Mithra Announces 2019 Half Year Results

- **Strong revenue growth from continuing operations (+191%) with best first half-year EBITDA since IPO**
- **Cash position remains solid at EUR 77.5 million, key for further R&D development**
- **Confirmed unique safety profile of Mithra's innovative contraceptive pill Estelle® following positive results in both Europe/Russia and United States/Canada. Filing with regulatory authorities planned by end of 2019**
- **Phase III E4 monotherapy study of Donesta® in menopause ready to start pending agency approvals**

Liege, Belgium, 19 September 2019 – 7 :30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, announces its financial results for the six-month period ending 30 June 2019, prepared in accordance with IFRS. The full interim report is available on the Investors section of the website.

Financial Highlights

- Group Revenue up 55% from EUR 12.6 million to EUR 19.6 million. Revenues from continuing operations up 191% from EUR 6.7 million[1], mainly due to licensing revenues recognized for partnership agreements with leaders in Women's Health such as Gedeon Richter for EUR 15 million.
- Non-recurring income of EUR 4.3 million in June 2019 thanks to gain on sale of disposal to Ceres Pharma realized in July 2018.
- Major improvement of EBITDA[2] with significant increase of 78% from EUR -11.5 million to EUR -2.5 million.
- R&D spend increased to EUR 20.9 million (from EUR 19.4 million in June 2018), reflecting beginning of the Phase III Donesta® programs.
- The positive results of Estelle Phase III leading to a filing preparation imply an increased probability of success for commercialization, resulting in an increase in net financial result (EUR -105,679k vs EUR -28,934k in June 2018).
- Net financial result of EUR -105,679k, driven by changes in fair value of contingent liabilities (earn outs) of EUR -98.9 million and by changes in amortized costs of refundable government advances of EUR -4.9 million. Both are non-cash items, the impact of which result from the above mentioned increase in probability of success.
- Cash position remains solid at EUR 77.5 million, key for further R&D development, with good visibility on backlog of contracts and new partnership deals to come.

[1] Excluding revenues from discontinued operations.
[2] EBITDA is an alternative performance measure disclosing earnings before interest, financial income, tax, amortization and depreciation and the change in fair value of contingent consideration payable.

Operational Highlights (including post-period end)

- Positive results of Estelle® Phase III oral contraceptive study ("E4 Freedom") in both Europe/Russia and United States/Canada. These results confirm the unique safety profile of Mithra's innovative contraceptive, as well as the previous data from the Estelle® Phase II study on hemostasis and ovarian function. Mithra on track for filing with agencies by end of 2019.
- Donesta® Phase III studies launching in second half of 2019 pending approvals and on track to target marketing authorization in 2023.
- Expansion of E4 development program with a potential third late stage clinical product candidate, PeriNesta®, for the underserved perimenopausal market.
- Received additional patent for Estelle® in Japan in the dysmenorrhea indication, a market four times larger than the contraceptive market.
- 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.
- Additional commercialization agreements signed for Estelle® in MENA region[3] with Itrom and in Israel with Dexcel Pharma.
- Additional commercialization agreements for Myring™ signed with Itrom (MENA region), Megalabs (Latin and South America), Hormosan (Germany) and Dexcel Pharma (Israel).
- Positive outcome of Myring™ registration procedure in Europe that will lead to an additional 15 Marketing Authorization for a total of 23.
- Launch of manufacturing process of Myring™ at Mithra CDMO[4] facility in Belgium, with production of first commercial batches for European market. Second production phase for Europe has already started. Production of Estelle® validation batches for both U.S. and EU filing ongoing.
- 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.
- Significant increase in staff from 190 to 250 (+30%). Further job creation is expected in the coming months.

François Fornieri, CEO of Mithra Women's Health, comments: *"Celebrating our 20th anniversary this year, 2019 has gotten off to a very good start. Our financial position was further strengthened with revenue growth, increasing 191% to EUR 19.6 million in 2019 from EUR 6.7 million last year. We've reported the best half-year EBITDA since our IPO in 2015. Furthermore, with a strong cash position, a backlog of contracts with regulatory milestones to be collected in the near term, and a very promising out-licensing activity, Mithra is able to fund trials and complete the development of the menopausal programs.*

Our comfortable financial situation also allows us to be selective in identifying the best commercial partner for our candidate blockbuster Estelle® in the United States. We are more than ever confident, as negotiations for key markets progress, in parallel with the filing preparation both in the United States

3 Middle East and North Africa
4 Contract Development and Manufacturing Organization

and Europe, planned by end 2019. We have also begun preparations for strategic and operational alignment for the launch of Estelle® worldwide.

