patents (96)	(66)
	(327)
Other (20)	23
Movements in working capital:	
Trade and other receivables (excluding government grants) (98)	(14)
Trade and Other Payables 327	(74)
	,573)
Cash received from grants related to forgivable loans 1,454	1,993
Cash received from grants related to patents  9	65
Cash received from grants related to patents  Cash received from grants related to tax credit  0	0
Income taxes paid 0	0
•	0
Discontinued operations 0	U
Net cash used in operating activities (3,913) (2	,515)
CASH FLOW FROM INVESTING ACTIVITIES	20
Interests received 18	29
	(889)
Purchases of intangible assets (4)	(46)
Proceeds from other current financial assets ()	0 13
Payments to acquire financial investments () Discontinued operations 0	0
	(893)
Net tash used in investing activities (2.551)	(693)
CASH FLOW FROM FINANCING ACTIVITIES	
Proceeds from government loans 623	854
	(135)
	(375)
Reimbursements of financial liabilities 0	0
Proceeds from loans from related parties 370	500
Reimbursements of financial lease liabilities (49)	(52)
Proceeds from other financial liabilities 2,858	0
Proceeds from government grants 0	0
Interests paid (57)	(22)
	1,491
Discontinued operations (1)	(1)
Net cash provided by financing activities 5,565	2,261
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS (705)	,148)
	<b>,148</b> ) 4,822

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

Attributable to owners of the parent						
(in thousands of euros)	Share capital	Share premium	Retained earnings	Total equity attributable to owners of the Company	Non- controlling interests	TOTAL EQUITY
Balance at 31 December 2012	8,417	6,014	(11,795)	2,636	0	2,637
Total comprehensive income of the period	0	0	(2,730)	(2,730)	10	(2,720)
Issue of share capital	871	629	0	1,500	0	1,500
Transaction costs for equity issue	0	(9)	0	(9)	0	(9)
Additional non-controlling interests	0	0	10	10	(10)	0
Balance at 30 September 2013	9,288	6,635	(14,515)	1,408	0	1,407
Balance at 31 December 2013	9,288	6,635	(15,860)	63	0	63
Total comprehensive income of the period			(3,853)	(3,853)	(44)	(3,897)
Issue of share capital	1,179	852		2,031		2,031
Transaction costs for equity issue		(6)		(6)		(6)
Additional non-controlling interests			(44)	(44)	44	0
Balance at 30 September 2014	10,466	7,481	(19,757)	(1,810)	0	(1,810)

#### NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### 1. General information

Bone Therapeutics SA (the "**Company**") is a limited liability company governed by Belgian law. The address of its registered office is Rue Adrienne Bolland 8, 6041 Gosselies, Belgium.

The Company and its subsidiary Skeletal Cell Therapy Support SA ("SCTS", together with the Company referred as the "Group") are active in regenerative therapy specialising in addressing unmet medical needs in the field of bone diseases and orthopaedics. The Company was incorporated by professionals from both the pharmaceutical industry and the hospital community. They share an in-depth knowledge of bone diseases and stem cell science, a strong expertise in cell manufacturing for human use, in cell therapy clinical trials and regulatory development.

The condensed consolidated financial statements were authorised for issue by the Board of Directors on 8 January 2015.

#### 2. Summary of significant accounting policies

#### Statement of compliance

The Group's condensed consolidated financial statements for the 9-month period ended 30 September 2014 have been prepared in accordance with International Accounting Standard 34 – *Interim Financial Reporting* as endorsed by the European Union ("IFRS").

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 31 December 2013, except for the impact of the adoption of new Standards and Interpretations as described below:

• Amendments to IAS 36 – *Impairment of Assets – Recoverable Amount Disclosures for Non-Financial Asset* (applicable for annual periods beginning on or after 1 January 2014)

This amendment did not have an impact on the consolidated financial statements.

