Mithra Reports 2018 Annual Results

- **Strong revenue growth (+42%) with significantly improved EBITDA (record level of EUR 38.3 M vs. EUR -18.4 M in 2017) and cash position (EUR 119 M vs. EUR 36.2 M in 2017) thanks to increased business development activities**
- **Strengthening Mithra's international deployment through key partnerships with women's health leaders**
- **Clinical milestones successfully achieved for highly promising portfolio E4 (Estetrol)-based pipeline, including the 5th generation contraceptive pill Estelle® and next-generation menopause therapy Donesta®**
- **Additional potential E4-based blockbuster for the underserved perimenopause market with PeriNesta™ in development (which brings Mithra's late clinical stage pipeline to a total of 3)**

Liege, Belgium, 01 March 2019– 7 :30 CET – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces its results for the year ended 31 December 2018, prepared in accordance with IFRS.

Financial highlights

- Revenues increased by over 42% to EUR 65.5 million (from EUR 46.3 million in 2017), mainly due to licensing revenues recognized for partnership agreements with leaders in Women's Health such as Gedeon Richter for EUR 40 million.
- EBITDA[1] significantly improved to EUR 38.3 million in 2018 compared to EUR -18.4 million in 2017 – increase by 308 %.
- The company raised EUR 77.5 million in gross proceeds in May 2018 with a capital increase by means of a private placement of 2,672,414 new shares to fund clinical development of its key assets.
- Increase of EUR 18.5 million of non-recurring income in 2018 due to the gain on sale of disposal of Ceres Pharma realized in July 2018.
- Cash at December 31 2018 was EUR 119 million (EUR 36.2 million in 2017); with the cash generated from operating and investment activities strengthened by the private placement in May 2018.
- R&D spend decreases to EUR 35.7 million (from EUR 48.2 million in 2017), reflecting the completion of the Phase III Estelle® and Phase II Donesta® programs.

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

Key Highlights (including post-period end)

- Positive top-line results of Estelle® Phase III oral contraceptive study ("E4 Freedom") in both Europe/Russia and the 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 intends to file with European and American regulatory agencies by the end of 2019.
- Positive top-line results of the Donesta® Phase II study ("E4 Relief") for the treatment of vasomotor symptoms, in particular hot flushes relief, in postmenopausal women. Phase III studies are expected to launch in the second half of 2019, pending approvals.
- Expansion of the E4 development program with a third late stage clinical product candidate, PeriNesta™, for the underserved perimenopausal market. PeriNesta™ has the potential to offer women an improved benefit/risk contraceptive solution while addressing the challenge of hot flushes.
- Commercialization agreements signed for Estelle® in key international markets including Europe and Russia (Gedeon Richter), Canada (Searchlight Pharma), South Africa (Adcock Ingram), South Korea (Hyundai Pharm) and, post-period end MENA region[2] (ITROM).
- Commercialization agreements for Myring™ signed with Alvogen (Russia), Orifarm (Denmark), Laboratorio Pasteur (Chile), Neo Health (Australia/New Zealand) and ITROM (MENA region).
- First marketing authorization (MA) received for Myring™ in Europe (United Kingdom), followed by MAs in seven other Eastern European countries (Hungary, Latvia, Croatia, the Czech Republic, Poland, Slovakia and Slovenia).
- Abbreviated New Drug Application (ANDA) accepted for filling by the FDA for the U.S. commercialization of Myring™. The production of test batches for the additional bioequivalence data requested by the FDA in a Complete Response Letter (CRL) received by Mithra's U.S partner Mayne Pharma will be finalized in the first half of 2019.
- Launch of the manufacturing process of Myring™ at Mithra CDMO[3] facility in Belgium, with the production of first commercial batches for the European market.
- Investment in new state-of-the-art equipment allowing Mithra CDMO to triple its production capacity to meet the expected international market demands.
- Strategic divestment of Belgian and Luxembourg activities to Ceres Pharma worth up to EUR 40 million.

François Fornieri, CEO Mithra Women's Health, commented: "*2018 was a very successful year from all points of view. Revenue growth in 2018 was significantly boosted by down payments and milestones from our strategic partnerships and divestment of non-strategic activities, increasing 42% to EUR 65.5 million in 2018 from 46.3 million in 2017. EBITDA also improved significantly to EUR 38.3 million, as did our cash position, which reached a record level of EUR 119 million. In 2019 and beyond, we expect further significant revenue growth based on the potential for further E4 partnerships in the U.S. and other international markets.*

Our key clinical programs have successfully completed significant milestones, bringing our three potential blockbusters closer to the market. The positive top-line results of the Estelle® Phase III study in both Europe/Russia and the U.S./Canada confirmed the novel efficacy and safety profile and great potential of Estelle®, a true 5th generation oral contraceptive, which will offer women a unique

[2] Middle East and North Africa
[3] Contract Development and Manufacturing Organization

innovative therapeutic solution. We intend to file for approval with regulatory agencies by the end of 2019 and will continue negotiations for commercial partners for Estelle® in the United States as well as in other leading markets.

