Mithra Reports Full Year 2019 Financial Results

- **Record revenue (EUR 96.5 million) and EBITDA (EUR 40.7 million) increased respectively by 47% and 6%, mainly driven by U.S. deal for Estelle®**
- **Anticipated future licensing milestones for Estelle® of EUR 322 million (out of a total of EUR 486 million)**
- **Net loss significantly reduced to EUR 26.6 million (EUR 89.7 million in June 2019) thanks to successful earnout renegotiation and landmark deal with Mayne Pharma for Estelle®**
- **Strengthening of book equity to EUR 163.3 million thanks to earnout renegotiation**
- **Continued good cash management with comfortable level of cash at year-end**
- **Key milestones achieved for environmental-friendly E4-based portfolio pipeline, with successful launch of Phase III study of Donesta® in menopause and regulatory submission of Estelle® in Europe**
- **Valuation of business entity for clinical development projects based on E4 in 2020**

Liege, Belgium, 09 March 2020 – 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 2019, prepared in accordance with IFRS.

Financial highlights

- Revenues were up 47% to EUR 96.5 million over last year, mainly driven by the Mayne Pharma transaction in October 2019, for the commercialization of Estelle® in the United States. From the backlog of contracts signed for Estelle®, Mithra should recognise an additional EUR 322 million of licencing milestones (out of a total of EUR 486 million) in the coming years.
- EBITDA[1] is at a new record high of EUR 40.7 million, although R&D expenses have increased to EUR 57 million from EUR 36 million in 2018, resulting from the Phase 3 clinical trial launch of Donesta®. This increased spend reflects the momentum behind, and drive of our R&D department in progressing our products versus ambitious timelines.
- Non-recurring income of EUR 7.9 million in 2019 thanks to gain on sale of disposal to Ceres Pharma realized in July 2018.
- The Company successfully renegotiated the earnout payment with the former owners of Uteron Pharma in October 2019[2]. This resulted in the significant reduction of the fair value of earnout debt on the balance sheet compared to June 2019, with underlying payments being

[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] Press release Mithra, 1 October 2019

reduced from EUR 662 million to EUR 250 million (-62%), in addition to reducing the total payment duration by twelve years.

- Thanks to the Patent Income Deduction ruling, the Company can apply a deduction of 80% of patent income relating to Estelle® and Donesta® products[3] from 2018 taxable income onwards.
- Book equity strengthened to EUR 163.3 million from EUR 150.9 million thanks to a conversion into equity of approximately EUR 40 million of the renegotiated earnout payments, partially offset by the net loss of EUR 26.6 million.
- Cash at December 31, 2019 was EUR 49.7 million (from EUR 77.5 million at 31 June 2019) and continues to be well-controlled (-33% cash used H2 vs H1 2019), even with the ramp-up of Donesta® Phase 3 clinical trials in Q4 2019. The Company's management team is currently evaluating various options for potential additional financing to be implemented in the near and medium term in order to support the further growth strategy and to strengthen the balance sheet. These financing options could include, among others, non-dilutive funding, equity based funding, monetising rights on additional indications based on E4 outside of women's health or a combination of these options.

Operational Highlights (including post-period end)

- Positive top-line results of Estelle® Phase III oral contraceptive study ("E4 Freedom") in the United States/Canada, after the Europe/Russia results, confirming the unique safety profile of Mithra's innovative contraceptive. The European Medicines Agency (EMA) has already accepted the regulatory submission (Marketing Authorization Application) for Estelle®.
- Landmark deal with Mayne Pharma for the commercialization of Estelle® in the United States, in addition to the agreements signed with Itrom (MENA Region), Dexcel Pharma (Israel) and Alvogen (Hong Kong/Taiwan).
- Received additional patent for Estelle® in Japan in the dysmenorrhea indication, a market four times larger than the contraceptive market.
- Launch of Donesta® Phase III study for the treatment of vasomotor symptoms in postmenopausal women. The "E4 Comfort" trial includes two pivotal studies, one in North America and one in Europe/Russia/South America. On track to target marketing authorization in 2023.
- Expansion of the E4 development program with a third late stage clinical product candidate, PeriNesta® for the underserved perimenopausal market. Finalization of the clinical development plan with the regulatory authorities ongoing.
- Regulatory environmental fate and ecotoxicity testing performed on E4 generated no adverse environmental effects of the proposed use of E4.
- The U.S. Food and Drug Administration granted Estetrol an Orphan Drug Designation for the treatment of hypoxic ischemic encephalopathy, a life-threatening form of neonatal asphyxia.
- Commercialization agreements for Myring™ signed with Itrom (MENA region), Megalabs (Latin and South America), Hormosan (Germany), Dexcel Pharma (Israel), Abbott (Chine), Aicore Life Sciences (Eastern Europe), Labatec (Switzerland), Searchlight Pharma (Canada) and Farmitalia (Italy).

