Mithra Announces 2021 Half Year Results

- **Historic year for the Company with first estetrol-based product Estelle® marketing authorizations obtained in the US, Canada, Europe and Russia, leading to a cash collection of two major out-licensing milestones for an amount of EUR 24 million**
- **Successful launch of Estelle® in the US, Canada and Europe, covering more than 80% of the contraceptive global market. Still around EUR 290 million cash to be collected for out-licensing and sales related milestones from Estelle® partners**
- **Revenues mostly driven by Estelle®'s first deliveries**
- **Complete buyout of all earnouts linked to Myring® and Zoreline® allowing the Company to be sole owner of all rights related to its Complex Therapeutics product, Zoreline®**
- **EUR 56 million cash position, which when added to EUR 67 million unused facilities, is a total amount showing the Company's financial strength and ability to progress on its Business Development strategy for Donesta® and R&D projects**

Liege, Belgium, 24 September 2021 – 7:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces its financial results for the six-month period ending on 30 June 2021, prepared in accordance with IFRS. The full interim report is available on the Investors section of the website.

Leon Van Rompay, CEO Mithra Women's Health, commented: "*The first six months of the year have been historical for Mithra, more specifically for our contraceptive product Estelle®. We have achieved a huge milestone by obtaining marketing authorizations covering more than 80% of the contraceptive global market. Our teams' hard work combined with the excellent alignment and preparation with our partners enabled us to ensure a fast and successful commercial launch in the United States, in Canada and in several European countries. On top of these achievements, Estelle's first sales revenues were booked at the end of the first half of the year.*

Thanks to our strong financial position supported by EUR 56 million cash flow and around EUR 67 million capital commitment and credit lines available, everyone involved in these developments has been able to focus on R&D and BD so as to achieve the highest value for the asset.

Despite the difficult circumstances in relation with Covid-19, we managed to make progress in our Phase III of Donesta®, limiting the delay of the marketing authorization by only three months for the US, the largest market worldwide, and by six months for Europe. More than ever, we are convinced of the strong potential of this major product and are determined to make the most of it.

In addition, we reinforced Mithra's portfolio with the acquisition of the full licensing and distribution rights for Zoreline®, which represents an attractive business opportunity in a market dominated by one product with worldwide sales of more than EUR 700 million with an annual growth close by 5 %.

Our CDMO facility also achieved key milestones with the reception of the accreditations for the hormonal tablets section as well as for the injectable zone from the Belgian Authorities. We are very pleased that the Belgian biotech ExeVir selected Mithra CDMO's new injectable facility for the manufacturing of its product candidate for potential treatment and prevention of Covid-19. This injectable zone of our CDMO will be key in the nearby future as it represents an activity that can generate nice margins."

Financial highlights

- Revenues mainly driven by EUR 6.3 million **first commercial sales/deliveries of Estelle®** during the second quarter of 2021 in the US, Canada and Europe; and an out-licensing revenue of EUR 4 million following the acquisition of full global licensing and distribution rights for Zoreline® allowing a deferred revenue to be recognized as earned revenue on the income statement.
- **Cash collection of two major Estelle® out-licensing milestones** with Mayne (USD 11 million) and Gedeon Richter (EUR 15 million), without impact on revenue as already recognized as per IFRS15 in 2019.
- **R&D expenses** (excluding depreciation) increased by 28% to reach EUR 32.9 million compared to EUR 25.7 million in H1 2020. These R&D expenses are of course the result of the ramp-up of activities under the Phase III Donesta®.
- **EBITDA** stands at EUR -31.9 million compared to EUR -30.0 million at H1 2020, so stable despite the R&D expenses increase.
- **Below EBITDA**, a net fair value loss on financial assets is reported at EUR -6.4 million which is mainly made of a charge of EUR 8 million related to a contingent receivable with Ceres Pharma, partly compensated by a gain on contract assets (related to the Mayne US deal).
- **Reception of second tranche of Mayne shares** (an Estelle® out-licensing milestones for the US territory) allowing the Company to become the first shareholder (with 9.57%) of Mayne Pharma Group Ltd, an Australia-listed company on ASX.
- **Complete buyout of all earnouts linked to Myring® and Zoreline®**, cancelling related amounts reported in the balance sheet in December 2020 (EUR 8.8 million) and thus providing better readability. This deal also allowed the Company to increase the value of Zoreline® IP rights on our balance sheet by EUR 8.5 million.
- As contractually agreed (see press release dated 1st October 2019), an **earnout of EUR 25 million** was paid to former owners of Uteron Pharma. This payment contributed to a reduction of the liability related to such earnouts reported at fair value on the balance sheet in December 2020 (from EUR 115.7 million to EUR 103.6 million in June 2021).
- **EUR 56 million cash position** which, when added to **EUR 67 million capital commitment and credit lines available**. This shows the Company's financial strength and ability to progress on its Business Development strategy for Donesta® and R&D projects.
- **Still around EUR 290 million cash to be collected for Estelle®** out-licensing and sales related milestones.
- **Equity stands at strong level of EUR 98 million**, logically reduced compared to December 2020 (EUR 157.7 million) by the net loss for the period.