We are also continuing to progress our novel candidate for menopausal symptoms, Donesta®. The results of the Phase II study of Donesta® for the treatment of vasomotor symptoms in postmenopausal women confirmed its unique potential with an improved benefit/risk profile. Following these positive results, we are accelerating Phase III study plans and intend to start in the second half of 2019, pending approvals.

Mithra has also entered a major new and untapped commercial market, perimenopause. Our third potential blockbuster, PeriNesta™, has the potential to become the first product on the market for perimenopausal women, offering an improved benefit/risk contraceptive solution while addressing the first menopausal symptoms. Pending approvals, Mithra is targeting a marketing authorization for both Donesta® and PeriNesta™ product candidates in 2023. With our three innovative products, Mithra has the potential to provide the right therapeutic option for women at each stage of their entire hormonal cycle.

Our successful partnering strategy continued to develop in 2018, with major commercial contracts including Gedeon Richter for Estelle® in Europe and Russia and Alvogen for Myring™ in Russia. The continuing expansion of our international partnerships demonstrates Mithra's growing reputation as a leading innovator in Women's Health.

In order to meet the expected international market demands, our Mithra CDMO will strengthen its activities in both the R&D and production. Thanks to its new state-of-the-art equipment and proven expertise, we have tripled our production capacity to deliver the next commercial batches of the vaginal ring Myring™ in the second half of 2019."

OPERATIONAL OVERVIEW

1. Estetrol (E4) Program

Estelle® - The combined oral contraceptive (COC) product candidate, composed of 15 mg Estetrol (E4) and 3 mg Drospirenone (DRSP) – Phase III study (« E4 Freedom »)

Positive top-line results for the Phase III studies in Europe/Russia and U.S./Canada were announced in August 2018 and, post-period end, in January 2019, respectively. A total of 3,725 women were included in the studies and these positive results confirm the outstanding safety profile of Estelle® as a novel, next-generation combined oral contraceptive.

- In March 2018, Mithra announced positive results from its Phase II hemostasis study of Estelle® at the International Society of Gynecological Endocrinology Conference (ISGE) in Florence. The aim of the study was to determine the risk profile of Estelle® for deep venous thrombosis (DVT) and pulmonary embolism. As required by the regulatory agencies, LNG (levonogestrel) was included as a comparator. Mithra elected to include Yaz® (DRSP COC, benchmark for Estelle®) as an additional comparative arm, given the well-documented elevated DVT risk for current DRSP-based COCs relative to LNG-based products. These results corroborate earlier findings, delineate the unique safety profile and contribute to the potential of Estelle® as a 'fifth generation pill', combining the quality of life offered by DRSP with a safer hemostatic profile compared to other DRSP COC's. Based on these positive data, Mithra applied for an additional patent relating to the E4 synthesis process and E4 as a potential new emergency option to further strengthen and extend the existing Estelle® and E4 intellectual property estate.
- In April 2018, Mithra announced it had signed a binding Heads of Terms agreement with Searchlight Pharma, for an exclusive license to commercialize Estelle® in Canada. Under the terms of the agreement, Mithra is eligible to receive up to EUR 15 million in upfront payments and sales-related income. Mithra will also manufacture Estelle® for Searchlight at its CDMO facility and will receive guaranteed annual recurring revenues based on Minimum Annual Quantities (MAQ). Mithra forecasts the agreement could achieve sales-related revenues of at least EUR 50 million for Mithra, based on market assumptions. The license and supply agreement was finalized with Searchlight Pharma in May 2018.
- In June 2018, Mithra announced it had signed a binding Heads of Terms agreement with Hyundai Pharm, for an exclusive license to commercialize Estelle® in South Korea. Under the terms of the agreement, finalized in September, Mithra is eligible to receive milestone payments, MAQ and further sales-related royalties. Mithra will also produce Estelle® for the South Korean market at its CDMO facility for the South Korean contraceptive market, which is worth approximately EUR 36 million a year, with Combined Oral Contraceptives (COCs)[4] accounting for EUR 27 million.
- In August 2018, Mithra announced positive top-line results for the Phase III Estelle® study in Europe and Russia. The study successfully met its primary endpoint and achieved key secondary endpoints including outstanding bleeding profile, cycle control, quality of life and safety and tolerability. The primary endpoint was contraceptive efficacy measured by the

[4] IQVIA Q3 2017; CAGR +9% (2013-2017)

number of pregnancies per 100 women per 12 months of exposure (Pearl Index; PI). The PI indicates a 99.5% efficacy rate over one year of use, exceeding the efficacy goals of the study.