[3] Press release Mithra, 10 February 2020

- Approval of two noteworthy modifications in Myring™ labelling by the European Authorities: removal of requirement for special temperature storage and extension of the shelf-life from 18 to 24 months.
- Launch of manufacturing process of Myring™ at Mithra CDMO[4] facility in Belgium, with production of first commercial batches for European market, including Belgium. Positive outcome of Myring™ registration procedure in Europe that will lead to an additional 15 Marketing Authorizations for a total of 23.
- Crucial Marketing Authorization for Tibelia® in Canada (New Chemical Entity), which plays a significant role in the international commercial expansion strategy in key markets like the United States. Commercialization agreements for Tibelia® signed with Farmitalia (Italy), Aicore Life Sciences (Eastern Europe) and Saval Pharmaceuticals (Chile)
- Significant increase in staff from 190 to 270 (+42%). Further job creation is expected in 2020.

Expected milestones for 2020

- Filling by Estelle® by the U.S. FDA is expected to be submitted in the second quarter of 2020.
- Start of ramp-up for Estelle® in H2 2020 by commercial partners, in order to prepare for commercial launch in the first half of 2021, generating and additional EUR 7 million in 2020.
- Completion of Donesta® Phase 3 trial recruitment.
- Finalization of the clinical development plan of Perinesta® with the regulatory authorities, with the start of clinical trials scheduled for 2020.
- FDA approval for vaginal contraceptive ring Myring™ expected in H2 2020, for commercialization in the U.S. by Mayne Pharma. Large-scale global commercialization of Myring™, especially in the world's three largest markets (U.S., Germany and Italy). Mithra CDMO expected to produce nearly 2 million rings in 2020.
- 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 portofolio, in particular through the recent bioavailability study conducted for Estelle® U.S. filling.

François Fornieri, CEO Mithra Women's Health, commented: "*2019 marked Mithra's 20th anniversary and was an exceptional year in more ways than one. From a financial perspective, our turnover increased by 47% to reach 95.6 million EUR versus 65.5 million EUR in 2018. Our EBITDA, which was positive for the first time in 2018, continued its momentum reaching a record level of EUR 40.7 million. The successful renegotiation of our earn-out payments allowed us to considerably reduce the weight of this contingent liability on our 2019 results.*

More than ever, our cash flow was solidly managed in 2019, allowing us to start the phase III study for Donesta® on time, while ensuring the growth of our business, which has entered commercial production. The expected launch of Myring ™ in 2020 in the three largest world markets, and that of Estelle® from 2021, will complete our transition into a commercial biotech company. Of the EUR 486 million in revenues linked to Estelle® license agreements, we should still recognize some EUR 322 million from additional future milestones.

[4] Contract Development and Manufacturing Organization

In this year of transition, Mithra diligently continues to explore various areas of clinical development. We are particularly excited to deepen and enhance the other areas of application of our promising E4 molecule, such as in pediatric neuroprotection and wound healing. On the operational side, Myring ™, having already started its transition to commercial production in 2019 for the European market, will reach cruising speed in 2020, with the production of some two million contraceptive rings. In addition, we are preparing the safety-stock of our Estelle® contraceptive for all our commercial partners, with whom we are rigorously preparing the fast-approaching commercial launch of our first blockbuster. To adjust as best as possible to the challenges that lie ahead, Mithra considerably strengthened its team in 2019, by increasing its workforce by 42%, and is looking forward to confirming the international reputation of excellence of Belgian biotechs."