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 2013:

- IFRS 9 *Financial Instruments* and subsequent amendments (normally applicable for annual periods beginning on or after 1 January 2018, but not yet endorsed in EU)
- IFRS 15 *Revenue from Contracts with Customers* (applicable for annual periods beginning on or after 1 January 2017)
- Improvements to IFRS (2010-2012) (normally applicable for annual periods beginning on or after 1 January 2015, but not yet endorsed in EU)
- Improvements to IFRS (2011-2013) (normally applicable for annual periods beginning on or after 1 January 2015, but not yet endorsed in EU)
- Improvements to IFRS (2012-2014) (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IAS 19 *Employee Benefits Employee Contributions* (applicable for annual periods beginning on or after 1 January 2015, but not yet endorsed in EU)
- IFRIC 21 Levies (applicable for annual periods beginning on or after 17 June 2014)

- Amendments to IAS 16 and IAS 38 Clarification of Acceptable Methods of Depreciation and Amortisation (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IFRS 11 Accounting for Acquisitions of Interests in Joint Operations (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)
- Amendments to IFRS 10 and IAS 28 Sale or Contribution of Assets between an Investor and its Associate or Joint Venture (normally applicable for annual periods beginning on or after 1 January 2016, but not yet endorsed in EU)

It is not expected that the initial application of the above mentioned IFRS standards, interpretations and amendments will have a significant impact on the consolidated financial statements.

#### **Basis of preparation**

The consolidated financial statements are presented in thousands of euros, unless otherwise stated. Euro is also the functional currency of both the Company and SCTS. The functional currency is the currency of the economic environment in which an entity operates. The consolidated financial statements have been prepared on a historical basis, unless otherwise stated.

#### Going-concern

On 30 September 2014, the consolidated results of the Company show a loss of  $\in$  3,897,000, and the consolidated statement of financial position includes a loss carried forward of  $\in$  19,758,000. These consolidated financial statements have been prepared assuming that the Group will continue as a going concern considering:

- the cash balance as per the beginning of January 2015 amounting to € 10.4 million (mainly resulting from the issue of convertible bonds on 18 December 2014 for a gross amount of € 10.0 million);
- In case of a successful IPO, the amount of funds raised in this context; and
- In case of no IPO taking place, the firm commitment of the bond holders to invest a further amount of € 10.0 million on 30 September 2015 (unconditional); and
- the support from the Walloon Region through non-dilutive financing instruments to support on-going and new research projects.

Considering all these elements, management is of the opinion that the Group's financial future is guaranteed in the near future.

#### 3. Disclosures to the condensed consolidated financial statements

#### Note 1 - Property, plant and equipment

The increase in property, plant and equipment is related to the property under construction of the new facility of SCTS at Gosselies. The completion of the facility is planned in different phases. Different parts of the building will be occupied at different points in time. Depreciation will start for the different parts in line with the start of the occupation and for the production zones following GMP approval of the zones. The Company plans to occupy the first phase (administration and R&D facilities) in the second quarter of 2015. The commissioning of the two first production zones is foreseen in the second half of 2016.

The evolution (decrease) in property, plant and equipment can mainly be detailed as follows:

- Additional investments to the property under construction for a total amount of € 2,315,000
- Government grant received related to the construction for a total amount of € 2,908,000, which has been deducted from the related property.

The Group received in 2014 a government grant for a total amount of € 2,908,000 for the new facilities under construction at Gosselies. The grant is payable in three tranches (after 40% of the investment, after 70% of the investment and when the investment is finished). The grant is based on 32% of the total estimated investment. The grant is subject to specific conditions, such as employment, location and innovation. If conditions are not met, the Group has to reimburse the grant partially or entirely.

Furthermore, SCTS obtained a long term financing instrument through BNP Paribas Fortis SA/NV and ING Belgique SA/NV to finance the construction of the new facilities. Each one of the banks foresees an amount of € 1,625,000 euro. The contracts were entered into on 27 May 2014 but have not yet been activated.