- In September 2018, Mithra signed an exclusive license and supply agreement with Gedeon Richter to commercialize Estelle® in Europe/Russia, a key market that is valued at more than a fifth of the global oral contraception market (EUR 5.2 billion) [5]. Upon signature of the contract, Richter made an upfront payment of EUR 35 million. Additional milestone payments amounting to EUR 20 million will be made depending on the progress of the regulatory process of the product. Further sales-related milestones and royalties will be payable to Mithra subsequent to the launch of the product. Moreover, Mithra will receive guaranteed annual recurring revenues based on MAQ in addition to tiered royalties on net sales.
- In October 2018, Mithra announced an exclusive licence and supply agreement with Adcock Ingram for the commercialization of Estelle® in South Africa. Mithra is eligible to receive a downpayment of EUR 1.5 million. Mithra will also be eligible to receive additional commercialization milestone payments, further sales-related royalties, guaranteed annual recurring revenues based on MAQ, single digit tiered royalties on net sales and additional high double digit royalties on sales exceeding forecasts. Moreover, Mithra will produce Estelle® for Southern Africa at its CDMO facility in Belgium.
- Post-period end, in January 2019, Mithra announced positive topline results of Estelle® Phase III study in U.S./Canada. Primary efficacy endpoint indicates excellent contraceptive efficacy, with a Pearl Index (PI) of 2.41[6] per 100 women (98% efficacy rate), in line with expectations and similar to a recently FDA approved combined hormonal contraceptive (Annovera™[7]) and one of the best-selling Combined Oral Contraceptives (COC) in the U.S. (Lo-loestrin®[8]) with USD 527.7 million sales (15% yoy growth[9]). Key secondary endpoints (same as the one for the EU/RU study) were also achieved.
- Post-period end, Mithra signed a partnership agreement with ITROM for commercialization of Estelle® in the Middle East. Under the terms of the agreement, ITROM will distribute Estelle® in MENA territories 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.

Donesta® – next-generation hormone therapy (HT) product candidate with oral administration of Estetrol – Menopause – Phase II study (« E4 Relief »)

The results of the Phase II study of Donesta® for the treatment of vasomotor symptoms (VMS) in postmenopausal women confirmed the potential of Donesta® as a new generation hormonal therapy with a better benefit/risk profile.

- In April 2018, Mithra announced the first positive results of this Phase II study of Donesta®. The results showed that 15mg E4 significantly reduces the frequency and severity of hot flushes, as well as secondary menopausal symptoms such as vulvo-vaginal atrophy (VVA), while confirming a promising safety profile. Based on these positive results, Mithra applied for

[5] IQVIA Analytics Link Q3/2017
[6] European definition
[7] Registered trademark of Therapeutics MD
[8] Registered trademark of Allergan Plc
[9] Allergan plc 2018 full year earnings release
[10] IQVIA Q3 2017: KSA, UAE, Lebanon, Jordan, Kuwait

an additional patent to further strengthen and extend the existing Donesta® intellectual property estate.

- In June 2018, Mithra presented the Phase IIb study results for Donesta® at the 16th World Congress on Menopause in Vancouver, Canada (these results were also presented at the North American Menopause Society in October 2018). These data reinforced the previously announced positive Phase IIb study results and also demonstrated an encouraging cardiovascular safety profile and lower bone turnover versus placebo[11]. The promising safety profile at both haemostatic and metabolic levels is consistent with the findings obtained during Phase II of Estelle® contraceptive.
- These promising results move Mithra's blockbuster potential to the next stage of clinical development: the Donesta® Phase III study, a worldwide randomized, multicenter, double-blind, partial, placebo-controlled, multicenter Phase III trial. This study will evaluate the efficacy and safety of E4 for the treatment of moderate to severe vasomotor symptoms in postmenopausal women. The start of patient recruitment for this phase III with E4 monotherapy is planned for the second half of 2019 pending approvals, with a marketing authorization expected as early as 2023. The global menopause market currently stands at USD 8.6 billion and is expected to grow to approximately USD 16 billion by 2025[12].

PeriNesta® – the candidate treatment for perimenopause (15 mg E4/3 mg DRSP + vitamin) - About to start Phase III study

Post-period end, Mithra announced the expansion of its E4 development program with a third product candidate, PeriNesta™, for the underserved perimenopausal market. This affects women between late reproductive and menopausal age. 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 life phase. It would offer women experiencing perimenopause an improved benefit-risk contraceptive solution and address the first menopausal symptoms.

This third E4-based product candidate 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. This addressable and underserved market is estimated up to 35 million patients each year in the U.S. and three major European markets[13]. This represents a multi billion EUR market value with no existing approved product on the market addressing the dual need of contraception and hot flushes relief and other menopausal symptoms during perimenopause. Pending regulatory agency approvals, Mithra should be in a position to target market authorizations in 2023.

[11] As measured by a decrease in both the CTX-1 and osteocalcin markers with E4 use vs placebo. The effect is most pronounced for the 15 mg dose (near-significant for CTX-1 and significant at $p < 0.05$ for osteocalcin)
[12] Transparency Market Research 2017
[13] IQVIA 2019 market analysis (US, France, UK, Germany)

2. Portofolio of complex therapeutic solutions

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

To date, Mithra has licensed Myring™ to industry leaders in eight international markets, including the United States, Austria, the Czech Republic, Russia, Denmark, Chile, MENA region, Australia and New Zealand. 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.