At our Mithra CDMO, several important milestones were reached during this first half of 2019. With state-of-the-art equipment and know how, the company has tripled its production capacity to deliver the next commercial batches of Mithra's vaginal ring Myring™ for the European market. We are very pleased to see Myring™ come to market, especially in Belgium and in Germany. Our Mithra CDMO has also valided new test batches of Myring™ for the potential commercialization in the U.S. by Mayne Pharma from 2020 and is currently manufacturing Estelle® validation batches for both the U.S. and EU filing.

In terms of R&D, we have launched pivotal studies for our implant Zoreline® and continue to explore additional indications for E4, in particular in pediatric neuroprotection which benefits from the Orphan Drug Designation. On the intellectual property front, there are over 30 patent families covering our E4 platform, and which we are striving to extend to protect our assets into the future."

Operational review

Estetrol (E4) unique native estrogen pipeline

Estelle®-- the fifth generation oral contraceptive

In H1 2019, Mithra announced a number of key milestones for Estelle®, Mithra's combined oral contraceptive (COC) candidate, composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP).

In January, Mithra announced positive topline results of Estelle® Phase III study in the United States/Canada ("E4 Freedom"). The primary efficacy endpoint indicates excellent contraceptive efficacy, with a Pearl Index (PI) of 2.41[5] per 100 women (98% efficacy rate), in line with expectations and similar to a recently FDA approved combined hormonal contraceptive (Annovera™[6]) and one of the best-selling Combined Oral Contraceptives (COC) in the U.S. (Lo-loestrin®[7]) with USD 527.7 million sales (15% yoy growth[8]). Key secondary endpoints (same as the one for the EU/RU study) were also achieved. These results confirm the unique benefit/risk profile of Mithra's innovative contraceptive, as well as the previous data from the Estelle® Phase II study on hemostasis and ovarian function.

In March, Mithra announced that it had signed a 20-year binding Head of Terms agreement with ITROM Pharmaceutical Group (ITROM) for the commercialization of Estelle® in the Middle East. Under the terms of the agreement, ITROM will distribute Estelle® in MENA[9] territories (Saudi Arabia, United Arab Emirates, Bahrain, Kuwait, Qatar, Oman, Lebanon and Jordan) where the COC market is estimated at EUR 30 million a year[10]. This agreement represents a deal worth up to EUR 55 million over the period.

In August (post period end), Mithra announced that it had entered into an exclusive license and supply agreement with Dexcel Pharma for the commercialization of Estelle® in Israel. Mithra will receive a down payment and recurring revenues based on minimum annual quantities (MAQ). Moreover, Mithra will manufacture Estelle® at its Contract Development and Manufacturing Organization facility (CDMO) in Belgium.

Also in August, Mithra announced that it had obtained a key additional patent for Estelle® for the dysmenorrhea[11] indication in Japan. Mithra considers Japan as one of its priority target territories for Estelle®, mainly due to the attractively priced and large market profile. Mithra already has a business partner - Fuji Pharma - for the commercialization of Estelle® in Japan and in the ASEAN countries, with a potential deal value of EUR 450 million over the period.

This additional patent opens the door for the dysmenorrhea market, which is four times larger than the contraceptive market, particularly thanks to the attractive reimbursement rate. Together, the contraception and dysmenorrhea markets in Japan account for at least EUR 270 million a year[12]. The issuance of this patent covering the management of dysmenorrhea extends Estelle's IP protection in Japan until 2037. In addition, Mithra will apply for a patent term extension based on its marketing authorization for Estelle® in Japan, which should extend the patent life for a maximum of 5 years. The patent application covering dysmenorrhea has also been filed in about 20 countries, mainly in Asia and

[5] European definition
[6] Registered trademark of Therapeutics MD
[7] Registered trademark of Allergan Plc
[8] Allergan plc 2018 full year earnings release
[9] Middle East and North Africa
[10] IQVIA Q3 2017: KSA, UAE, Lebanon, Jordan, Kuwait
[11] Dysmenorrhea refers to the symptom of painful menstruation
[12] IQVIA 2017

Latin America where the dysmenorrhea market is particularly attractive in terms of sales volume and pricing.

Following the positive results of Phase III, Mithra is currently compiling the data for the filing with the regulatory authorities that should be completed by the end of 2019. Mithra will also continue its partnering discussions for the exclusive license and commercialization rights, in particular in the U.S., as well as in other key international markets.

PeriNesta®-- the first complete oral treatment for perimenopause

In January, Mithra announced the expansion of its E4 development program with a third E4-based product candidate, PeriNesta®, for the underserved perimenopausal market. Perimenopause affects women between late reproductive and menopausal age, and is characterized by persistent irregular menstrual cycles, extreme fluctuations in hormonal levels, frequent anovulation and the appearance of VMS[13]. PeriNesta® (E4 15 mg/DRSP 3 mg/Vit) has the potential to be the first product on the market to meet the needs of women during this phase of life. It would offer women experiencing perimenopause an improved benefit-risk contraceptive solution and address the first menopausal symptoms such as hot flushes.