Operational Highlights (including post-period end)

- Landmark milestone for the Company with **marketing authorizations for Estelle®** obtained in Canada (March), United States (April), Europe (May) and Russia (September). Estetrol is the first new estrogen introduced in over 50 years.
- **Successful commercial launch of Estelle®** in the United States by Mayne Pharma (June) and in Canada by Searchlight Pharma (August) under the trademark Nextstellis®. Marketing exclusivity granted for five years by the FDA as a new chemical entity (NCE).
- **Launch of Estelle® phased European commercialization** by Richter under the trademark Drovelis® in Germany, Hungary, Poland and Austria.

- **Phase III Donesta®:** recruitment completion of American study and additional recruitment in the European study. Primary efficacy data of both studies on track for end of 2021. Depending on the evolution of the Covid-19 situation, study results and regulatory approvals, marketing authorization expected for Donesta® in H1 2024 for the United States/Canada and in H2 2024 for Europe.
- Based on regulatory agencies' feedback, the Board of Directors decided that the initial **PeriNesta® development project** was no longer timely nor a priority for the Company. Alternative scenarios based on Estelle® and Donesta® could potentially target this perimenopausal market without incurring substantial development costs.
- **Topline results of the Coronesta Phase II study,** which aimed to assess the safety and efficacy of estetrol (E4) for the treatment of patients who were hospitalized with moderate Covid-19. E4 did not differ from placebo on the primary study endpoint, but the results further support the unique safety profile of estetrol.
- **Acquisition of full licensing and distribution rights on Zoreline®**, allowing Mithra to significantly increase its margin in some of the most attractive locations outside of Mithra's former geographical scope.
- Launch of an animal **PK/PD comparative study for Zoreline®** with first results expected by the end of 2021.
- **Commercial launch of Myring®** in Italy (Farmitalia), Switzerland (Labatec), Poland and France **(Zentiva).** Myring® is currently commercialized in 12 countries worldwide and we have already reached a 5% market share while our market share in Germany, the European's largest market stands at 10%.
- **Commercialization agreement for Tibelia®** signed with Dampe for Venezuela and additional commercial launches in Chile, Switzerland, UAE and KSA.
- **Accreditations for the Mithra CDMO's hormonal tablets section as well as for the injectable zone** from the Belgian Federal Agency for Medicines and Health Products.
- **Agreement with ExeVir for the manufacturing at Mithra CDMO's new injectable facility** of a novel llama-derived antibody therapies for potential treatment and prevention of Covid-19.
- **E4 Intellectual Property Strategy:**
    - Application for patent term extensions of the basic patent on the use of Estetrol in a combined contraceptive.
    - In August, **Health Canada delivered a 2-year Certificate of Supplementary Protection** for the patent on the use of Estetrol in a combined contraceptive, extending the patent end date up to May 2024. In September, the **Belgian patent office** allowed the Supplementary patent certificate of the Belgian counterpart of the EP1390042. This SPC will cover the period between May 2022 and May 2027.
    - **Obtention of an additional key patent for the product Estelle® and product candidate Donesta®** in Europe and Eurasia covering various pharmaceutical compositions, as well as their manufacturing process. This patent with an expected end date in 2036 is now granted in Japan as well and is still under prosecution in more than 50 other territories.
    - The 2021 approved product Estelle® is covered by **data and market exclusivity of 8 years, 5 years and 10 years** in Canada, Europe and the United States respectively.
    - The two patent applications filed following the **positive results of the Donesta® Phase II study** for the effective treatment of vasomotor symptoms are in the national

phases. Once granted, these patents will consolidate and extend the protection around Donesta®.