- In March 2018, Mithra announced it had granted an exclusive license and supply agreement to Alvogen for the commercialization of Myring™ in Russia, a market worth approximately EUR 13 million[14].
- Also In March, Mithra announced that the Abbreviated New Drug Application (ANDA) for its vaginal contraceptive ring, Myring™, had been accepted for filing by the U.S. Food and Drug Administration (FDA). The ANDA was submitted by Mithra's partner for the U.S. commercialization of the vaginal ring, Mayne Pharma (ASX:MYX). For this contract, Mithra received a EUR 2.4 million down payment and is eligible to receive further milestones of at least EUR 7.6 million from approval by the U.S. FDA through to commercial launch of the product. Following the FDA's request in December 2018, new test batches will be produced at the Mithra CDMO facility in Belgium during the first half of 2019. According to the latest commercial information, Mayne Pharma is still one of the best positioned players to launch the first generic version of Merck's NuvaRing® in the U.S. market, which represents over 75% of NuvaRing®'s annual global revenues[15].
- In June 2018, Mithra announced an exclusive license and supply agreement with Orifarm for the commercialization of Myring™ in Denmark, a market worth approximately EUR 0.75 million[16].
- In July 2018, Mithra received its first Marketing Authorization (MA) for Myring™ in the United Kingdom, following approval by the MHRA (Medicines and Healthcare Products Regulatory Agency). The UK market is worth approximately EUR 1.2 million[17] with no generic competition on the market yet. Under the same decentralized procedure, MAs for seven other countries (Latvia, Hungary, Croatia, the Czech Republic, Poland, Slovakia and Slovenia) were also granted.
- In September 2018, an exclusive license and supply agreement for the commercialization of Myring™ in Chile was signed with Laboratorio Pasteur. The Chilean market for contraceptive rings accounts for €5.8 million and is fast-growing, with an 18% increase between 2016 and 2017[18].
- In November 2018, Mithra signed an exclusive license and supply agreement with Neo Health for Myring™ in Australia and New Zealand. An important area where the contraceptive market

[14] NuvaRing® (Merck) sales IMS Analytics Q3 2017
[15] IQVIA as provided by Mayne Pharma
[16] Estimation provided by Orifarm
[17] CAGR (2013-2017): +6.6%
[18] IQVIA Q3 2017 ; CAGR+ 4 % (2013-2017)

represents about 107 million euros with a growing demand for products such as the vaginal contraceptive ring[19].

- Post-period end, Mithra signed an exclusive license and supply agreement with ITROM for Myring™ in MENA region, where the hormonal contraceptive market is estimated at EUR 37.5 million[20].

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

To date, Mithra has granted about ten Tibelia® licenses.

- In July 2018, Mithra signed an exclusive license and supply agreement with Mediner for the commercialization of Tibelia® in Hungary, a market worth approximately EUR 0.6 million[21].
- In September 2018, Mithra and Pei Li Pharm entered into an exclusive licensing and supply agreement for the commercialization of Tibelia® in Taiwan, which has a menopause market worth approximately EUR 4.1 million[22].
- In December 2018, Mithra signed a licensing agreement with UAE-based company ITROM for Tibelia® and Daphne Continu (contraceptive pill 21 +7). Combined, the products will generate at least €8 million of value for Mithra. ITROM will distribute the products in the Middle East and North Africa region (Saudi Arabia, United Arab Emirates, Bahrain, Kuwait, Qatar, Sultanate of Oman, Lebanon and Jordan). The hormonal contraceptive market in the MENA region represented a potential of EUR 37.5 million in 2017, while the overall hormonal menopause market was worth EUR 2.65 million[23].

Zoreline® – generic version of goserelin (Zoladex®) for prostate & breast cancer and benign gynecological conditions – subcutaneous implant 1&3 month

- In February 2018, Mithra received positive results of its one-month pilot pharmacokinetic (PK) and pharmacodynamic (PD) study for Zoreline®. The safety profile of the 1-month implant (3.6 mg) is similar to the branded Zoladex® implant (AstraZeneca) and therefore meets regulatory requirements.
- In December 2018, Mithra announced positive results for the three-month formulation of Zoreline®, enabling it to initiate the final clinical studies. The pivotal studies on 3-month and 1-month formulations are intended to take place in the first and second half of 2019, respectively.
- Following the results of these studies, Mithra plans to file for marketing authorization via partners. Zoreline® represents a significant business opportunity, with total sales of Zoladex® worldwide of USD 693 million in 2017[24]. No generic version of Zoladex® has been approved to date, except for a few Eastern European countries. The one-month implant accounts for over

[19] IQVIA Q3 2017 – CAGR 3% (2016-2017)
[20] IQVIA Q32017excluding Bahrain, Qatar and Oman
[21] IQVIA 2017. CAGR in volume (2013-2017) : +5%
[22] IQVIA 2017
[23] IQVIA Q3 2017, excluding Bahrain, Qatar and Oman
[24] IQVIA Q3 2017

55% of the sales volume[25].

Sterile Injectables

In May 2018, Mithra announced it had closed a contract with Midas Pharma for the development of a sterile injectable product at Mithra's CDMO in Belgium.