They have a term of 15 years and can be called upon in function of the progress of the completion of the project (for a full description see section 6.10 "Financing Agreements").

BNP Paribas Fortis SA/NV has, amongst other things, requested a number of securities in respect of the above loans/facilities to be granted in parity with the security granted to ING Belgique SA/NV. Amongst others this concerns the following:

- a first ranking mortgage granted by SCTS on the assets built with the funds provided for an amount of € 27,500 (€ 25,000 for ING Belgique SA/NV);
- a mandate to a first ranking mortgage granted by SCTS on the assets built with the funds provided for an amount of € 1,760,000 (€ 1,600,000 for ING Belgique SA/NV).

Committed expenditure on 30 September 2014 amounts to € 1,873,000.

*Note 2 – Equity* 

Share capital and share premium

On 24 February 2014, the shareholders of the Company resolved upon a share split, dividing the 314,960 shares, without nominal value, each representing 1/314,960th of the share capital of the Company by 1,000, creating 3,149,600 shares, without nominal value, each representing 1/3,149,600th of the share capital of the Company. On the same day, the share capital was increased by a contribution in cash in the amount of  $\varepsilon$  580,000 with issuance of 152,000 shares. The aggregate share premium amounted to  $\varepsilon$  420,000. Following the capital increase, the share capital of the Company amounted to  $\varepsilon$  9,868,000 and was represented by 3,301,600 shares.

On 10 July 2014, the share capital was increased by a contribution in cash in the amount of  $\in$  598,000 with issuance of 156,640 shares. The aggregate share premium amounted to  $\in$  432,000. Following the capital increase, the share capital of the Company amounted to  $\in$  10,466,000 and was represented by 3,458,240 shares.

The shares have no nominal value.

Non-controlling interests

The gross liability relating to the put option on non-controlling interest in SCTS (see note 7.1.) has been recognised against equity, as a reduction of non-controlling interests. Considering however that this gross liability exceeds the amount of non-controlling interests, the balance has been recognised as deduction of group equity (retained earnings) and the amount reported as non-controlling interest is nil.

*Note 3 – Financial liabilities* 

Current financial liabilities amounted to  $\in$  3.34 million representing an increase of  $\in$  2.83 million. This is resulting from the company taking up several straight loans to address short term funding requirements:

On 27 May 2014 BNP Paribas Fortis SA/NV and ING Belgique SA/NV provided both a straight loan facility, each for an amount of  $\in$  1,450,000 to pre-finance an investment premium granted by the Walloon Region (see also Section 6.7 "Investments" and Section 6.17 "Properties and facilities"). The applicable interest rates and terms are decided based on what is appropriate for the chosen term at the time funds are withdrawn. Up to the end of end of September 2014 an amount of  $\in$  2.36 million was drawn on these facilities (50/50) and up to the end of December 2014 an additional amount of  $\in$  0.54 million was drawn resulting in a total liability of  $\in$  2.9

million or the entire amount. Repayment is foreseen following the receipt of the grant money the Company has been granted from the Walloon Region in respect of this project.

Bone Therapeutics has withdrawn a first tranche of  $\in$  0.5 million from a bridge loan facility provided by BNP Paribas Fortis SA/NV to pre-finance funding for research activities covered by contracts with the Walloon Region (see also Section 6.10 "Financing Agreements"). On 18 August 2014, a straight loan facility was provided by BNP Paribas Fortis for a total amount up to  $\in$  1,500,000 and is running until 30 June 2015. This facility allows to pre-finance amounts due by the Walloon Region on recoverable cash advances ("avances récuperables" referred to as "forgivable loans" under IFRS) and subsidies (see Section 6.11 "Grants and subsidies") granted by the Walloon Region. In respect of this arrangement the Company has pledged the amounts to be received from the Walloon Region during the term of this credit facility as well as granted a business pledge mandate ("mandat de fonds de commerce") in respect of the Company for as long the Company wants to use this credit facility. This facility bears a Euribor-based interest rate (2.76% per year for the last drawing made early December 2014). Consistently with accounting policies, this straight loan facility is recognised as a financial liability and measured at amortised cost using the effective interest rate method.

