Mithra Reports Full Year 2020 Financial Results

- **Strengthening of the financial resources and balance sheet structure via various funding transactions for an amount of EUR 260 million, diversifying the sources of financing**
- **Record cash position of EUR 138.7 million allowing the continuation of our Business Development strategy for Donesta® and R&D projects beyond Women's Health, notably in Covid-19 treatment**
- **Licensing milestones from backlog contracts signed for Estelle® amount to more than EUR 450 million, with more than EUR 300 million cash to still be collected**
- **First marketing authorization (MA) obtained for lead asset Estelle® in Canada, with other MA expected in Europe and the United States in the first half of 2021**

Liege, Belgium, 09 March 2021 – 7:30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces its financial results for the year ended 31 December 2020, prepared in accordance with IFRS.

Leon Van Rompay, CEO Mithra Women's Health, commented: "*In 2020 and despite the emergence of Covid-19, Mithra has managed to strongly consolidate its financial structure thanks to various financing operations for a total amount of EUR 260 million signing one of the most important fund raising operations in the Belgian biotech sector. Once again investors have clearly demonstrated their confidence and interest in the potential of our company and in particular in its flagship asset Estetrol. Estetrol is recognized as a new active substance by the European Medicines Agency, 80 years after the last such designation in contraception. This is a true recognition of the innovative nature of our contraceptive pill candidate Estelle®, which has just received its first Marketing Authorization for the Canadian market ahead of the decisions of American and European agencies expected during the first semester of 2021.*

The record high cash position has also enabled us to pursue the Donesta® phase III clinical program in the current Covid -19 context. This puts us in an comfortable position to negotiate a global marketing deal for Donesta targeting the growing menopause market. Finally, and also thanks to this financial position, we initiated last year a strategic shift by exploring the action of Estetrol outside of women's health, particularly in the treatment of covid-19 and neuroprotection of newborns. As for our CDMO, we met all planned production targets for the Myring™ contraceptive ring to ensure the success of commercial launches in Europe, particularly in Germany and Italy, the world's 2nd and 4th largest markets respectively. Today our ring is marketed in 7 countries representing a total market of more than 60 million euros and nearly 7 million rings per year with further launches planned for 2021.

The renewal of our Board of Directors last November provided a dynamic momentum to the development of Mithra entering this groundbreaking year in its existence. Supported by the vast experience of the new governance team, we are more determined than ever to successfully delivering on our promises."

Financial highlights

- **Revenues** of EUR 9 million (EUR 96.5 million for the year ended December 2019), mainly driven by product sales, including the first sales of Myring™ and by Estelle® out-licensing fees in Latam. 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 more than EUR 300 million in cash of licencing milestones revenues in the coming years (EUR 286 million to be recognized under IFRS 15).
- **EBITDA**[1] amounts to EUR -73 million compared to EUR +32.7 million in 2019[2]. As expected, the decrease is mainly explained by lower revenues collected in 2020 compared to 2019, which was a year driven by record highlicense revenues following partnership agreements for Estelle® with Mayne Pharma, Gedeon Richter and Searchlight. In addition to the lower revenues, the R&D expenses increased by 38% due to the ramp up of the Donesta® Phase III "E4 Comfort" clinical program and the Covid study, resulting in a significant decrease of the reported EBITDA.
- **Fair value of earnout debt** related to Estelle® increased by EUR 18.1 million to EUR -115.7 million, which is the result of a timing effect. As a reminder, thanks to the successful renegotiation of the earnout payments to the former owners of Uteron Pharma, the earnouts are now capped at a lump sum payable in annual instalments (depending on the cash position of the group).
- **Record cash position** of EUR 138 million at the 31 December 2020 (EUR 49 million at 31 December 2019). Together with the convertible bond of EUR 125 million, the private placement via an accelerated bookbuild offering of EUR 65 million, the capital commitment line with LDA Capital Limited for up to EUR 50 million (EUR 3.2 million drawn down to date and committed until April 2023), and a bank loan of EUR 20 million (fully undrawn and committed until June 2022), Mithra has secured the necessary financial resources to finance its business development strategy, and to carry on its R&D expenses.

