Mithra Announces 2020 Half Year Results

- **Substantial funding transactions of EUR 135 million that should secure Mithra for all future working capital needs, and more so if Estelle® receives marketing authorization**
- **Total revenues from licensing milestones for Estelle® of EUR 487 million, with EUR 349 million cash to still be collected (EUR 322 million under IFRS15) with a payment horizon dependent on the commercial success of Estelle®**
- **Revenues of EUR 2.5 million, to be bolstered by licensing and supply agreements for Estelle® in major territories such as Latam, sales of Myring, and CDMO revenues**
- **Net loss significantly improved (-62%) thanks to substantial reduction on the impact of the fair value of the earnouts (-94%)**
- **Regulatory submission for Estelle® accepted for review by the FDA, Health Canada, and the EMA with approval anticipated in H1 2021**
- **Business development strategy of Donesta® progressed, targeting major global partners**

Liege, Belgium, 24 September 2020 – 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 30 June 2020, prepared in accordance with IFRS. The full interim report is available on the Investors section of the website.

Financial highlights

- Revenues of EUR 2.5 million (EUR 19.6 million in June 2019), mainly driven by product sales, including the first sales of Myring. The decrease in revenues reflects the business development strategy for Donesta®, which is progressing well, targeting major global partners. At the same time, we are generating more data in the Phase III trial to be able to conclude a higher deal value.
- From the backlog of contracts signed for Estelle®, Mithra should collect an additional EUR 349 million in cash (IFRS15 EUR 322 million of licencing milestones revenues out of a total of EUR 487 million) in the coming years. Additional revenue generation expected from future licensing and supply agreements for Estelle®, namely in key markets such as Latam.
- EBITDA[1] of EUR -30 million versus EUR -6.8 million in June 2019, as a consequence of the revenues and the slight increase in R&D spend due to the ramp up of the Donesta® Phase III "E4 Comfort" clinical program
- Fair value of earnout debt increased by EUR 5.8 million to EUR -102.3 million, which is the result of a timing effect. Thanks to the successful renegotiation of the earnout payments to the former owners of Uteron Pharma, the earnouts are now a lump sum payable in regular

[1] EBITDA is an alternative performance measure calculated by excluding the depreciations & amortization from EBIT (operating loss) from the consolidated statement of income prepared in accordance with IFRS.

annual instalments that are no longer tied to the commercial success of Estelle®, which could have implied a much higher payment than the renegotiated lump sum.

- Net result significantly improved to EUR -33.9 million, versus EUR -89.7 million in June 2019, thanks to the substantial reduction on the impact of the fair value of the earnouts (EUR -5,8 million impact in H1 2020, compared to EUR -98,9 million in H1 2019)
- Cash at 30 June 2020 was EUR 62 million (49 million at 31 December 2019) and continues to be well-controlled. Together with the unutilized capital commitment line with LDA Capital Limited for up to EUR 50 million (EUR 3.2 million drawn down to date), and the 18-month committed bank loan of EUR 20 million (fully unutilized), Mithra is able to finance its business development strategy, and to carry on its R&D development
- Successful private placement via an accelerated bookbuild offering of EUR 65 million

Operational Highlights (including post-period end)

- Regulatory submission for Estelle® accepted for review by the US Food and Drug Administration (FDA), Health Canada, and the European Medicines Agency (EMA). The respective authorities are expected to complete their review in the first half of calendar 2021.
- Alignment of commercial partners for a united global launch campaign to bring Estelle® to market, including single branding with limited number of brand names worldwide, single positioning, single messaging.
- Estelle® has the potential to be the first Combined Oral Contraceptive based on an environmentally friendly estrogen as demonstrated in an Environmental Risk Assessment study
- Commercialization agreements for Estelle® signed with Alvogen (Hong Kong and Taiwan) and Mayne Pharma (Australia)
- Commercialization agreements for Myring™ signed with Gynial (Switzerland), Zentiva (France, Poland, UK), Megalabs (Mexico) and Farmitalia (Italy)
- Commercial launch of Myring™ in Belgium, the Netherlands and in Germany, the biggest European market, under the trademark name MYCIRQ®.
- Further shelf life extension of Myring™ to 36 months from 24 months by the European Authorities, offering distributors, pharmacists and patients a more convenient option compared to competitor products.
- Commercialization agreements for Tibelia® signed with Spirig Healthcare (Stada Group) for Liechtenstein and Switzerland
- Commercial launch of Tibelia® in Canada, under the trademark name Tibella®. Tibella® is the first tibolone-based hormone treatment available in Canada.
- Continued job creation, with recruitment returning to normal since the slowdown experienced earlier this year due to Covid19.