Non-current liabilities amounted to  $\in$  6.57 million compared to  $\in$  6.50 million at 31 December 2013. A new subordinated loan from a related party for an amount of  $\in$  370,000 was taken up (SA Fonds de Capital à Risque – see also section 6.10 Financing agreements). The duration of the loan is for 15 years. The loan carries an interest of 6.66% payable on a monthly basis. Capital reimbursement is based on fixed monthly instalments but with a two year moratorium during which no capital reimbursements will take place. There are no securities provided by the Group in respect of this loan agreement. The increase is however to a large extent counterbalanced by the reimbursement of the unforgivable loans to the Walloon Region.

*Note 4 – Trade and other receivables* 

The trade and other receivables are detailed as follows:

(in thousands of euros)	30/09/2014	31/12/2013	
Trade receivables			
Trade receivables	5	19	
Write-downs on trade receivables	0	0	
Total trade receivables	5	19	
Other receivables			
Receivable related to taxes	197	226	
Receivable related to tax credit	0	0	
Receivable related to Forgivable loans	3,621	5,063	
Receivable related to Patents	126	192	
Receivable related to other grants	5	13	
Receivable related to GIE	2,908	0	
Total other receivables	6,857	5,494	
Total trade and other receivables	6,862	5,513	

The other receivables amounting to  $\in$  6.86 million relate to on the one the hand the capital grant mentioned above still be received from the Walloon Region for an amount of  $\in$  2.91 million (being the main reason for the increase in value of this item) and on the other hand an amount of  $\in$  3.62 million forgivable loans (being the amount receivable of the so called "Avance récupérables" which are classified as forgivable loans – see also note 5). The remaining amount of refers patent grants to be received for an amount of  $\in$  0.13 million and tax to receive for an amount of  $\in$  0.2 million.

*Note 5 – Other operating income* 

The other operating income relate to the different grants received by the Group.

Forgivable loans

er operating Income 9-month period		od ended	
(in thousands of euros)	30/09/2014	31/12/2013	
Grants income related to forgivable loans	1,733	1,681	
Grants income related to exemption on withholding taxes	402	297	
Grants income related to tax credit	320	327	
Grants income related to patents	96	66	
Other grants income	92	47	
Total	2,644	2,418	

The forgivable loans ("Avances récupérables") are granted to support specific research and development programs. After the approval of these loans by the government (i.e. Walloon Region), a receivable is recognised for the loan to be received and presented as other receivables (see note 5.5). These loans become refundable under certain conditions, including the fact that the Group decides to exploit the R&D results of the project. In such case, part of the loan (typically 30%) becomes refundable within an agreed schedule, whereas the remaining part (typically 70%) only becomes refundable to the extent of revenue generated within 10 years after the date at which exploitation has been decided. Accordingly, if no revenue is generated within that period of 10 years, any non-refunded part of the loan is forgiven. In addition, no interest is charged on the loan.

In accordance with IFRS, a forgivable loan from government should be treated as a government grant when there is a reasonable assurance that the Group will meet the terms for forgiveness of the loan. Consistently with the length of the products' development cycle, it is expected that no significant revenue will be generated within a period of 10 years starting from the exploitation date of the R&D project. Consequently, there is a reasonable assurance that related part of the loan (typically 70%) will be forgiven. Till date, the Group decided to exploit all R&D projects which were supported by the Walloon Region under the scheme of "Avances récupérables". These decisions have triggered the repayments of the related part of the loans (typically 30%) as per the agreed terms.