3. Mithra CDMO

- Mithra CDMO, Mithra's Research, Development and Manufacturing Platform strengthened its environmental policy in 2018 with the creation of an internal committee aiming to implement various measures to reduce its environmental footprint. With the installation of 1800 solar panels, the Mithra CDMO is aiming to secure approximately 50% of its electricity consumption through a renewable energy source. This green source allows Mithra to reduce its carbon footprint and reduce a major cost driver. Opened in 2016, Mithra's technological platform incorporates strict environmental considerations in terms of air treatment, containment measures, modern solutions for energy monitoring and choice of reusable consumables.
- In December 2018, Mithra CDMO acquired new manufacturing equipment to triple its production capacity. The upgraded equipment will be used to sustain commercial demand thanks to commercial agreements and expected market increase.
- Post-period end, Mithra CDMO started the commercial manufacturing process of the vaginal contraceptive ring Myring™ with a first batch for the European market (Czech Republic). The Mithra CDMO development and production center plans to start manufacturing further commercial batches for the European market (Austria, Denmark, Belgium, Luxembourg and the Netherlands) in the second half of 2019, as scheduled.
- Post-period end, Mithra announced it signed a contract with CEVA Animal Health, leading global veterinary pharmaceutical group. With this first veterinarian project in development, Mithra will develop a hormonal device for the fertility market. This new polymer-based device would be a real innovation and bring an additional competitive edge to our partner while expanding Mithra's polymer based technology expertise

4. Belgium and Luxembourg Business

In July 2018, Mithra announced that it had signed a comprehensive partnership in Belgium and Luxembourg worth up to EUR 40 million with Ceres Pharma, a Belgian-based company focused on over-the-counter (OTC) and specialist healthcare. The agreement covers the sale of the women's health branded generics business in Belgium and Luxembourg as well as non-exclusive license and supply agreements for a number of Mithra's products and product candidates developed in-house, including licenses for the commercialization in Belgium and Luxembourg of Tibelia®, Myring™ and Estelle®.

For Mithra, the sale of the branded generics business realized the value of the divestment of a non-core asset, as the Company continues to become an innovative biopharma company fully-focused on its innovative E4 based asset portfolio and its Complex Therapeutics development know-how.

[25] IQVIA Q3 2015

Following the successful private placement in May 2018, the cash inflow realized through the agreement with Ceres Pharma will further strengthen Mithra's financial position and investments in its potential blockbusters.

5. Outlook

Building on the progress made in 2018, Mithra is looking forward to continued progress in 2019, which will further strengthen its position as a leading innovative international Women's Health company.

Following the positive top-line Phase III results for Estelle® in Europe/Russia and U.S./Canada, Mithra is entering the final stages of clinical development for its oral combined contraceptive candidate and intends to file for market authorization in Europe and the U.S. by the end of 2019. Mithra will also continue its partnering discussions for the exclusive license and commercialization rights in the U.S., as well as in other key international markets.

Mithra will also continue to prepare for Phase III studies of Donesta® and PeriNesta™, its second and third potential blockbuster candidates, which could begin in H2 2019. 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 both trials and complete the 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.

Mithra also continues to explore further additional indications for E4, in particular in pediatric neuroprotection, to treat hypoxic ischemic encephalopathy (HIE).

The Mithra CDMO in Belgium will reinforce the Company's R&D and commercial production activities. With state-of-the-art equipment and know how, the company is preparing to triple its production capacity to deliver the next commercial batches of Mithra's vaginal ring Myring™ during H2 2019. Mithra also anticipates that its U.S.-partner Mayne Pharma should receive FDA approval for the commercialization of Myring™ in the U.S. from 2020. In terms of R&D, Mithra will launch pivotal studies for Zoreline® in 2019 as well as undertake additional research projects.

In 2019 and beyond, we expect further significant revenue growth based on the potential for further E4 partnerships in the U.S. and other international markets.

FINANCIAL RESULTS

1. Consolidated income statement

GROUP TOTAL

	Year ended 31 December	
Thousands of Euro	***2018***	***2017***
Revenues	65,465	46,252
Gross Profit	60,211	37,158
Operating Profit / (Loss)	35,457	(21,081)
Financial income	237	377
Change in fair value[26]	(46,550)	(25,455)
Cost of debt	(5,375)	(267)
Financial result	**(51,689)**	**(25,345)**
Profit / (Loss) before taxes	(16,232)	(46,426)
Income taxes	3,869	11,421
Net Profit / (Loss) for the year	(12,363)	(35,006)
Attributable to		
Owners of the parent	(12,363)	(35,006)
Non-controlling interest	-	-

CONTINUING OPERATIONS

	Year ended 31 December	
Thousands of Euro (€)	*2018*	*2017*
Revenues	57,876	32,042
Cost of sales	(1,571)	(2,595)
Gross profit	**56,306**	**29,447**
Research and development expenses	(35,713)	(48,185)
General and administrative expenses	(8,979)	(8,697)
Selling expenses	(1,977)	(1,734)
Other operating income	4,552	3,007
Total operating expenses	(42,118)	(55,609)
Operating profit / (loss)	**14,188**	**(26,162)**
Financial income	237	377
Change in fair value[27]	(46,550)	(25,455)
Cost of debt	(5,365)	(267)
Financial result	**(51,679)**	**(25,345)**
Loss before taxes	**(37,491)**	**(51,507)**
Income taxes	9,885	13,148
Net loss of the year	**(27,606)**	**(38,360)**