Expected milestones and outlook for the remainder of 2020

- Start of ramp-up for Estelle® by commercial partners, in order to prepare for commercial launch in the first half of 2021, generating and additional EUR 7 million in 2020.
- At the current recruitment rate, patient enrolment for the Donesta® Phase III E4Comfort program is on track to be completed around year-end. As the evolution of the pandemic is

uncertain and cannot be predicted at present, both studies may encounter a delay compared to the anticipated schedule. The situation in Europe, Russia, Latin America and the United States is actively and closely monitored on an ongoing basis.[2]

- FDA approval for vaginal contraceptive ring Myring™, for commercialization in the U.S. by Mayne Pharma.
- US Good Manufacturing Practices (GMP) approval for Myring™.
- Valuation of business entity for clinical development projects based on E4, outside of the spectrum of women's health, such as neuroprotection and wound healing.
- Further strengthening E4 Intellectual Property portfolio.

François Fornieri, CEO Mithra Women's Health, commented: "*In this year of transition leading to the commercialization of Estelle® early next year, Mithra significantly strengthened its financial position with a very successful private placement, raising EUR 65 million. Together with the unutilized capital commitment line with LDA Capital Limited of up to EUR 50 million and the EUR 20 million 18-month loan, we have more than enough funding to see us through to commercial launch and beyond. The combined total of EUR 135 million represents one of the largest capital rounds in Belgium in 2020, of which I'm very proud, especially considering the uncertain environment resulting from Covid19. In tandem, we have been working diligently with our worldwide partners for Estelle® to achieve both strategic and operational alignment for a unified global approach.*

Earlier this year, we were very pleased to see the commercial launch of Myring™ in the Netherlands, Belgium and in Germany, the largest European market. Today, Myring is commercialized in a total of 6 countries, representing a total market size of EUR 40 million, or 4.7 million rings per year. Licensing and supply agreements have already been signed for 37 countries to date. At the same time, we are eagerly awaiting the FDA approval of Myring, which is expected soon.

Thanks to the continuous commitment of the Mithra team, we were able to stay on track throughout the ongoing Covid-19 pandemic, ensuring the continuity of production and preparation of safety stock for further delivery to partners. As the second half of this year is already well underway, we remain confident in our vision to transform women's health through innovation."

[2] Refer to Annual Report 2019 Section 1.9 (x) for details regarding adverse events by global health pandemics.

FINANCIAL RESULTS

1. Interim consolidated statement of income statement (unaudited)

Thousands of Euro	*30 June 2020*	*30 June 2019*
Revenues	**2,507**	**19,563**
Cost of sales	**(1,331)**	**(2,021)**
Gross profit	**1,176**	**17,542**
Research and development expenses	(28,183)	(20,944)
General and administrative expenses	(7,226)	(7,539)
Selling expenses	(926)	(679)
Other operating income	2,319	2,748
Total operating expenses	**(34,015)**	**(26,884)**
Loss from Operations	**(32,840)**	**(9,341)**
Change in the fair value of contingent consideration payable[3]	(5,803)	(98,901)
Net fair value gain/(losses) on financial assets at fair value through profit or loss[4]	(3,748)	4,352
Financial income	237	52
Financial expenses	(2,504)	(6,830)
Loss before taxes	**(44,659)**	**(110,669)**
Income taxes	**10,664**	**20,922**
Net Loss for the period	**(33,994)**	**(89,747)**

[3] Fair value is computed on the contingent considerations payable which are reported under Other financial loans

[4] Fair value is computed on the financial assets which are reported under 6.12. Financial instruments: the amount reported on this line is the adjustment of the fair value (loss) on Contract assets, Mayne's participation for EUR 3,310k (for the second equity tranche at FDA approval) and the adjustment of the contingent consideration receivable related to Ceres for EUR 437k.