On this basis, a financial liability is recognised for the discounted value of the minimum refundable amount in case of exploitation (presented as government loans in note 5.9. above), and any difference with the amount receivable from the government is accounted for as a grant and presented as deferred income within other current liabilities in the consolidated statement of financial position (see note 5.12.). The deferred income is released as other operating income as the R&D costs compensated by the grant are incurred, whereas the part of the grant representing the discount effect on the minimum refundable amount is released as interest income over the period of interest free loan.

The receivable related to the forgivable loans is reconciled as follows:

(in thousands of euros)	30/09/2014	31/12/2013
Opening balance	5,063	6,362
New grants	635	2,220
New loans	0	641
Cash received	(2,077)	(4,160)
Closing balance	3,621	5,063

The movements related to the government loans are detailed in the following table:

(in thousands of euros)	30/09/2014	31/12/2013
Opening balance	3,982	3,460
New loans	0	641
Repayment	(203)	(135)
Unwind of discount	73	16
Closing balance	3,852	3,982

The deferred income related to the forgivable loans recognised in the consolidated statement of financial position can be reconciled as follows:

(in thousands of euros)	30/09/2014	31/12/2013
Opening balance	3,906	4,083
Released as operating income	(1,733)	(2,382)
Released as finance income	(73)	(16)
Increase on new grants	635	2,222
Closing balance	2,735	3,906

#### Grants related to tax credit

The Company has applied for an income tax credit that corresponds to a percentage of qualifying R&D costs to which the income tax rate (33.99%) is applied. In case of insufficient current tax payable against which to set off the tax credit, the latter is carried-forward to the following four years. At the end of this period, the balance of the unused tax credit is paid by the tax authorities. Considering that R&D tax credits are ultimately paid by the authorities, the related benefit is treated as a government grant and released as other operating income when the R&D costs compensated by the grant are expensed.

Grants related to the exemption of withholding taxes for researchers

Companies that employ scientific researchers benefit from a partial exemption from payment of withholding tax on their salaries. They must transfer to the tax authorities only 20% of the withholding tax due on the salary of these researchers while the remaining amount is considered to be a government grant. These grants are recognised in the consolidated statement of comprehensive income at the same moment the related personnel expenses are incurred.

#### *Grants related to patents*

The Group receives government grants related to patents. On average, the grants received cover 70% of the fees incurred in the process of obtaining patents.

Considering that patent costs are expensed as incurred, related patent grants are immediately recognised as other operating income when the patent fees are incurred.

#### *Note* 6 – *Research and development expenses*

The main movement compared to previous period relates to increased expenses incurred in the context of clinical trials and strengthening of the research team.

#### Note 7 – Overview of financial instruments

The following table provides the category in which financial assets and financial liabilities are classified in accordance with IAS 39 – *Financial Instruments: Recognition and Measurement.* 

(in thousands of euros)	IAS 39 Category	30/09/2014	31/12/2013
Other non-current financial assets			
Non-current receivables	Loans and receivables	181	180
Trade and other receivables	Loans and receivables	6,664	5,287
Cash and cash equivalents	Loans and receivables	1,735	2440
Total financial assets		8,580	7,907
Non-current financial liabilities			
Finance lease liabilities	At amortised cost	97	100
Government loans	At amortised cost	3,537	3,774
Loans from related parties	At amortised cost	1,448	1,178
Other non-current liabilities			
	At fair value through profit		
Put on non-controlling interests	or loss	1,488	1,450
Current financial liabilities			
Bank loans	At amortised cost	2,858	0

(in thousands of euros)	IAS 39 Category	30/09/2014	31/12/2013
Finance lease liabilities	At amortised cost	40	229
Government loans	At amortised cost	314	208
Loans from related parties	At amortised cost	128	72
Trade and other payables			
Trade payables	At amortised cost	1,472	1,136
Total financial liabilities		11,382	8,147

The carrying amounts of financial assets recognised in the consolidated financial statements approximate their fair values. The same situation is applicable for financial liabilities, except as detailed in the following tables.