PeriNesta® will be the subject of a limited safety study with a comparable formulation to E4 15mg/DRSP 3 mg in women aged around 50 years with vasomotor symptoms. The cost of the study will be low thanks to the extensive clinical data available. Mithra has also filed an additional patent application based on the existing data generated in previous clinical studies. This patent would strengthen and extend the E4 intellectual property estate for menopause and perimenopause until 2039.

This new blockbuster potential represents a significant new business opportunity while requiring limited additional investment. Up to 35 million patients each year in the U.S. and three major European markets make up this underserved market[14]. This represents a multi-billion EUR market value with no existing approved product on the market addressing the dual need of contraception and relief of hot flushes and other menopausal symptoms during perimenopause. Pending regulatory agency approvals, Mithra should be in a position to target market authorizations in 2023.

Donesta®-- the next-generation hormone therapy

The results of the Phase II study of Donesta® confirmed the potential of Donesta® as a next generation hormone therapy with a better benefit/risk profile. After these promising results, the Company announced early 2019 plans to accelerate preparations for its proposed Phase III E4 monotherapy study of Donesta® in menopause. This worldwide randomized, multicenter, double-blind, partial, placebo-controlled Phase III trial will evaluate the efficacy and safety of E4 for the treatment of moderate to severe VMS in postmenopausal women. Mithra appointed leading specialist Contract Research Organization (CRO) ICON Plc (NASDAQ: ILCR) to manage the study.

The start of patient recruitment for this Phase III with E4 monotherapy is planned for the second half of 2019 pending approvals. The global menopause market currently stands at USD 12.6 billion and is expected to grow to approximately USD 16 billion by 2025[15].

With a strong cash position, a backlog of contracts with regulatory milestones to be collected in the near term, and a very promising out-licensing activity, Mithra is able to fund trials and complete the

---

[13] Climacteric. 2012 Apr;15(2):105-14. doi: 10.3109/13697137.2011.650656. Epub 2012 Feb 16
[14] IQVIA 2019 market analysis (US, France, UK, Germany)
15 IQVIA analysis 2019

development of both the perimenopause and menopause programs itself. Depending on regulatory approvals, Mithra believes it could achieve marketing authorization for both candidates in 2023. Ongoing patent applications would protect Donesta® and PeriNesta® intellectual property rights until 2039. Furthermore, Mithra remains focused on establishing the best commercial partnerships for these product candidates and to further accelerate commercial licensing agreements in menopause and in perimenopause in the U.S. and in the main European markets.

Estetrol platform

In March, Mithra presented the results of a new study on Estetrol at the 101st Annual Meeting of the Endocrine Society (ENDO 2019) held in New Orleans (U.S.) During the late breaking news session of this key international conference in endocrinology, Mithra presented the most recent findings on E4's mode of action. The results of this study delineate further E4's unique profile as an estrogen with selective actions in tissues, demonstrating the absence of specific membrane receptor effects. This additional data strengthens E4's unique character and the innovation of the E4 research platform. The specificity of E4 activity with lower hepatic effects should ultimately translate into safer clinical use across a broad range of indications, starting with contraception, perimenopause and menopause.

In April, Mithra announced that it had received Orphan Drug Designation (ODD) from the Food and Drug Administration (FDA) for the use of E4 in Neonatal Encephalopathy (NE). In addition to its three late-stage E4-based product candidates for contraception, perimenopause and menopause, Mithra is developing E4's potential in other therapeutic areas, particularly in neuroprotection for the treatment of hypoxic ischemic encephalopathy (HIE), a life-threatening form of neonatal asphyxia that affects 30,000 newborns each year in Europe and the United States[16]. The FDA granted Orphan Drug designation for E4 in the treatment of HIE based on promising preclinical results, in particular in pathophysiology, general well-being and motor functions. Mithra had already obtained this Orphan Drug Designation from the European Medicines Agency (EMA) in June 2017 and the non-clinical program is moving forward. Given its significant mortality and morbidity in newborns and the lack of available therapeutic alternatives, the development of a new E4-based treatment could meet a serious unmet medical need.

Portofolio of complex therapeutics

Myring™ - hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA)

To date, Mithra has licensed Myring™ to industry leaders in 11 international markets, including the United States, Austria, the Czech Republic, Russia, Denmark, Chile, MENA territories, Australia/New Zealand, South America, Germany and Israel. All contracts provide for the production of vaginal contraceptives at the Mithra CDMO facility in Belgium, which has tripled its production capacity to meet orders placed and the expected market increase. Further contracts are expected to follow in the next months, including in Europe, where Mithra will have 23 marketing authorizations granted.