FINANCIAL RESULTS

1. Consolidated income statement

GROUP TOTAL

	Year ended 31 December	
Thousands of Euro	*2019*	*2018*
Revenues	96,520	65,465
Gross Profit	94,033	60,211
Operating Profit / (Loss)	34,974	35,457
Financial income	271	237
Change in fair value[5]	(54,728)	(46,550)
Change in fair value through P&L (impairment losses on financial and contract assets)	(5,073)	-
Financial expenses	(6,869)	(5,375)
Profit / (Loss) before taxes	(31,424)	(16,232)
Income taxes	4,859	3,869
Net Profit / (Loss) for the year	**(26,564)**	**(12,363)**

CONTINUING OPERATIONS

	Year ended 31 December	
Thousands of Euro (€)	*2019*	*2018*
Revenues	96,520	57,876
Cost of sales	(2,487)	(1,571)
Gross profit	**94,033**	**56,306**
Research and development expenses	(57,073)	(35,713)
General and administrative expenses	(14,774)	(8,979)
Selling expenses	(1,539)	(1,977)
Other operating income	5,401	4,552
Total operating expenses	**(67,985)**	**(42,118)**
Operating profit / (loss)	**26,047**	**14,188**
Financial income	271	237
Change in fair value[5]	(54,728)	(46,550)
Change in fair value through P&L (impairment losses on financial and contract assets)	(5,073)	-
Financial expenses	(6,869)	(5,365)
Loss before taxes	**(40,350)**	**(37,491)**
Income taxes	7,448	9,885
Net loss of the year	**(32,902)**	**(27,606)**

[5] Fair values are computed on the contingent considerations payables which are reported under Other financial loans

DISCONTINUED OPERATIONS

	Year ended 31 December	
Thousands of Euro	*2019*	*2018*
Revenues	0	7,589
Cost of sales	0	(3,684)
Gross profit	**0**	**3,905**
Selling expenses	0	(1,989)
Other operating income	928	876
Gain on sale of disposal	7,999	18,477
Total operating income	**8,927**	**17,363**
Operating Profit / (Loss)	**8,927**	**21,269**
Financial result	**(1)**	**(10)**
Profit / (Loss) before taxes	**8,926**	**21,258**
Income taxes	**(2,589)**	**(6,016)**
Net Profit / (Loss) for the period	**6,338**	**15,242**

2. Consolidated Statement of financial position

	As at 31 December	
Thousands of Euro (€)	*2019*	*2018*
ASSETS		
Property, plant and equipment	23,502	84,396
Right of use assets	70,535	-
Goodwill	5,233	5,233
Other Intangible assets	87,490	81,907
Deferred income tax assets	34,431	27,045
Contract assets	53,975	14,350
Other non-current assets	13,096	3,435
Financial assets at fair value through other comprehensive income	22,860	-
Non-current assets	**311,121**	**216,366**
Inventories	16,227	10,945
Contact assets	8,242	1,000
Trade & other receivables	12,238	12,468
Other Short Term deposits	46	0
Cash & cash equivalents	49,720	118,949
Current assets	**86,522**	**143,362**
TOTAL ASSETS	**397,643**	**359,728**

Thousands of Euro (€)	*As at 31 December 2019*	*2018*
EQUITY AND LIABILITIES		
Share capital	28,018	26,925
Additional paid-in-capital	259,529	220,344
Other reserves	3,423	1,243
Accumulated deficit	(127,673)	(97,620)
Equity attributable to equity holders	**163,298**	**150,893**
Subordinated loans	12,305	14,222
Other loans	6,751	53,148
Lease liabilities	45,728	-
Refundable government advances	13,086	10,252
Other financial liabilities	99,866	88,620
Contract liabilities	4,056	4,017
Provisions	607	266
Deferred tax liabilities	4,148	2,202
Non-current liabilities	**186,546**	**172,727**
Current portion of subordinated loan	256	173
Current portion of other loans	6,269	12,405
Current portion of lease liabilities	6,746	-
Current portion of Refundable government Advance	791	668
Current portion of Other financial liabilities	6,624	7,007
Trade payables, Accrued charges & other current liabilities	27,114	15,520
Corporate tax payable	-	334
Current liabilities	**47,799**	**36,109**
TOTAL EQUITY AND LIABILITIES	**397,643**	**359,728**

3. Consolidated statement of cash flows

GROUP TOTAL (INCLUDING DISCONTINUED OPERATIONS)

Thousands of Euro	*Year ended 31 December 2019*	*2018*
Cash flow from operating activities	(48,123)	3,542
Cash flow from investing activities	(19,926)	5,567
Cash flow from financing activities	(1,134)	73,653
Net increase/(decrease) in cash and cash equivalents	**(69,184)**	**82,760**
Cash & cash equivalents at beginning of the year	**118,949**	**36,190**
Cash & cash equivalents at end of the year	**49,766**	**118,949**

