



## MITHRA REPORTS 2017 ANNUAL RESULTS

- Significant operational progress for highly promising E4 (Esetrol)-based pipeline, including 5<sup>th</sup> generation oral contraceptive Estelle<sup>®</sup> and next-generation menopause therapy Donesta<sup>®</sup>
- Important commercialization partnerships established with leaders in Women's Health, including Libbs for Estelle<sup>®</sup> in Brazil, Fuji Pharma for Donesta<sup>®</sup> in Japan & ASEAN and Mayne Pharma for Myring<sup>™</sup> in the US
- Strong revenue increase and improved EBIT thanks to accelerating business development activity and solid Benelux operations

Liège, Belgium, 2 March 2018 – 7:45 AM : Mithra Pharmaceuticals (Euronext Brussels: MITRA), a company focused on Women's Health, today announces its results for the year ended 31 December 2017, prepared in accordance with IFRS.

### KEY HIGHLIGHTS

- **Operational & Corporate Highlights (including post-period end)**
  - Phase III Estelle<sup>®</sup> oral contraceptive studies, *E4Freedom*, progressing well, with recruitment completed in the EU/Russia and US/Canada Phase III pivotal studies. Top-line results for Mithra's novel contraceptive product candidate are still expected in Q3 2018 (EU/Russia) and Q1 2019 (US/Canada)
  - Phase II study of Donesta<sup>®</sup> for menopausal symptoms, *E4Relief*, completed, with top-line results expected towards the end of Q1 2018/early Q2 2018
  - E4 partnership contracts signed with Libbs for Estelle<sup>®</sup> in Brazil and with Fuji Pharma for Donesta<sup>®</sup> in Japan and ASEAN
  - Post-period, very promising hemostasis results obtained, pointing to favourable safety profile of Estelle<sup>®</sup>
  - Commercialization agreements signed for Myring<sup>™</sup>, Mithra's vaginal contraceptive ring, with Mayne Pharma (US), Gynial (Austria) and Adamed (Czech Republic)
  - Myring<sup>™</sup> on track for regulatory approval in EU in Q2/Q3 2018, with launch shortly thereafter; launch in the US by Mithra's partner Mayne Pharma planned for H1 2019
  - Mithra's CDMO<sup>1</sup> ramping up its R&D activity and product supply; GMP approval for manufacturing of Myring<sup>™</sup> in Europe obtained and first contract signed for injectables section with GSP
- **Financial Highlights**
  - Revenues increased by over 100% to EUR 46.3 million (from EUR 22.5 million in 2016), mainly due to the licensing revenue recognized for partnership agreements with leaders in Women's Health

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<sup>1</sup> Contract Development and Manufacturing Organization

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- R&D expenditures came in below budget and rose to EUR 48.2 million (from EUR 34.3 million in 2016), reflecting targeted investment in the Phase III Estelle<sup>®</sup> and Phase II Donesta<sup>®</sup> programs as well as the activity ramp up at the Mithra CDMO
- Selling expenses amounted to EUR 4.7 million, compared to EUR 7.6 million in 2016. The significant decrease is mainly driven by reduced commercial operations in France and Germany, and the sale of Mithra's French subsidiary in December 2017
- As a result, REBITDA significantly improved to EUR -18.1 million in 2017 compared to EUR -34.9 million in 2016
- Cash at December 31 2017 was EUR 36.2 million (EUR 45.7 million in 2016); cash position strengthened by oversubscribed private placement of EUR 26.1 million in June 2017

**Commenting on the 2017 results, François Fornieri, CEO, said:**

*“2017 has been a crucial year for Mithra during which we made substantial progress on our key clinical programs. This includes the pivotal Phase III trials of our innovative 5<sup>th</sup> generation oral contraceptive, Estelle<sup>®</sup>, which is designed to overcome both the safety and convenience concerns of current oral contraceptives. The recently published hemostasis safety study reinforced our confidence in the unique potential of Estelle<sup>®</sup> compared with existing products, and we look forward to top line results from the EU/Russia study expected in Q3 2018, and the US/Canada results expected to follow in Q1 2019. The Phase II study of Donesta<sup>®</sup>, our novel candidate for menopausal symptoms, also yields top line results towards the end of Q1/early Q2. In Complex Therapeutics, Myring<sup>™</sup> is expected to receive marketing approval in Europe in Q2/Q3 2018, with launch shortly thereafter, and our partner Mayne Pharma plans a US launch in H1 2019. As Myring<sup>™</sup> will be manufactured at our CDMO, this product is expected to be an important revenue driver going forward.*

*In 2017, business development activity accelerated significantly, marked by important commercialization contracts, including Libbs for Estelle<sup>®</sup> in Brazil, Fuji Pharma for Donesta<sup>®</sup> in Japan and Mayne Pharma for Myring<sup>™</sup> in the US. The agreements clearly underline Mithra's attractiveness for collaborations as well as the confidence of international specialist partners in our transformational product candidates and in the expertise of Mithra's CDMO.*