In February, Mithra announced an exclusive 20-years license and supply agreement with ITROM for the commercialization of its combined hormonal contraceptive vaginal ring in the MENA territories[17],

16 Kurinczuk et al. Early Hum Dev 2010; 86: 329-338, 2010.
17 Middle East and North Africa: Saudi Arabia, United Arab Emirates, Bahrain, Kuwait, Qatar, Oman, Lebanon and Jordan

where the hormonal contraceptive market is worth EUR 37.5 million[18]. This agreement represents a deal worth at least EUR 6 million over the period.

In February, Mithra announced that its Mithra CDMO had successfully produced its first commercial batch of Myring™ for the European market. This first order of the vaginal contraceptive ring will be sold in the Czech Republic, a market worth approximately EUR 1.3 million[19].

In April, Mithra granted an exclusive 10-year license and supply agreement to Megalabs for the commercialization of its vaginal contraceptive ring in Latin America and South America (Argentina, Paraguay and the Dominican Republic). In Argentina alone, the market for contraceptive rings accounts for EUR 1.4 million a year[20], and is rapidly growing.

In May, Mithra announced that it had entered into an exclusive license and supply agreement with Hormosan for the commercialization of Myring™ in Germany. Hormosan is a subsidiary of the innovation-driven pharmaceutical company Lupin Group. Under the terms of this 5-year agreement, Hormosan will distribute Myring™ in Germany, which is the largest European market in terms of volume. With 3 million vaginal rings sold per year, the German contraceptive vaginal rings market is worth EUR 27 million per year[21]. Globally, this agreement could generate revenues of at least EUR 2.5 million for Mithra.

Post-period end, in August, Mithra granted an exclusive license to Dexcel Pharma for the commercialization of Myring™ in Israel. Under the terms of the agreement, Mithra will receive a down payment and recurring revenues based on minimum annual quantities (MAQ). Moreover, Mithra will manufacture hormonal rings at its Contract Development and Manufacturing Organization facility in Belgium.

Tibelia® – generic version of tibolone (Livial®) for use in Hormone Therapy (HT)

Tibelia® is currently marketed in about ten countries through existing license and supply agreements.

In March, Mithra granted a license and supply agreement to Saval Pharmaceuticals, a leading pharmaceutical company based in Chile, to commercialize Tibelia® in Chile. Under the terms of the 7-year agreement, Saval will distribute Tibelia®, which has a tibolone market worth approximately EUR 3.2 million per year[22].

In May, the Canadian Health authorities (Health Canada) granted the Marketing Authorization for Tibelia®, indicated for the short-term treatment of vasomotor symptoms due to estrogen deficiency in postmenopausal women, more than one year after menopause. There are currently no tibolone-based products on the market in Canada (originator and generic included) for the relief of postmenopausal symptoms and prevention of osteoporosis in post-menopausal women. With the approval from Health Canada, Tibelia® will be launched as a new treatment option for these indications in Canada. The introduction of Tibelia® on the North American continent plays a crucial role in the international commercial expansion strategy in key attractive markets like the United States.

18 IQVIA Q3 2017, excluding Bahrain, Qatar and Oman
19 IMS Analytics Q3 2017
20 IQVIA Q3 2017, CAGR 19% (2012-2017).
21 IQVIA Q4 2018
22 IQVIA Q3 2017 CAGR +2.6% (2013-2017)

Zoreline® – generic version of goserelin (Zoladex®) for prostate & breast cancer and benign gynecological conditions

Having previously announced positive pharmacokinetic (PK) results for the one-month and three-month formulation of Zoreline®, Mithra initiated a pivotal clinical phamacodynamic study on the three-month formulation in the first half of 2019, as planned. The patient recruitment phase is expected to be completed by the end of 2019.

Zoreline® represents a significant business opportunity, with total sales of Zoladex® worldwide of USD 693 million in 2017[23]. No generic version of Zoladex® has been approved to date, except for a few Eastern European countries.

Mithra CDMO

Thanks to its tripled production capacity and the acquisition of new equipment, Mithra's Research, Development and Manufacturing Platform is continuing to deploy its range of services, both in the Injectables division and for other complex therapeutics.

In February, Mithra CDMO started the commercial manufacturing process of its vaginal contraceptive ring Myring™ with a first batch for the European market (Czech Republic). Post-period end, the Mithra CDMO also started the manufacturing for further commercial batches for the European market. In addition, Mithra has produced new test batches of Myring™ for the commercialization by Mayne Pharma in the U.S. from 2020 and is currently manufacturing Estelle® validation batches for both the U.S. and EU filing.