[26] Fair values are computed on the contingent considerations payables which are reported under Other financial loans
[27] Refer to footnote 26

DISCONTINUED OPERATIONS

	Year ended 31 December	
Thousands of Euro	*2018*	*2017*
Revenues	7,589	14,211
Cost of sales	(3,684)	(6,499)
Gross profit	**3,905**	**7,711**
Selling expenses	(1,989)	(2,961)
Other operating income	876	330
Gain on sale of disposal	18,477	-
Total operating expenses	**17,363**	**(2,630)**
Operating Profit / (Loss)	**21,269**	**5,081**
Financial result	**(10)**	**-**
Profit / (Loss) before taxes	**21,258**	**5,081**
Income taxes	**(6,016)**	**(1,727)**
Net Profit / (Loss) for the period	**15,242**	**3,354**

2. Consolidated Statement of financial position

	As at 31 December	
Thousands of Euro (€)	**2018**	**2017**
ASSETS		
Property, plant and equipment	84,396	59,519
Goodwill	5,233	5,233
Other Intangible assets	81,907	80,385
Deferred income tax assets	27,045	22,718
Other non-current assets	3,435	2,644
Non-current assets	**202,017**	**170,500**
Inventories	10,945	4,141
Trade & other receivables	23,773	33,881
Cash & cash equivalents	118,949	36,190
Current assets	**153,667**	**74,212**
TOTAL ASSETS	**355,684**	**244,712**

	As at 31 December	
Thousands of Euro (€)	**2018**	**2017**
EQUITY AND LIABILITIES		
Equity		
Share capital	26,925	25,036
Share premium	221,587	148,279
Retained earnings	(97,557)	(86,374)
Translation differences	(62)	(59)
Equity attributable to equity holders	**150,893**	**86,882**
Subordinated loans	14,222	11,158
Bank borrowings	52,702	37,578
Refundable government advances	10,252	7,785
Other financial liabilities	89,066	46,727
Provisions	266	266
Deferred tax liabilities	2,202	2,099
Non-current liabilities	**168,710**	**105,612**
Current portion of financial loan	172	167
Short term financial debts	20,081	16,070
Trade payables and other current liabilities	14,624	24,174
Corporate tax payable	335	(4)
Accrued charges & Deferred income	868	11,811
Current liabilities	**36,082**	**52,217**
TOTAL EQUITY AND LIABILITIES	**355,684**	**244,712**

3. Consolidated statement of cash flows

GROUP TOTAL (INCLUDING DISCONTINUED OPERATIONS)

	Year ended 31 December	
Thousands of Euro (€)	*2018*	*2017*
Cash Flow from operating activities		
Operating result	**35,457**	**(21,081)**
Depreciation and amortisation	2,851	2,156
Gain on disposal of asset	(18,477)	-
Tax credit	(739)	(2,406)
Share based payments	1,181	1,021
Taxes paid	-	(85)
Subtotal	**20,273**	**(20,395)**
Changes in working capital		
Increase/(decrease) in Trade payables and other current liabilities	(9,050)	8,493
(Increase)/decrease in Trade receivables and other receivables	10,108	(25,925)
(Increase)/ decrease in Inventories	(7,604)	29
Increase/(decrease) in deferred revenue and others	(10,185)	6,739
Net cash provided by/ (used in) operating activities	**3,542**	**(31,061)**
Cash Flow from investing activities		
Payment for acquisition of tangible fixed assets	(10,009)	(14,803)
Payment for acquisition of intangible fixed assets	(90)	(1,255)
Disposal of assets	19,353	312
Contingent liabilities payments	(3,690)	-
Net cash provided by/ (used in) investing activities	**5,564**	**(15,746)**
Cash Flow from financing activities		
Payments on financial loan & government advances	(1,365)	(574)
Proceeds from financial loan & government advances	3,282	11,204
Interest paid	(3,460)	(1,271)
Proceeds from issuance of shares (net of issue costs)	75,196	27,887
Net cash provided by/ (used in) financing activities	**73,653**	**37,246**
Net increase/(decrease) in cash and cash equivalents	**82,760**	**(9,561)**
Cash & cash equivalents at beginning of the year	36,190	45,750
Cash & cash equivalents at end of the year	**118,949**	**36,190**

DISCONTINUED OPERATIONS

	Year ended 31 December	
Thousands of Euro	*2018*	*2017*
Cash flow from operating activities	2,791	5,081
Cash flow from investing activities	18,477	-
Cash flow from financing activities	-	-
Cash flow from discontinued operations	**21,269**	**5,081**