- **Renewal of the Board of Directors** for a two-year mandate achieving a perfect parity: 5 women directors/5 men directors, as well as 5 independent/5 non-independent directors. Mr. Ajit Shetty succeeds Ms. Patricia van Dijck as Chairman of the Board.
- **Appointment of Leon Van Rompay** as Chief Executive Officer ad interim.

Expected milestones and outlook for the remainder of 2021

- **Estelle® launches** expected in additional European countries, namely in Italy, the largest market in Europe. **Marketing approval** for the Australian market should be granted at the end of the year, with a commercial launch that is expected to start in the second half of 2022. Continuation of **expansion of international partnerships**, in uncovered territories such as India and China.
- **Primary efficacy results of the Donesta® Phase III Program** on track for end of 2021. Our business development strategy is progressing according to our plan to fully leverage the potential of its product candidate in menopause.
- Advanced negotiations with additional partners for the **injectable zone at the Mithra CDMO** platform.
- **Additional commercial launches for Myring®** in significant markets during the second half of the year. FDA approval for vaginal contraceptive ring Myring® for commercialization in the U.S. by Mayne Pharma, expected in early 2022.
- Finalization of **Zoreline® formulation development** for a new 1 month and 3 month dosage form based on previous clinical experience. Launch of clinical studies expected in 2022.

FINANCIAL RESULTS

1. Interim consolidated statement of income statement

Thousands of Euro (€)	*30 June 2021*	*30 June 2020*
Revenue	12,142	2,507
Cost of sales	(8,246)	(1,331)
Gross profit	**3,897**	**1,176**
Research and development expenses	(36,756)	(28,183)
General and administrative expenses	(5,896)	(7,226)
Selling expenses	(686)	(926)
Other operating income	2,908	2,319
Loss from operations	**(36,534)**	**(32,840)**
Change in the fair value of contingent consideration payable	(12,813)	(5,803)
Net fair value gains/(losses) on financial assets at fair value through profit or loss	(6,351)	(3,748)
Financial income	1,310	237
Financial expenses	(6,090)	(2,504)
Loss before taxes	**(60,478)**	**(44,659)**
Income taxes	5,584	10,664
NET LOSS FOR THE PERIOD	**(54,894)**	**(33,994)**

2. Interim consolidated statement of financial position

Thousands of Euro (€)	*30 June 2021*	*31 December 2020*
ASSETS		
Property, plant and equipment	33,902	29,921
Right-of-use assets	70,586	69,572
Goodwill	5,233	5,233
Other intangible assets	101,452	89,005
Deferred income tax assets	59,317	50,905
Contracts assets	-	200
Derivatives financial assets	1,985	6,184
Investments in equity securities	34,119	18,088
Other non-current assets	8,218	14,401
Non-current assets	**314,811**	**283,509**
Inventories	39,422	35,382
Contract assets	8,831	51,472
Derivatives financial assets	1,654	2,881
Trade and other receivables	16,047	10,052
Other short-term deposits	-	14
Cash and cash equivalents	55,830	138,675
Current assets	**121,784**	**238,475**
TOTAL ASSETS	436,596	521,985

Thousands of Euro (€)	*30 June 2021*	*31 December 2020*
EQUITY AND LIABILITIES		
Share capital	32,020	31,271
Additional paid-in-capital	335,286	332,535
Other reserves	5,426	13,690
Accumulated deficit	(274,652)	(219,759)
Equity attributable to equity holders	**98,080**	**157,737**
Subordinated loans	11,962	12,610
Other loans	112,695	111,898
Lease liabilities	43,912	44,282
Refundable government advances	13,476	15,195
Other financial liabilities	103,365	101,180
Contract liabilities	-	3,706
Provisions	266	266
Deferred tax liabilities	5,703	4,363
Non-current liabilities	**291,379**	**293,500**
Current portion of subordinated loans	1,002	1,002
Current portion of other loans	10,249	10,475
Current portion of lease liabilities	6,160	7,315
Current portion of refundable government advances	1,664	1,259
Current portion of other financial liabilities	8,687	23,424
Derivative financial liabilities	65	-
Trade and other payables	19,310	27,272
Current liabilities	**47,137**	**70,747**
TOTAL EQUITY AND LIABILITIES	436,596	521,985