(in thousands of euros)	30/09/2014		
	Carrying amount	Fair value	Fair value level
Non-current financial liabilities			
Finance lease liabilities	97	97	Level 2
Government loans	3,537	3,357	Level 2
Loans from related parties	1,448	1,547	Level 2
Other non-current liabilities			
Put on non-controlling interests	1,488	1,488	Level 3
Current financial liabilities			
Bank loans	2,858	2,858	Level 2
Finance lease liabilities	40	40	Level 2
Government loans	314	314	Level 2
Loans from related parties	128	128	Level 2
Trade and other payables			
Trade payables	1,472	1,472	
Total	9,910	9,829	

		31/12/2013		
(in thousands of euros)	Carrying amount	Fair value	Fair value level	
Non-current financial liabilities				
Finance lease liabilities	100	100	Level 2	
Government loans	3,774	3,655	Level 2	
Loans from related parties	1,178	1,159	Level 2	
Other non-current liabilities				
Put on non-controlling interests	1,450	1,450	Level 3	
Current financial liabilities				
Finance lease liabilities	229	229	Level 2	
Government loans	208	208	Level 2	
Loans from related parties	72	72	Level 2	
Trade and other payables				
Trade payables	1,136	1,136		
Total	7,011	6,873		

The fair values of the financial assets and financial liabilities included in the level 2 and level 3 categories above have been determined in accordance with generally accepted pricing models based on a discounted cash flow analysis, with the most significant input being the discount rate that reflects the credit risk of counterparties.

The only financial liability subsequently measured at fair value on Level 3 fair value measurement is the put option granted by the Group to non-controlling interests in SCTS, which has been fully consolidated. These commitments to purchase equity instruments have been recognized under other non-current liabilities and concern 50.1% of SCTS.

The following table includes a reconciliation of the level 3 fair value measurements:

(in thousands of euros)	30/09/2014	31/12/2013
Opening balance	1,450	1,811
Total gains or losses in profit or loss	38	14
Decrease of capital	0	(375)
Closing balance	1,488	1,450

The put option has been measured using a discounted cash flow analysis based on significant unobservable inputs, such as expected rate of return (6.5%) and discount rate (3.5%).

If the above unobservable input linked to the expected rate of return was 10% higher/lower while all the other variables were held constant, the carrying amount of the put option would increase/decrease by  $\in$  48,000 (2013: increase/decrease by  $\in$  47,000).

#### *Note* 8 – *Contingent liabilities*

Management uses its judgement to estimate the portion of forgivable loans for which there is reasonable assurance that the terms for forgiveness will be met. Consistently with past practices, management expects that it will decide to exploit the results of the R&D project, which triggers the repayment of a portion of the loan (typically 30%). Similarly, management expects that revenue potentially generated from the R&D project within 10 years after the exploitation date is insignificant considering the length of the products' development cycle, and consequently that there is reasonable assurance that the remaining part (typically 70%) of the loan will be forgiven. This latter part treated as government grants contains a contingent liability as there might be scenarios under which the Company will have to repay a portion of it.

As of 30 September 2014, the total amount of forgivable loans released in income amounts to  $\varepsilon$  9,253,000. This amounts corresponds to the maximum contingent liability. For part of this amount, repayment will indeed occur only if the Company generates revenue for such an amount and in such a timing that the probability associated with this scenario is assessed to be remote. For further information regarding the expiring dates of the period of 10 years together with details on the amounts for each forgivable loans, we refer to Sections 6.11.1.1 and 6.11.2.1 of the Prospectus.

*Note 9 – Events after the reporting period* 

Straight loan facility

On 18 August 2014, a straight loan facility was provided by BNP Paribas Fortis SA/NV for a total amount up to € 1,500,000 and is running until 30 June 2015. The Company has repaid in full the outstanding amount of € 1,500,000 on 31 December 2014. Post Offering, the Company will discontinue the facility.