2. Interim consolidated statement of financial position (unaudited)

Thousands of Euro	*30 June 2020*	*31 December 2019*
ASSETS		
Property, plant and equipment	26,772	23,502
Right-of-use assets	69,596	70,535
Goodwill	5,233	5,233
Other Intangible assets	91,933	87,490
Deferred income tax assets	45,092	34,431
Contracts assets	200	48,975
Other non-current assets	13,385	13,096
Derivatives financial assets	114	-
Investments in equity securities	19,652	22,860
Non-current assets	**271,977**	**306,121**
Inventories	24,126	16,277
Contract assets	53,108	13,242
Derivatives financial assets	140	-
Trade & other receivables	9,519	12,238
Other short-term deposits	16	46
Cash & cash equivalents	62,576	49,720
Current assets	149,486	91,522
TOTAL ASSETS	**421,463**	**397,643**

Thousands of Euro	*30 June 2020*	*31 December 2019*
EQUITY AND LIABILITIES		
Equity		
Share capital	30,458	28,018
Additional paid-in-capital	320,407	259,529
Other Reserves	2,757	3,423
Accumulated deficit	(161,668)	(127,673)
Cash flow hedging reserve	(4,430)	-
Equity attributable to equity holders	**187,525**	**163,298**
Subordinated loans	12,053	12,430
Other loans	6,665	6,626
Lease liabilities	46,092	45,728
Refundable government advances	12,909	13,086
Other financial liabilities	106,827	99,866
Derivative financial liabilities	4,620	-
Contract liabilities	4,056	4,056
Provisions	266	607
Deferred tax liabilities	4,145	4,148
Non-current liabilities	**197,633**	**186,546**
Current portion of Subordinated loan	696	340
Current portion of Other loans	6,428	6,186
Current portion of lease liabilities	5,676	6,746
Current portion of Refundable government advances	1,433	791
Current portion of Other financial liabilities	5,466	6,624
Trade payables, Accrued charges & other financial liabilities	16,607	27,114
Current liabilities	**36,306**	**47,799**
TOTAL EQUITY AND LIABILITIES	421,463	397,643

3. Interim Consolidated Cash Flow statement (unaudited)

Thousands of Euro	*30 June 2020*	*30 June 2019*
Result from operations	**(32,840)**	**(9,342)**
Adjustments for:		
Depreciation and amortization	2,820	2,460
Tax credit	(723)	(517)
Share-based payments	2,554	2,594
Grant income	(489)	-
Subtotal	**(28,678)**	**(4,805)**
Increase/(decrease) in trade payables and other current liabilities	(9,143)	(2,122)
Increase/(decrease) in trade receivables and other receivables	(2,579)	(15,643)
(Increase)/decrease in inventories	7,850	(3,165)
Increase/(decrease) in contract assets	(5,598)	-
Net cash (used in)/ provided by operating activities	**(38,148)**	**(25,735)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Payment for acquisition of tangible fixed assets	(4,442)	(7,025)
Payment for acquisition of intangible fixed assets	(4,663)	(3,754)
Other financial liabilities payments	-	(4,500)
Net cash (used in)/ provided by investing activities	**(9,105)**	**(15,279)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Repayment of subordinated loans and others loans	(455)	(10,679)
Repayment of refundable government advances	(854)	
Proceeds from subordinated loans & other loans	715	12,466
Proceeds from refundable government advances & Other grants	160	
Lease payments	(1,268)	(621)
Interests paid	(1,507)	(1,804)
Proceeds from issuance of shares (net of issue costs)	63,318	170
Net cash used in/ (provided by) financing activities	**60,109**	**(469)**
Net increase/(decrease) in cash & cash equivalents	**12,857**	**(41,483)**
Cash & cash equivalents at beginning of year	**49,720**	**118,949**
Cash and cash equivalents at end of period	**62,576**	**77,466**

Profit and Loss

The Group reported a net loss of EUR 33,994k for the first six months of 2020, compared to a net loss of EUR 89,747k for the first six months of 2019.