In February, Mithra signed a contract with CEVA Animal Health, leading global veterinary pharmaceutical group. For this first veterinarian project, Mithra will develop a hormonal device for the fertility market. This new polymer-based device would bring innovation and an additional competitive edge to our partner while expanding Mithra's polymer based technology expertise.

In April, Mithra entered into a new agreement with Generic Specialty Pharma (GSP) for the development and supply of a sterile hormonal injectable product at Mithra CDMO. This contract follows the first collaboration agreement concluded with GSP in 2017 for the development of four injectable products and confirms GSP's confidence in the technological know-how of Mithra CDMO in this complex field.

Corporate information

In January, Mithra was awarded BelMid Company of the Year 2018 by Euronext Brussels at its annual New Year's Ceremony held in Brussels and presented by the Belgian Minister of Finance, Alexander De Croo. This prize is awarded to a company that has demonstrated the highest relative increase in market capitalization year-over-year.

In April, Mithra won the essenscia Innovation Award 2019, the most prestigious prize for industrial innovation in Belgium. Selected amongst a hundred candidates, Mithra was elected "Most innovative company 2019" for the development of its contraceptive pill Estelle®. Beside innovation, the essenscia Innovation Award takes into account various criteria, such as the strategy for intellectual property management, the environmental impact and the value added for the Belgian economy. Capping more

23 IQVIA Q3 2017

than 20 years of research and development, this award was presented by her Royal Highness, the Princess Astrid, during a ceremony at the Palace of the Academies in Brussels.

In May, Mithra informed the shareholders during its Ordinary and Extraordinary Shareholders Meeting about Mithra Group future restructuring. Post-period end, Mithra completed the restructuring of the Group in accordance with what had been announced at the Ordinary and Extraordinary Shareholders Meeting. On July 31st, it has formalized two contributions of branch Unit.

In H1 2019, Mithra strengthened its Management Team with key appointments: Mrs. Alexandra Deschner as Investor Relations Officer, Mrs. Maud Vanderthommen as Communication Manager, Dr. Graham Dixon as Chief Scientific Officer and Mr. Renaat Baes as Plant Manager.

During the first half of the year and post-period end, the expertise of the R&D team has been considerably consolidated, particularly in the Medical Affairs and Regulatory departments, in order to prepare for the next stages of development of the Mithra portfolio. Since the beginning of 2019, the number of staff has increased significantly from 190 to 250 (+30%), and further job creation is expected in the coming months.

Financial Review

Consolidated income statement

CONTINUING OPERATIONS

Thousands of Euro	*30 June 2019*	*30 June 2018*
CONSOLIDATED INCOME STATEMENT		
Revenues	**19,563**	**6,718**
Cost of sales	**(2,021)**	**(687)**
Gross profit	**17,542**	**6,031**
Research and development expenses	(20,944)	(19,401)
General and administrative expenses	(7,539)	(4,511)
Selling expenses	(679)	(932)
Other operating income	1,695	4,413
Total operating expenses	**(27,467)**	**(20,431)**
Loss from Operations	**(9,926)**	**(14,401)**
Change in fair value of contingent consideration payable[24]	(98,901)	(27,225)
Financial income	52	238
Financial expense	(6,830)	(1,947)
Loss before taxes	**(115,604)**	**(43,334)**
Income taxes	**22,318**	**7,800**
Net Loss for the period	**(93,285)**	**(35,534)**
Weighted average number of share for the purpose of basic loss per share	37,462,950	34,735,780
Basic loss per share (in Euro)	(2.49)	(1.02)
Diluted loss per share (in Euro)	(2.49)	(102)

[24] Contingent consideration payables which is reported under Other financial liabilities, is fair valued through profit or loss

DISCONTINUED OPERATIONS[25]

Thousands of Euro	*30 June 2019*	*30 June 2018*
CONSOLIDATED INCOME STATEMENT		
Revenues	**-**	**5,906**
Cost of sales	**-**	**(2,933)**
Gross profit	**-**	**2,973**
Selling expenses	-	(1,458)
Other operating income	583	-
Gain on sale of disposal group	4,352	-
Total operating expenses	**4,935**	**(1,458)**
Profit from Operations	**4,935**	**1,516**
Financial result	**(1)**	**0**
Profit before taxes	**4,935**	**1,516**
Income taxes	**(1,397)**	**(429)**
Net Profit for the period	**3,538**	**1,087**