Profit and Loss

- Net sales encompass revenue recognized resulting from transferring control of products sold to customers. In addition, during the year, the Group has entered into a number of contracts through which it has out-licensed to customers the IP it developed related to drugs that have not yet received regulatory approval. Revenue recognized during the year under these arrangements include: upfront fees when the license is distinct from other performance obligations in the contract, if any, as the license provides the customer the right to use the IP as it then exists; and milestone payments for specific clinical or other development-based outcomes when the Group's related performance obligation has been satisfied and management has determined that it is highly probable that there will not be a significant reversal of cumulative revenue recognized in future periods.
- Mithra's revenues increased 42% from EUR 46.3 million to EUR 65.5 million. The main reasons for the increase in out-licensing revenue were the Estelle® deals with Gedeon Richter for EUR 40 million, Ceres Pharma for EUR 1.4 million (for the out-licensing part of the deal), Adcock Ingram for EUR 0.7 million, and Searchlight Pharma for EUR 1 million. Additional milestones related to licensing agreements already signed during previous years for which recognition was deferred at the prior year-end have been also recognized, including EUR 6.75 million from Fuji Pharma and EUR 5 million from Libbs. In total, and including additional smaller deals and product sales revenue from discontinued operations, Mithra recognized EUR 56.3 million revenue from licensing agreements in 2018, compared to EUR 29.4 million in 2017. Additional payments were received related to licensing agreements for which revenue recognition was deferred to future periods (refer to Statement of financial position section below). With regard to the Belux business, which was sold to Ceres in July 2018, Mithra's revenues were EUR 7.6 million in 2018, compared to 14 million in 2017. These revenues have been recognized over 7 months. Since August 2018, Mithra is considered an Agent, so that sales have been netted with COGS. Indeed, Mithra is still selling some products on behalf of Ceres during a transition period, until all market authorizations will be formally transferred.
- Gross profit for 2018 at Group level increased by EUR 23 million to EUR 60.2 million in 2018 from EUR 37.2 million in 2017. The increase of 62% is due to the increase of licensing agreement deals referred to above. The gross margin on the Belux business was EUR 3.9 million in 2018 (7 months as principal and 5 months as agent without gross margin), compared to EUR 7.7 million in 2017 (12 months as principal).
- R&D expenses decreased by EUR 12.5 million from EUR 48.2 million in 2017 to EUR 35.7 million in 2018. This is mainly related to the end of Phase III of Estelle® (EUR 12.7 million in 2018 compared to EUR 23.7 million in 2017) and the Phase II of Donesta® (EUR 2.8 million in 2018 compared to EUR 5.5 million in 2017). R&D expenses for Myring™, Zoreline® and Tibelia® amounted to EUR 1.7 million. The remainder of the R&D expenses relate to payroll and consultancy expenses, and more specifically to expenses at the level of the CDMO facility in Belgium.
- G&A expenses are well controlled and have slightly increased to EUR 9 million in 2018 from EUR 8.7 million in 2017, on a consolidated basis.
- Selling expenses have decreased in 2018, mainly due to the disposal of the Belux operations to Ceres. As a result, selling expenses came to EUR 3.9 million at 31 December 2018, down from EUR 4.7 million, on a consolidated basis.

- In the discontinued income statement at operating income level, a realized gain on the sale of the Belux business to Ceres of EUR 18.5 million has been booked, since the Belux Business is no longer part of the operational business of Mithra.
- EBITDA[28] amounts EUR 38.3 million in 2018 compared to EUR -18.4 million in 2017 (refer to section Alternative performance measure).
- The net financial result for 2018 amounts to EUR -51.7 million and is driven by changes in the fair value of contingent liabilities (earn outs) for EUR -46.6 million and by changes in amortized costs of refundable government advances for EUR -2.2 million (reported in the consolidated income statement under Cost of debt), which are non-cash elements. Regarding the contingent liabilities, this reflects management's higher estimate for future sales revenues, including the new estimate about the generic market development. The remaining part of the Cost of debt is related to the interests paid for EUR -3.2 million.
- With the fair value impact over 2018 of EUR 46.6 million, the Group ends with a loss before taxes for the period amounting to EUR 16.2 million, which thanks to the strong increase of EBITDA is a significant improvement of EUR 30.2 million compared to a loss before taxes of EUR 46.4 million in 2017, on a consolidated basis.
- The Group recorded a tax income of EUR 3.9 million for the year that results from an increase of the deferred tax asset from the prior year-end which is to be offset against taxable income in the future. Taking this tax income into consideration, the net loss for 2018 was EUR 12.4 million (loss of EUR 35 million for 2017), on a consolidated basis.

Statement of Financial position

- As of 31 December 2018, the Statement of financial position shows a total of EUR 202 million in non-current assets, the majority of which are Other intangible assets (EUR 81.9 million) and Property, plant and equipment (EUR 84.4 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 2018, EUR 1.5 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.
- In the non-current assets, the Group recorded EUR 24.9 million additional net book value of tangible fixed assets (EUR 84.4 million at the end of 2018 vs. EUR 59.5 million in 2017). 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 2018, EUR 6.6 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™.