Operational Highlights (including post-period end)

Estetrol (E4) Platform

- **First marketing authorization (MA) for the contraceptive pill Estelle®** obtained in Canada.
- **Regulatory submission** for Estelle® by the American (FDA), European (EMA), Brazilian (ANVISA), Australian (TGA), Swiss (Swissmedic) and Russian (Roszdravnadzor) regulatory agencies. American, European and Russian MA are expected to be issued in the first half of 2021.

---

[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.

[2] Compared to the published press release for the full-year results 2019, the figures as at 31 december 2019 were adjusted in terms of presentation, in order to further improve the readability and comparability of the financial information. More specifically, the item related to the variance of Contingent Assets and presented under the line "Other Operating Income" in the Discontinued Operations for EUR 7,999k now appears as part of the Net fair value gains/(losses) on financial assets at fair value through profit or loss of the Continuing Operations as mentioned in the annual report 2019.

- Qualification of Estetrol as a "**New Active Substance**" (NAS) by the European Medicines Agency (EMA). This is the first NAS designation in contraception in over 80 years.
- **Commercialization agreements for Estelle®** signed with Gedeon Richter for Latin America, the third largest market after the United States and Europe[3], as well as with Mayne Pharma (Australia), Alvogen (Hong Kong and Taiwan) and GyneBio (North Africa).
- Roll-out of Estelle®'s **global marketing and sales strategy** with all partners.
- Significantly more **environmentally friendly profile of Estetrol** compared to other estrogens, as demonstrated in an ecotoxicity study. Additional studies are ongoing at the University of Namur.
- Finalization of patient enrolment for the **Phase III E4Comfort program of oral hormonal therapy Donesta®** (menopause), which is expected to be completed in early Q2 2021. The Data Safety Monitoring Board (DSMB) independent expert committee issued a positive opinion at the end of 2020, confirming Estetrol's safety profile. Despite the Covid-19, the clinical program is currently almost on track.
- Recruitment of patients ongoing for the clinical program on Estetrol's effect in **Covid-19 treatment**. This Phase II "Coronesta" trial aims to study the action of Estetrol on the immune, inflammatory and vascular response of patients (male/female) infected with Covid-19. It is in line with other international studies, such as the one conducted at King's College London, which demonstrated the protective effect of estrogen present in the body at high levels. The results of the Coronesta study are expected in early H2 2021.
- The Covid-19 pandemic lead us to **review our R&D pipeline**. In 2020, we focused on the development of Donesta® and identified a new opportunity with the Coronesta program relating to the potential of Estetrol in the field of respiratory diseases which might broaden the use of Estetrol beyond women's health. Regarding **PeriNesta®**, although the clinical program has not yet been launched, the opportunistic development previously announced is ongoing, together with other development strategies under consideration in order to fully leverage the potential of this product candidate.
- Further strengthening **Estetrol Intellectual Property portfolio** thanks to a new patent extending the 35 patent-family filed by Mithra. Exclusivity of Estelle® and Donesta® product candidates is extended until 2036 in Europe. A similar application is currently being examined in the United States.

Complex therapeutics

- **Commercialization agreements for vaginal contraceptive ring Myring™** signed with Gynial (Switzerland), Zentiva (France, Poland, United Kingdom), Megalabs (Mexico), Farmitalia (Italy) and Chemical Dampe (Venezuela). To date, Myring™ licenses cover 36 countries.
- **Commercial launch of Myring™** in Germany (2nd world market), Italy (4th world market), Belgium, the Netherlands, Austria and Denmark. Compilation of additional data requested by the FDA in the US marketing approval process.
- **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. This recognition confers a significant competitive advantage for Myring™.

[3] IQVIA 2019

- **Commercial launch of Tibelia® in Canada** as first tibolone-based hormone treatment. Commercial agreement for Tibelia® signed with Spirig Healthcare (Stada Group) for Liechtenstein and Switzerland.