The Revenues of the Group decreased in the first half of 2020 to EUR 2,507k from EUR 19,563k in H1 2019. On the one hand, no additional performance obligations were considered as highly probable by Mithra, meaning that no revenue on backlog of signed contracts was recognised. On the other hand, no significant partnership was signed during 2020 first semester. Regarding Donesta ®, this is in line with our current business development strategy.

The decrease of revenues impacted the Gross Profit which decreased from EUR 17,542k in 2019 to EUR 1.176k in 2020.

R&D expenses, G&A and selling expenses combined, have increased by 23% (EUR 6,702k) in H1 2020.

Research and development expenses increased in the first half 2020 by 35% to EUR 28,183k (H1 2019: EUR 20,944k). This increase is primarily due to increased R&D activity for the Phase III studies of Donesta®. R&D expenses for Donesta® should continue to increase in the second half of 2020.

G&A expenses remain stable. It contains booking entries related to share-based payment expenses that amount EUR 2,554k in H1 2020, which is a non-cash element.

Operating expenses, depreciation included, increased by 27%. All this resulted in an increased operating loss of EUR -32,840k in H1 2020 compared to EUR -9,341k in half year 2019.

The improvement of financial expense to EUR -2,505 (from EUR -6,830k in H1 2019) is the result of a limited impact in H1 2020 (EUR -800k EUR) of the amortized cost treatment of government advances compared to H1 2019. The remaining part of the financial expenses is related to the interests paid for EUR -1.507k.

The loss before taxes of EUR -44,659k in H1 2020 is driven by an increase in the fair value of contingent consideration liabilities (earn outs) for EUR -5.8 million. The increase is explained by adjustment to the fair value related to the timing effect.

The loss before taxes are also impacted by the adjustment to the fair value of Mayne's contract assets (non-monetary part) for EUR -3,310k (for the second equity tranche at FDA approval) and by the adjustment to the contingent receivable related to Ceres for EUR -437k.

Except the interest payments, all elements impacting the loss before taxes are non-cash.

The group recorded a tax income of EUR 10,665k for the six months that results from an increase in the deferred tax asset from prior year-end which is to be offset against taxable income in the future. Taken this tax income into consideration, the net loss for half year ended 2020 was EUR -33,994k on a consolidated basis, significantly improved over H1 2019 (EUR -89,747k) and is the result of the renegotiation of the earn out contracts related to Estelle®.

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 REBITDA[5] and EBITDA in order to provide information on recurring

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

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 items, share-based payments and all discontinued operations results as non-recurring items.

EBITDA is an alternative performance measure calculated by excluding the depreciation & 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 2020*	*30 June 2019*
Operational profit	**32,840**	**(9,341)**
Depreciation	2,820	**2,460**
Share-based payments	2,554	**2,594**
REBITDA	**(27,465)**	**(4,287)**
Share-based payments	(2,554)	(2,594)
EBITDA	**(30,019)**	**(6,881)**

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Webcast

Mithra will host a live webcast on **Thursday, 24 September 2020 at 15:00 CEST/ 09:00 EDT** to announce its 2020 Half Year financial and operating results. The live webcast can be accessed on the Mithra website or by clicking here. To participate in the questions and answers session, please register on this link, five to ten minutes prior to the scheduled start of the call.

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. Its three lead development candidates are built on Mithra's unique native estrogen platform, Estetrol (E4): Estelle®, a new era in oral contraception, PeriNesta®, the first complete oral treatment targeting perimenopause and Donesta®, the next-generation hormone therapy. 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 250 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.