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

- Current assets at the end of 2018 represent a value of EUR 153.7 million. The cash position accounts for EUR 119 million of cash and cash equivalents on 31 December 2018 and Trade & other receivables for EUR 23.7 million.

  The Trade & other receivables balance takes into account unbilled revenue for EUR 15.3 million related to out-licensing revenue, among which EUR 5 million milestones related to Gedeon Richter, EUR 7.6 million related to Mayne Pharma and EUR 2.3 million milestones related to Fuji Pharma. Finally, Trade & other receivables comprises EUR 1.6 million of recoverable VAT that relates to the recognition of tangible fixed assets by Mithra CDMO.

  Inventories have significantly increased from EUR 4.1 million in 2017 to EUR 10.9 million in 2018. It is mainly explained by the increase of API stock from EUR 1 million in 2017 to EUR 7.4 million in 2018 which has been constituted in order to be ready for the production of Myring™.

  The cash & cash equivalents balance mainly increased thanks to the EUR 77.5 million gross proceeds of the capital increase by means of private placement and to the many out-licensing contracts signed during 2018.

- The equity position at the end of the year has increased to EUR 150.9 million in 2018 from EUR 86.9 million in 2017. The increase is the net result of EUR 77.5 million in gross proceeds by means of a private placement as well as the net result of the period.

- Non-current liabilities increased to EUR 168.7 million at the end of 2018, compared to EUR 105.6 million in 2017, primarily due to the leases (EUR +14 million) and Subordinated financing (EUR + 3 million) for the CDMO facility, as well as due to an increase of the fair values of the contingent considerations payables (EUR + 42.4 million) which are reported under Other financial liabilities.

- The current liabilities decreased to EUR 36 million at the end of 2018, compared to EUR 52.2 million in 2017. The decrease of the current liabilities is the net result of a decrease in the Trade payables and other current liabilities (EUR -9.5 million), in the Accrued charges & deferred income (EUR -10.9 million) and an increase of the short term financial debts which includes the current portion of the contingent considerations.

  The decrease of the Trade payables is closely related to the reduction of R&D expenses.

  The decrease in Deferred income is the result of the recognition of the following revenues in 2018 : Estelle® deal with Libbs for EUR 5 million and Estelle® deal with FUJI for EUR 5.5 million.

Cash Flow

Full year cash flow of the group amounted to EUR +82.8 million including cash flows from discontinued operations for EUR +21.3 million, which is comprised of:

- *Operating cash flow*: The cash used for operating activities amounts to EUR +3.5 million for the full year 2018, including cash flows from discontinued operations (EUR + 2.8 million). The EBIT of EUR +35.5 million has been adjusted for the non-cash items amounting in net to EUR +3.3 million.

  In order to report the gain on sale of disposal for EUR 18.5 million (refer to discontinued operations cash flow) under *net cash provided by investing activities*, as it is a cash item, we remove it from the EBIT in operating activities.

  Working capital is also impacting the cash used for operating activities as a result of a decrease in Trade & other receivables (EUR -10.1 million), in Trade & other Payables

(EUR -9 million) and in Deferred revenue (EUR -10.2 million). The global decrease is partially offset by an increase of inventories (EUR +7.6 million).

- *Investing cash flows*: EUR +5.6 million. Disposal of assets for EUR 19.4 million relates mainly to the gain on sale of disposal reported in the cash flows from discontinued operations for EUR 18.5 million (see above). The purchase of tangible assets relates predominately to property, plant & equipment acquired at the Mithra CDMO facility (EUR 1.9 million) self-financed with the Group treasury (excluding lease financed assets) and to development costs capitalization (EUR 8 million). Indeed, the assets financed by a leasing are netted together. It reports also contingent liabilities payments (EUR 3.7 million).
- *Financing cash flows*: EUR +73.7 million relates entirely to cash flows from continuing operations. Proceeds from financing refer to subordinated loans granted to Mithra CDMO to launch phase 2 of the construction. Proceeds from issuance of shares refer to the net amount (gross amount less transaction costs) of a capital increase by means of a private placement of EUR 75.2 million closed on 31 May 2018, which strengthened Mithra's financial profile.

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 & amortisation 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 & amortisation from EBIT (operating loss) from the consolidated statement of income prepared in accordance with IFRS.

	Year ended 31 December	
Thousands of Euro (€)	*2018*	*2017*
Operational profit (from continuing activities)	**14,188**	**(26,534)**
Depreciation	2,851	2,655
Exceptional results	-	372
Share-based payments	1,181	1,020
REBITDA	**18,221**	**(22,487)**
Discontinued EBITDA	21,269	5,081
Share-based payments	(1,181)	(1,020)
EBITDA	**38,308**	**(18,426)**

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Financial Calendar

- 8 April 2019 : Annual Report 2018
- 16 May 2019 : Annual General Shareholders Meeting
- 19 September 2019 : Interim Report 2019

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® and next-generation hormone therapy Donesta® - are built on Mithra's unique native estrogen platform, E4 (Estetrol). Mithra also develops, manufactures and markets 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 Mr. 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.