Corporate Governance

- **Renewal of the Board of Directors** in accordance with the Strategic Plan, with the appointment of Ajit Shetty and Erik Van Den Eynde as independent directors and the appointment of Patricia Van Dijck as chairman ad interim until the general shareholders' meeting of May 20, 2021.
- **Appointment of Leon Van Rompay** as Chief Executive Officer ad interim for a maximum period of 12 months, replacing François Fornieri.
- **Continued job creation**, with recruitment returning to normal since the slowdown experienced early 2020 due to Covid-19. In 2021, some 80 additional profiles should be created in addition to the 280 current collaborators.

Expected milestones for 2021

- **Marketing authorizations for Estelle®** expected in the first half of 2021in the United States, Europe and Russia, with **commercial launch** to follow. Marketing approval for the Australian market is expected to be granted at the end of the year. Continuation of expansion of international partnerships.
- **Completion of Donesta® Phase III trial recruitment** and continuation of business development strategy.
- **FDA approval for vaginal contraceptive ring Myring™** expected end 2021–begin 2022, for commercialization in the US by Mayne Pharma. Further **commercial launches** planned in Europe, Chili, Canada and Israel.
- Results of the **Coronesta study** expected in early H2 2021.
- Approval of the new **Board of Directors** for a 2-year mandate at the General Meeting of Shareholders on May 20, 2021.

FINANCIAL RESULTS

1. Consolidated income statement

	Year ended 31 December	
Thousands of Euro (€)	*2020*	*2019*
Revenues	9,030	96,520
Cost of sales	(3,457)	(2,487)
Gross profit	**5,573**	**94,033**
Research and development expenses	(78,458)	(57,073)
General and administrative expenses	(15,933)	(14,774)
Selling expenses	(1,434)	(1,539)
Other operating income	6,574	6,329
Total operating expenses	**(89,251)**	**(67,057)**
Operating loss	**(83,678)**	**26,975**
Change in fair value of contingent consideration payable	(18,114)	(54,728)
Net fair value loss on financial assets at fair value through profit or loss	(4,925)	2,763
Financial income	1,782	271
Financial expenses	(5,987)	(6,705)
Loss before taxes	**(110,922)**	**(31,424)**
Income taxes	18,835	4,859
Net loss of the year	**(92,086)**	**(26,564)**

2. Consolidated Statement of financial position

	Year ended 31 December	
Thousands of Euro (€)	*2020*	*2019*
ASSETS		
Property, plant and equipment	29,921	23,502
Right-of-use assets	69,572	70,535
Goodwill	5,233	5,233
Other intangible assets	89,005	87,490
Deferred income tax assets	50,904	34,431
Contract assets	200	48,975
Other non-current assets	14,401	13,096
Derivatives financial assets	6,184	-
Investment in equity securities	18,088	22,860
Non-current assets	**283,509**	**306,121**
Inventories	35,382	16,277
Contact assets	51,472	13,242
Derivatives financial assets	2,881	-
Trade & other receivables	10,052	12,238
Other short term deposits	14	46
Cash & cash equivalents	138,675	49,720
Current assets	**238,475**	**91,522**
TOTAL ASSETS	**521,985**	**397,643**

Thousands of Euro (€)	*Year ended 31 December 2020*	*2019*
EQUITY AND LIABILITIES		
Share capital	31,272	28,649
Additional paid-in-capital	332,177	258,898
Other reserves	5,918	3,423
Accumulated deficit	(219,467)	(127,673)
Cash flow hedging reserve	7,838	-
Equity attributable to equity holders	**157,737**	**163,298**
Subordinated loans	118,546	12,430
Other loans	5,963	6,626
Lease liabilities	44,282	45,728
Refundable government advances	15,195	13,086
Other financial liabilities	101,180	99,866
Contract liabilities	3,706	4,056
Provisions	266	607
Deferred tax liabilities	4,363	4,148
Non-current liabilities	**293,500**	**186,547**
Current portion of subordinated loan	6 232	340
Current portion of other loans	5,524	6,186
Current portion of lease liabilities	7,037	6,746
Current portion of Refundable government Advance	1,259	791
Current portion of Other financial liabilities	23,424	6,624
Trade payables, Accrued charges & other current liabilities	27,272	27,114
Current liabilities	**70,747**	**47,800**
TOTAL EQUITY AND LIABILITIES	**521,985**	**397,643**