3. Interim consolidated statement of cash flow

Thousands of Euro (€)	*30 June 2021*	*30 June 2020*
Cash flow from operating activities	(31,548)	(38,148)
Cash flow from investing activities	(43,915)	(9,105)
Cash flow from financing activities	(7,352)	60,109
Net increase/(decrease) in cash and cash equivalents	**(82,815)**	**12,856**
Cash and cash equivalents at beginning of year	**138,675**	**49,720**
Effects of exchange rate changes on cash and cash equivalents	(30)	-
Cash and cash equivalents at end of period	**55,830**	**62,576**

Profit and Loss

The Group reported a net loss of EUR 54.9 million for the first six months of 2021, compared to a net loss of EUR 34.0 million for the first six months of 2020.

Product sales were largely driven by our first deliveries of Estelle® (EUR 6.3 million) to our European, US and Canadian partners. Sales from generic products in our portfolio, at EUR 1.9 million, remained steady compared to last year.

Out-licensing revenue, at EUR 4.0 million, are essentially Zoreline® milestones, previously invoices and paid, that could be recognized in line with the agreement signed with SVR Invest BV for the full global licensing and distribution rights for the Zoreline® implant. Otherwise, no new significant partnership was signed during 2021 first semester and no triggering event on our portfolio of signed contracts, implying that no additional performance obligations (and related revenues) could be recognized in our accounts.

As anticipated, R&D expenses increased by 30% compared to last year due to Donesta® Phase III clinical studies and, to a lesser extent, Coronesta studies.

G&A and sales expenses decreased by 19%, essentially due to a much lower impact of share-based payments accounting entries (charge of EUR 0.5 million compared to EUR 2.6 million for June 2020). Not considering this non-cash impact, G&A expenses would have remained stable despite the ramp-up of our activities.

Estelle® approval led to a review of the different scenarios and probabilities related to contingent consideration payable, hence the EUR 12.8 million change in fair value charge recorded in our first semester 2021 accounts.

Fair value loss on financial assets is mainly made of the charge of EUR 8.0 million related to contingent receivable with CERES, partially compensated by a fair value gain on contract assets (re-evaluation of Mayne's shares up to their issuance in May 2021) for EUR 1.6 million.

Increase of net financial expenses is mostly driven by the interest charge of the EUR 125 million convertible bond negotiated in December 2020.

The group recorded a tax income of EUR 5.6 million for the six months that mainly results from the recognition of tax losses of the period in several entities as deferred tax assets, which are to be offset against future taxable income.

Alternative performance measures

Mithra decided to use some alternative performance measures (APMs) that are not defined in IFRS but that provide helpful additional information to better assess how the business has performed over the period. Mithra decided to use REBITDA1 and EBITDA in order to provide information on recurring items, but those measures should not be viewed in isolation or as an alternative to the measures presented in accordance with IFRS.

REBITDA is an alternative performance measure calculated by excluding the non-recurring items and the depreciation & amortization from EBIT (operating loss) from the consolidated statement of income prepared in accordance with IFRS. The Group considers one-off item, share-based payments as non-recurring item.

EBITDA is an alternative performance measure calculated by excluding the depreciation and amortization from EBIT (operating loss) from the consolidated statement of income prepared in accordance with IFRS.

Refer to note on Financial Highlights and table below for the reconciliation to operating loss:

Thousands of Euro (€)	*30 June 2021*	*30 June 2020*
Loss from operations	(36,534)	(32,840)
Depreciation	4,637	2,820
Share-based payments	485	2,554
REBITDA	(31,412)	(27,465)
Share-based payments	(485)	(2,554)
EBITDA	(31,897)	(30,019)

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[1] Recurring earnings before interest, taxes, depreciation and amortization

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Webcast

Mithra will host a live webcast on **Friday, 24 September 2021 at 09:30 CEST** to announce its 2021 Half Year financial and operating results. The live webcast can be accessed on the Mithra website or by clicking here. To participate to the conference call, please register on this link. A replay of the webcast will be available on the Mithra investor's website shortly after the close of the call.

About Mithra

Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Mithra explores the potential of the unique native estrogen Estetrol in a wide range of applications in women health and beyond. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 300 staff members and is headquartered in Liège, Belgium. www.mithra.com

Important information

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.