Profit and Loss

- Group revenues increased to EUR 96,520k in 2019 (EUR 65,465k in 2018) mainly driven by license revenues related to our partnership agreements, which increased to EUR 92,912k mainly thank to Estelle® with Mayne Pharma for EUR 74,364k, Gedeon Richter for EUR 15,000k and with Searchlight for EUR 500k. The discontinued product sales decreased as expected as a consequence of the Ceres asset deal, however, product sales from continuing operations have increased. The revenues contain also the revenue recognized from the injectables activities for EUR 1,268 k. We also reported a further drop in sales in Germany. As previously announced, the German company is on hold and reported an insignificant amount of sales revenues as we no longer develop a sales and distribution organization.
- The total of R&D expenses, G&A and selling expenses, have increased by 52% (EUR 73,993k) in 2019.
- R&D expenses increased by 60% in 2019 to EUR 57,073k (2018: EUR 35,713k). 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 first half of 2020.
- G&A increased mainly due to booking entries related to share-based payment expenses of EUR 4,898k in 2019, a non-cash element. Without this non-cash element, G&A increased by only EUR 1.137k compared to 2018, while the ramp-up of activities was important over the period.
- Operating expense (aggregated from continuing and discontinued operations) increase is limited and mainly explained by the discontinued operations for which we recognized a gain of EUR 7,999k in 2019 related to a contingent consideration receivable for a gain on sale of disposal (Ceres).
- Stable operating profit of EUR 34,974k in 2019 compared to EUR 35,457k in 2018.
- Financial expense are mainly resulting from the IFRS adjustment in the amortized cost of government advances for EUR 3,218 k (reported in the consolidated income statement under financial expenses). The remaining part of the financial expenses is related to the interests paid for EUR 3,321k.
- Loss before taxes at EUR -31,424k in 2019 driven by an increase in the fair value of contingent consideration liabilities (earnouts) for EUR -13,364k and by the decision of the Company to pay EUR 38,863k to the former owners of Uteron a part of the earnouts in ordinary shares of the Company instead of cash as allowed under the renegotiated earnout contract. The increase in in the fair value of contingent consideration liabilities (earnouts) are non-cash elements, and is mainly explained by the better terms renegotiated under the earnout contract with the former owners of Uteron. The loss before taxes are also impacted by the adjustment of the fair value on Mayne's participation for EUR 5,073k (for the second equity tranche at FDA approval).
- Group tax income of EUR 4,859k for the year that results from an increase of the deferred tax asset from prior year-end, to be offset against future taxable income. The net loss for the year ended 2019 was EUR 26,564k (loss of EUR 12,363k for 2018) on a consolidated basis. Without the earnout renegotiation, the net loss would have been higher (by EUR 83 million) as per the fair value increase stated in June 2019 (based on the increased probability of success of Estelle® to 78% after end of Phase III). Under the old contract terms, based on our conservative forecasts we were expecting to pay EUR 662 million, which was reduced to EUR 250 million under the new contract.