3. Consolidated statement of cash flows

GROUP TOTAL

Thousands of Euro	*Year ended 31 December 2020*	*2019*
Cash flow from operating activities	(81,284)	(46,826)
Cash flow from investing activities	(14,310)	(20,455)
Cash flow from financing activities	184,549	(1,949)
Net increase/(decrease) in cash and cash equivalents	**88,955**	**(69,184)**
Cash & cash equivalents at beginning of the year	**49,720**	**118,949**
Cash & cash equivalents at end of the year	**138,675**	**49,720**

Profit and Loss

- Group revenues decreased to EUR 9,030k in 2020 (EUR 96,520k in 2019). No significant new milestones were reached triggering the recognition of revenue from contracts with customers signed in prior years, meaning that no revenue on backlog of signed contracts was recognised. On the other hand, no significant partnership was signed during 2020.
- The decrease of out-licensing revenues impacted the Gross Profit which decreased from EUR 94,033k in 2019 to EUR 5,573k in 2020.
- The total of R&D expenses, G&A and selling expenses, have increased by 31% (EUR 95,825 k) in 2020.
- R&D expenses increased by 37% in 2020 to EUR 78,458k (2019: EUR 57,073k). This is primarily due to the R&D activity for the Phase III studies of Donesta® and the Covid-19 study launched in the second semester 2020. R&D expenses for Donesta® should continue to increase in the first half of 2021.
- G&A increased mainly due to booking entries related to share-based payment expenses of EUR 7,267k in 2020, a non-cash element. Without this non-cash element, G&A decreased by EUR 1,210k compared to 2019, while the ramp-up of activities was important over the period.
- Operating loss of EUR 83,678k in 2020 compared to the operating profit EUR 26,975k in 2019 is mainly explained by the lower revenues and the increased R&D activity.
- Loss before taxes at EUR 110,922k in 2020 as a result of the increase in the fair value of contingent consideration liabilities (earnouts) for EUR 18,114k which impacts profit and loss below Operating loss. The fair value is determined using a probability weighting approach applied to earnouts cash flows (based on the cash position at year-end on going forward) which are discounted.
- The loss before taxes is also impacted by the adjustment of the fair value on Mayne's contract assets (non-monetary part) for EUR 4,925k (for the second equity tranche at FDA approval).
- Financial expenses are mainly resulting from interest paid (EUR 3,588k), hedging impact (EUR 827k) and the adjustment in the amortized cost of government advances (EUR 1,334k).
- Financial income increased by EUR 1,512k and is mainly explained by the realized exchange gain on foreign USD exchange contracts.
- The group recorded a tax income of EUR 18,835k 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. The net loss for the year 2020 was EUR 92,086k (loss of EUR 26,564k for 2019) on a consolidated basis.

Alternative performance measure

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 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 items, share-based payments 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.

	Year ended 31 December	
Thousands of Euro (€)	*2020*	*2019*
Operational profit	**(83,678)**	**26,975**
Depreciation	6,136	5,777
Non-recurring items	3,734	-
Share-based payments	7,267	4,898
REBITDA	**(66,541)**	**37,650**
Share-based payments	(7,267)	(4,898)
EBITDA	**(73,807)**	**32,752**

****

For more information, please contact:

Benoît Mathieu (IRO) : +32 473 35 80 18 - investorrelations@mithra.com
Maud Vanderthommen (Press) : +32 473 58 61 04 – press@mithra.com

Annual report 2020

The Annual Report for the year ended 31 December 2020 will be published on 20 April 2021, on the website of the Company. The auditor, BDO Réviseurs d'Entreprises SCRL, has confirmed that the audit procedure, which is substantially complete, has not revealed any material corrections required to be made to the financial information included in this press release.

Webcast

Mithra will host a conference call and live webcast today (March 9, 2021) at 09.30 CET. 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.

Financial Calendar

- 20 April 2021 : 2020 Annual Report
- 20 May 2021 : Annual General Shareholders Meeting
- 24 September 2021 : Half Year Report 2021

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 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.