GROUP TOTAL

Thousands of Euro	*30 June 2019*	*30 June 2018*
CONSOLIDATED INCOME STATEMENT		
Revenues	**19,563**	**12,624**
Gross Profit	**17,542**	**9,004**
Loss from Operations	**(4,990)**	**(12,885)**
Change in fair value of contingent consideration payable[26]	(98,901)	(27,225)
Financial income	52	238
Financial expense	(6,830)	(1,947)
Loss before taxes	**(110,669)**	**(41,818)**
Income taxes	20,922	7,371
Net Loss for the period	**(89,747)**	**(34,448)**

25 Please refer to note 6.17 Discontinued operations
26 Contingent consideration payables which is reported under Other financial liabilities, is fair valued through profit or loss

Consolidated Statement of financial position

Thousands of Euro	*30 June 2019*	*31 December 2018*
ASSETS		
Property, plant and equipment	21,658	84,396
Right-of-use assets	69,172	-
Goodwill	5,233	5,233
Other Intangible assets	85,502	81,907
Deferred tax assets	49,532	27,045
Contract assets	29,418	14,350
Other non-current assets	8,605	3,435
Non-current assets	**269,120**	**216,366**
Inventories	14,110	10,945
Contract assets	1,000	1,000
Trade and other receivables	8,697	12,468
Cash and cash equivalents	77,466	118,949
Current assets	**101,274**	**143,362**
TOTAL ASSETS	**370,394**	**359,728**

Thousands of Euro	*30 June 2019*	*31 December 2018*
EQUITY AND LIABILITIES		
Equity		
Share capital	26,961	26,925
Additional paid-in-capital	221,720	221,587
Accumulated deficit	(184,710)	(97,557)
Translation differences	(38)	(62)
Equity attributable to equity holders of the parent	**63,933**	**150,893**
Subordinated loans	12,279	14,222
Other loans	7,204	53,148
Lease liabilities	47,728	-
Refundable government advances	14,330	10,252
Other financial liabilities	184,558	88,620
Provisions	607	266
Contract liabilities	4,017	4,017
Deferred tax liabilities	3,403	2,202
Non-current liabilities	**274,126**	**172,727**
Current portion of Subordinated loan	901	173
Current portion of Other loans	6,290	12,405
Current portion of Lease liabilities	4,329	-
Current portion of Refundable government advances	1,266	668
Current portion of Other financial liabilities	5,472	7,007
Trade payables, Accrued charges & other current liabilities	13,693	15,520
Corporate tax payable	386	334
Current liabilities	**32,335**	**36,109**
TOTAL EQUITY AND LIABILITIES	**370,394**	**359,728**

Consolidated statement of cash flows

GROUP TOTAL (INCLUDING DISCONTINUED OPERATIONS)

Thousands of Euro	*30 June 2019*	*30 June 2018*
CASH FLOWS FROM OPERATING ACTIVITIES		
Result from operations	**(4,990)**	**(12,885)**
Depreciation and amortisation	2,460	1.,363
Gain on sale of disposal group	(4,352)	-
Tax credit	(517)	(597)
Share-based payments	2,594	217
Subtotal	**(4,805)**	**(11,901)**
Changes in Working Capital		
Increase/(decrease) in Trade payables and other current liabilities	(2,174)	(18,186)
(Increase)/decrease in trade receivables and other receivables	(15,643)	16,066
(Increase)/decrease in inventories	(3,165)	(2,534)
Increase/(decrease) in corporate tax payables and others	52	(637)
Net cash provided by/(used in) operating activities	**(25,735)**	**(17,192)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Payment for acquisition of tangible fixed assets	(7,025)	(3,187)
Payment for acquisition of intangible fixed assets	(3,754)	(1,232)
Other financial liabilities payments	(4,500)	(3,190)
Net cash provided by/(used in) investing activities	**(15,279)**	**(7,609)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on loans & government advances	(10,679)	(303)
Proceeds from loans & government advances & subsidies	12,466	903
Repayments of lease liabilities	(621)	-
Interests paid	(1,804)	(1,427)
Proceeds from issuance of shares (net of issue costs)	170	75,196
Net cash provided by/(used in) financing activities	**(469)**	**74,370**
Net increase/(decrease) in cash & cash equivalents	**-41,483**	**49,568**
Cash & cash equivalents at beginning of year	**118,949**	**36,190**
Cash and cash equivalents at end of period	**77,466**	**85,757**

CONTINUING OPERATIONS

Thousands of Euro	*30 June 2019*	*30 June 2018*
Cash flow from operating activities	(30,670)	(22,554)
Cash flow from investing activities	(15,279)	(4,185)
Cash flow from financing activities	(469)	74,370
Cash flow from continuing operations (net increase/decrease)	46,418	47,630