Statement of Financial position

- As of 31 December 2019, the Statement of financial position shows a total of EUR 311,121k in Non-current assets, the majority of which are Other intangible assets (EUR 87,490k), Property, plant and equipment (EUR 23,502k), Right-of-use assets (EUR 70,535k) and Deferred tax assets (EUR 34,431k) and Contract assets (EUR 53,975k).
- Other intangible assets are the result of assets acquired as part of former business combinations. Note that Donesta® qualified as an asset deal, for EUR 8,000k. The book value mainly relates to Estelle® for an amount of EUR 30,600k, to Zoreline® for an amount of EUR 24,400k, and to Myring™ for an amount of EUR 11,400k. Other intangible assets consist mainly of a portfolio of acquired product rights and market access rights. Over 2019, EUR 1,530k has been added to the Other intangible assets as a result of a capitalization of development costs incurred for the development of the API E4. An additional fee has also been added regarding the license rights acquired from GSP in 2019 for EUR 1,000k, for the CDMO development activities.
- Tangible fixed assets (Property, plant and equipment and the Right-of-use assets) increased EUR 9.6 million, mainly relating to the construction of the second phase of Mithra CDMO, where Mithra is producing Myring™. Property, plant and equipment increased EUR 7.4 million as a result of a capitalization of development costs incurred for the development of the production zone of Myring™ and all the related equipment.
- Contract assets of EUR 62,216k (non-current and current) versus EUR 15,350k in 2018 related to out-licensing revenue, mainly from Gedeon Richter (EUR 15,000k) and Mayne (EUR 33,233k), offset by unbilled revenues recognized in 2018 and billed in 2019.
- Deferred tax assets increased EUR 7,386k mainly due to the creation of additional tax losses carried forward.
- Current assets at the end of 2019 of EUR 86,522k. The total cash position includes Cash and cash equivalents of EUR 49,720k, Trade & other receivables of EUR 12,238k, and Inventories of EUR 16,277k.
- Inventories increased to EUR 16,277k from EUR 10,945k in 2018, mainly due to the increase of API stock from EUR 7.4 million in 2018 to EUR 13.8 million in 2019, which has been created in order to be ready for the production of Myring™ and Estelle®.
- Total equity at year-end increased to EUR 163,298k from EUR 150,893k in 2018, mainly due to the increase of capital of EUR 38,863k, representing the equity tranche due to the former owners of Uteron as per the renegotiation of the earnout contract, partially offset by the net loss of the period (EUR 26.554k).
- Non-current liabilities increased to EUR 186,546 at the end of year 2019, compared to EUR 172,727k in 2018, primarily due to an increase of the fair value of contingent considerations payables (EUR +11.2 million), which are reported under Other financial liabilities, and to the amortized cost treatment of refundable government advances (EUR +2.8 million) reported under Financial expense. These increases are attributable to the renegotiation of the earnout contract and to the probability of success of obtaining a marketing authorization for Estelle® increasing from 38% to 78%, following positive results the Phase III during the first half of the year.
- Current liabilities increased to EUR 47,799k at the end of 2019, compared to EUR 36,109k in 2018. The increase of the current liabilities is the net result of an increase in Trade payables and other current liabilities (EUR 11.6 million).

Cash Flow

Full year cash flow of the group amounted to EUR -69.2 million:

- *Cash flow from operating activities* of EUR -48.1 million for 2019, including cash flows from discontinued operations. The operating profit of EUR 35 million has been adjusted for the non-cash items amounting in net to EUR +2 million.
- *Cash flow from investing activities* of EUR -19.9 million. The purchase of tangible assets relates predominately to property, plant & equipment acquired for Mithra CDMO facility and related machinery and equipment (EUR 11.9 million) self- financed with the Group treasury (excluding Right-of-use assets) and to the capitalization of development costs incurred for the development of the API E4 (EUR 1.5 million). The assets financed by lease liabilities are netted together, and also reports payments for contingent liabilities (EUR 5 million).
- *Cash flow from financing activities* amounts to EUR -1.1 million related entirely to cash flow from continuing operations. The Group made new drawdowns under its bank loans over the course of the first half 2019, which partially offset a reimbursement of another straight loan facility (EUR 8.7 million). The facility was secured by partially collected "subsidies", (EUR 5.1 million), triggering the repayment.

The Company's management team is currently evaluating various options for potential additional financing to be implemented in the near and medium term in order to support the further growth strategy and to strengthen the balance sheet. These financing options could include, among others, non-dilutive funding, equity based funding, monetising rights on additional indications based on E4 outside of women's health or a combination of these options.

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 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.

	Year ended 31 December	
Thousands of Euro (€)	*2019*	*2018*
Operational profit (from continuing activities)	**26,047**	**14,188**
Depreciation	5,777	2,851
Exceptional results	-	-
Share-based payments	4,898	1,181
REBITDA	**36,722**	**18,221**
Discontinued EBITDA	8,927	21,269
Share-based payments	(4,898)	(1,181)
EBITDA	**40,751**	**38,308**

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Annual report 2019

The Annual Report for the year ended 31 December 2019 will be published on 22 April 2020, 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, 2020) at 15:00 CET/9:00 EST. The live webcast can be accessed on the Mithra website or by clicking here. To participate in the conference call, please call one of the numbers bellow, five to ten minutes prior to 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.

- Telephone access :
    - Brussels Brussel/Bruxelles "Brussels" : +32 (0) 2 792 0434
    - Netherlands Local Amsterdam : +31 (0) 20 794 8426
    - New York New York : +1 212 999 6659
    - Standard International Access : +44 (0) 20 3003 2666
- Access code : Mithra

Financial Calendar

- 22 April 2020 : 2019 Annual Report
- 22 May 2020 : Annual General Shareholders Meeting
- 24 September 2020 : Half Year Report 2020

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 for 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 85 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.