On 27 May 2014 SCTS obtained a straight loan facility from BNP Paribas Fortis SA/NV and ING Belgique SA/NV each for an amount of  $\in$  1,450,000 to pre-finance the investment premium granted by the Walloon Region (see also Section 6.7 "Investments" and Section 6.17 "Properties and facilities"). For these straight loan facility interest rates and terms are decided based on what is appropriate for the chosen term. On the date of this Prospectus, these facilities are fully used for the total amount of  $\in$  2,900,000. Compared to the position as reported at the end of September 2014 an additional amount was withdrawn of  $\in$  544,000.

Automatically convertible bonds

On 18 December 2014 and 8 January 2015, the Company issued automatically convertible bonds for an aggregate amount of  $\in$  10,350,000 (the "**Bonds**"). The Bonds are issued in registered form. Each Bond has a nominal value of  $\in$  1,000. The Bonds bear interest as from their issue date, at the rate of 7% per annum. Transactions costs amounting  $\in$  470,000 have been incurred on the issuance of the Bonds.

The Bonds will automatically be converted into Shares at the earliest date between (i) the Closing Date and (ii) and 30 September 2015.

If the conversion occurs on the Closing Date, the number of Shares issued upon conversion of the Bonds will be equal to a fraction, whereby the numerator is equal to 166.5% of the nominal value of the Bonds, and the denominator is equal to the Offer Price. The exact number of shares to be issued upon conversion of the Bonds is unknown at the date of this Prospectus. On the basis of hypothetical offer prices, the potential dilution can be calculated as follows:

- if the Offer Price is set at the low end of the Offer Price Range, i.e. € 14.5, 1,188,465 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the mid-point of the Offer Price Range, i.e. € 15.5, 1,111,790 Shares will be issued upon conversion of the Bonds;
- if the Offer Price is set at the high end of the Offer Price Range, i.e. € 16.5, 1,044,409 Shares will be issued upon conversion of the Bonds.

If the conversion occurs on 30 September 2015, 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  $\in$  11.

The Bonds were subscribed to as follows:

- 35.5% of the Bonds were subscribed by existing shareholders (and their affiliates) of the Company; and
- 64.5% of the Bonds were subscribed by certain new investors, including SFPI SA.

Each investors subscribing to the Bonds have 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 case the conversion occurs on the Closing Date. As a result, the Bonds will not be classified as equity instruments of the Company before the Bonds are converted into Shares, including in the annual financial statements ended 31 December 2014.

#### Offering related costs

After the reporting period, the Company has incurred several costs in connection with the Offering. The commitments of the Company in that respect include legal, consulting, administrative, audit, and other costs ( $\in$  786,000), remuneration of the Belgian Financial Services and Market Authority ( $\in$  20,000), legal publications, printing of the prospectus ( $\in$  35,000), advisors, management, placing and selling fees (estimated at 6.7% of the gross proceeds of the offering) and the fees payable to Euronext Brussels and Euronext Paris ( $\in$  70,000).

Considering that the Offering is also expected to result in the issuance of new shares, a rationale allocation of the above mentioned costs will be determined between (i) costs linked to equity transactions that are immediately deducted from the equity of the Company, and (ii) and other costs relating to the Offering that are expensed in the statement of profit or loss.

### Share-based payments

After the reporting period, the Company has created an additional warrant plan:

• Next to Warrant Plan A and B representing 159,760 warrants in total, a new Warrant Plan C was created for three members of the Managament Team: 145,000 warrants issued and proposed to designated beneficiaries after the reporting period on 18 December 2014. These warrants are exercisable at a strike price of € 11 and are subject to the following graded vesting: 25% at Offering date (or 1 January 2016 if no Offering), 25% on 1 January 2016, 25% on 1 July 2016 and 25% on 1 January 2017. These warrants expire in December 2019.

Consistently with accounting policies, above warrants are equity settled share-based payment transactions. As a result, the fair value of warrants will be measured at grant date and recognised as an expense against equity over the related vesting period.