Profit and Loss

- The Revenues of the Group increased in the first half of 2019 to EUR 19,563k (from EUR 12,624k in H1 2018), mainly driven by license revenues related to our partnership agreements which increased by EUR 10,180k from EUR 5,685k in H1 2018 to EUR 15,865k in H1 2019 (mainly for Estelle® with Gedeon Richter for EUR 15,000k and with Searchlight for EUR 500k). The discontinued product sales decreased as a consequence of the Ceres asset deal, but important to note that the Product sales from continuing operations have increased. In the third segment information "Others" the revenue recognized from the injectables activities has been reported. We also reported a further drop in sales in Germany. We remind that the German company is on hold and reported an insignificant amount of sales revenues as we don't develop a sales and distribution organization anymore.
- The increase of revenue together with a decrease in the cost of Sales drove the increase in Gross Profit from EUR 9,004k in 2018 to EUR 17,542k in 2019.
- The total of R&D expenses, G&A and selling expenses, have increased by 13% (EUR 3,330k) in H1 2019.
- Research and development expenses increased in the first half 2019 by 8% to EUR 20,944k (H1 2018: EUR 19,401k). 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 2019.
- The G&A increased mainly due to booking entries related to share-based payment expenses of EUR 2,594k in H1 2019, a non-cash element.
- The increase in Operating expenses is however limited and explained by the discontinued operations for which we recognized a gain of EUR 4,352k in H1 2019 related to a contingent consideration receivable for a gain on sale of disposal (Ceres).
- All this resulted in an improved operating loss of EUR -4,990k in June 2019 compared to EUR -12,885k in June 2018.
- The financial expense of EUR -6,830k is mainly the result of the IFRS adjustment in the amortized cost of government advances for EUR -4.9 million (reported in the consolidated income statement under financial expenses). The remaining part of the financial expenses is related to the interests paid for EUR -1.9 million.
- The loss before taxes at EUR -110,669k in H1 2019 is driven by an increase in the fair value of contingent consideration liabilities (earn outs) for EUR -98.9 million. Both the increase in the amortized cost of government advances and the change in the fair value of contingent consideration liabilities (earn outs) are non-cash elements, and their increases are explained by the increase of probability of success of obtaining a marketing authorization for Estelle® from 38% to 78%, reflecting the regulatory progress post positive results of Phase III during the first half of the year.
- The group recorded a tax income of EUR 20,922k for the six months that results from an increase of the deferred tax asset from prior year-end which is to be offset against taxable income in the future. Taking this tax income into consideration, the net loss for half year ended 2019 was EUR 89,747k (loss of EUR 34,447k for H1 2018) on a consolidated basis.

Statement of Financial position

- As of 30 June 2019, the Statement of financial position shows a total of EUR 269 million in Non-current assets, the majority of which are Other intangible assets (EUR 85.5 million), Property, plant and equipment (EUR 21.7 million), Right-of-use assets (EUR 69.2 million) and Deferred tax assets (EUR 49.5 million).

  These Other intangible assets are the result of acquired assets as part of former business combinations. Note that Donesta® qualified as an asset deal, for EUR 8 million. The book value mainly relates to Estelle® for an amount of EUR 30.6 million, to Zoreline® for an amount of EUR 24.4 million, and to Myring™ for an amount of EUR 11.4 million. Other intangible assets consist mainly of a portfolio of acquired product rights and market access rights. Over H1 2019, EUR 2.4 million 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 million, for the CDMO development activities.

- In the Property, plant and equipment and the Right-of-use assets, the Group recorded an additional EUR 7 million in tangible fixed assets (EUR 90.8 million at the end of June 2019 vs. EUR 84.4 million in 2018). The increase relates mainly to the construction of the second phase of the new production facility for the manufacturing of pharmaceutical products (Mithra CDMO), where Mithra is preparing the production of Myring™. Over the first half of 2019, EUR 4.3 million have also been added to the Property, plant and equipment 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 are the result of unbilled revenue for EUR 30.4 million (non-current and current) regarding EUR 15.3 million in 2018 related to out-licensing revenue, among which EUR 20 million in milestones related to Gedeon Richter (increased by EUR 15 million compared to 2018), EUR 7.6 million related to Mayne (unchanged), EUR 1.3 million milestones related to Fuji Pharma (current part is reported under the current assets and EUR 1 million has been invoiced in H1 2019) and EUR 1 million related to Searchlight Pharma (EUR 0.5 million over six months period ended June 2019 and EUR 0.5 million in December 2018).

- The increase in Deferred tax assets of EUR 22.5 million mainly related to the tax effects arising from the recognition of a deferred tax asset on the fair values of the Estetra earn-out from EUR 16.9 million end of 2018 to EUR 36.2 million in the first half 2019, a total increase of EUR 19.2 million.

- Current assets at the end of June 2019 represent a value of EUR 101.3 million. The cash position accounts for EUR 77.5 million of cash and cash equivalents on 30 June 2019, Trade & other receivables for EUR 8.7 million and Inventories for EUR 14.1 million.

- Trade & other receivables decreased by EUR 3,770k which is mainly the result of the settlement of client invoices during the first semester and VAT proceeds.

- Inventories have increased from EUR 10.9 million in 2018 to EUR 14.1 million in June 2019. It is mainly explained by the increase of API[27] stock from EUR 7.4 million in 2018 to EUR 9.9 million end of June 2019 which has been constituted in order to be ready for the production of Myring™.

[27] API : Active Pharmaceutical Ingredient

- The equity position at the end of the year has decreased to EUR 63.9 million in June 2019 from EUR 150.9 million in 2018. The decrease is mainly explained by the net loss of EUR 89.7 million of the period.

  Non-current liabilities increased to EUR 274.1 million at the end of June 2019, compared to EUR 172.7 million in 2018, primarily due an increase of the fair values of the contingent considerations payables (EUR + 95.9 million) which are reported under Other financial liabilities and to refundable government advances (EUR +4.1 million) reported under Financial expense. The increase is attributable to the probability of success of obtaining a marketing authorization for Estelle® that increased from 38% to 78%, reflecting the regulatory process post positive results of Phase III during the first half of the year.

- The current liabilities decreased to EUR 32,3 million at the end of June 2019, compared to EUR 36.1 million in 2018. The decrease of the current liabilities is the net result of a decrease in the Trade payables and other current liabilities (EUR -1.8 million), a decrease in the portion of Other financial liabilities (EUR -1.5 million) and of the others current debt positions.

Cash Flow

Full year cash flow of the group amounted to EUR -41.5 million including cash flows from discontinued operations for EUR +4.9 million, which is comprised of:

- ***Operating cash flow*:** The cash used for operating activities amounts to EUR -25.7 million for the six month ended June 2019, including cash flows from discontinued operations (EUR + 4.9 million). The operating loss of EUR -4.9 million has been adjusted for the non-cash items amounting in net to EUR +0.2 million.

  In order to report the gain on sale of disposal for EUR 4.3 million (refer to discontinued operations cash flow), as it is a non-cash item, we remove it from the operating loss in operating activities.

  Working capital is also impacting the cash used for operating activities as a result of an increase in Trade & other receivables and contract assets (EUR +15.6 million), a decrease in Trade payables, Accrued charges & other current liabilities (EUR -2.2 million) and an increase of inventories (EUR +3.2 million).

- ***Investing cash flows*:** EUR -15.3 million. The purchase of tangible assets relates predominately to property, plant & equipment acquired for Mithra CDMO facility and related machines and equipment (EUR 7 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 2.4 million). The assets financed by lease liabilities are netted together, and also reports payments for contingent liabilities (EUR 4.5 million).

- ***Financing cash flows*:** EUR -0.5 million related entirely to cash flows from continuing operations. The Group made new drawdowns under its bank loans (EUR 6.9 million) 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.

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.

EBITDA is an alternative performance measure which represents Earnings before financial income and expense, tax, amortization, depreciation and impairment and changes in the fair value of contingent consideration payable.

REBITDA is an alternative performance measure which represents EBITDA adjusted for (non-cash) equity-settled shared-based payment expense and EBITDA from discontinued operations.

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

	Six months ended 30 June	
Thousands of Euro (€)	*2019*	*2018*
Loss from continued operations	**(9,926)**	**(14,400)**
Depreciation	2,460	1,363,
Exceptional results	-	-
Share-based payments	2,594	217
REBITDA	**(4,872)**	**(12,821)**
Discontinued EBITDA	4,935	1,516
Share-based payments	(2,594)	(217)
EBITDA	**(2,531)**	**(11,522)**

****

For more information, please contact:

Alexandra Deschner (IRO) : +32 490 58 35 23 - investorrelations@mithra.com
Maud Vanderthommen (Press) : +32 473 58 61 04 – press@mithra.com

About Mithra

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in Women's Health, with a particular focus on contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its three lead development candidates – a fifth generation oral contraceptive Estelle®, the first complete oral treatment for perimenopause PeriNesta® and next-generation hormone therapy Donesta® - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops and manufactures complex therapeutics and offers partners a complete spectrum of research, development and specialist manufacturing at its CDMO. Mithra was founded in 1999 as a spin-off from the University of Liège by François Fornieri and Prof. Dr. Jean-Michel Foidart. Mithra is headquartered in Liège, Belgium. Further information can be found at 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.