*Our revenues benefited from the down payments and milestones from our strategic partnerships, increasing over 100% in 2017 versus 2016 to EUR 46.3 million, while REBITDA also improved strongly to EUR -18.1 million. In 2018 and beyond, we expect further significant revenue growth based on the potential for E4 partnerships in the core territories of the US and EU. Furthermore, as the production of our different products accelerates, we also expect growth in recurring revenues at the CDMO.*

*We look forward to building on the progress made to date, with important read-outs for both the Donesta<sup>®</sup> and Estelle<sup>®</sup> clinical trials during 2018 and the addition of commercial partners for our portfolio in new territories. We are confident that with Donesta<sup>®</sup> and Estelle<sup>®</sup>, we have two potential blockbusters in our pipeline that position Mithra for long-term international growth as a transformational leader in Women's Health.”*

## OPERATIONAL OVERVIEW

### Clinical Developments

#### Clinical Development in Contraception: Estelle®

- Phase III studies in the US & Canada as well as in Europe & Russia for lead compound, Estelle®, Mithra's combined oral contraceptive (COC) candidate composed of 15mg of E4 (Esetrol) and 3mg of DRSP (drospirenone) are advancing well, with recruitment finalized in both the EU/Russia and the US/Canada. The Phase III Estelle® studies are on track to report top-line results between Q3 2018 (EU/Russia) and Q1 2019 (US/Canada).
- The Phase III studies are open-label single arm trials to assess the safety and efficacy of Estelle® in approximately 1,550 participants in Europe/Russia, and 2,000 participants in the US and Canada, over a period of 13 cycles.
- As per regulatory requirements, Mithra also conducted a Phase I study evaluating the effect of single, multiple and suprathreshold oral doses of E4/DRSP combinations (up to 5 times the therapeutic dose) on safety, tolerability and pharmacokinetic (PK) parameters, showing a good tolerability of all combinations, thus completing the PK data package. This study also included a QT assessment indicating a satisfactory safety profile for the QT interval.
- In May, Mithra initiated a PK ethnobridging study in order to determine the PK profile of Estelle® in Japanese and Caucasian subjects. The full results of the study, which forms part of the Estelle® studies with partner Fuji Pharma for the Japanese and ASEAN markets, are expected in the course of Q1 2018.
- In August, Mithra finalized recruitment for the Estelle® population PK substudy, which aims to determine the impact of demographic parameters (such as BMI, race and smoking) on the absorption, distribution and excretion of Estelle®. This study, which is part of the Estelle® Phase III program in the US/Canada, will also report top line results in Q1 2019, and can further delineate the unique profile of Estelle® in contraception.
- Post-period, Mithra published very promising top-line results for its hemostasis Phase II study. This substudy, which runs in parallel with the ongoing Phase III studies for Estelle®, analyzes a series of hemostatic, endocrine and metabolic parameters. Data are analyzed for 100 women divided over three treatment groups: 15 mg E4/3 mg DRSP (Estelle®), 30 mcg LNG (Melleva®) and EE/3 mg DRSP (Yaz®). Given the importance of these parameters to help determine the venous thromboembolism (VTE) risk profile of a (combined) oral contraceptive, the results are closely studied by the regulatory bodies and keenly awaited by clinicians and (potential) commercialization partners for Estelle®. Detailed results will be available in coming weeks, and presented at scientific conferences, including ISGE on March 8, 2018.

#### Clinical Development in Menopause: Donesta®

- Donesta®, the Company's next-generation hormone therapy (HT) with oral administration of E4, entered into a Phase II dose-ranging study in Europe in May 2016. Post-period, in January 2018, Mithra announced that over 200 patients in Czech Republic, Poland, Belgium,

the Netherlands and the UK have completed at least 12 weeks of treatment, allowing Mithra to confirm the time line towards top-line results at the end of Q1/early Q2 2018.

- The main objective of the Phase II clinical trial is to identify the minimum dose required to effectively treat vasomotor menopausal symptoms (VMS), or hot flashes. In total five doses are tested in this blinded study, including placebo.
- In addition to assessing the effect of E4 on the reduction of the number and severity of hot flashes, the protocol evaluates a series of important secondary parameters, including vulvo-vaginal atrophy improvement (VVA), bone metrics and patient satisfaction (well-being). Moreover, the study will provide a detailed understanding of key safety issues including the E4 coagulation profile and lipid and glucose metabolism.
- The global menopause market currently stands at USD 8.6 billion and is expected to grow to approximately USD 16 billion by 2025, driven by growing awareness for Women's Health issues, the unmet medical need in menopause and the aging population, in addition to market expansion with the availability of new treatment options that provide a safer alternative to currently available therapies<sup>2</sup>.
- Given the important market opportunity, Mithra is well-positioned for partnering discussions following the Phase II results of Donesta<sup>®</sup>. Pending the results and in order to maximize the global potential of Donesta<sup>®</sup>, the Board of Directors considers several options for the further Phase III development of Donesta<sup>®</sup>.
- Mithra plans another Donesta<sup>®</sup> KOL (Key Opinion Leaders) Board meeting in April 2018 to fully assess the Donesta<sup>®</sup> Phase IIb results with leading experts in the field.

#### **Clinical Development of Myring™:**

- In January 2017 and November 2017, Mithra announced the results of two bioequivalence studies for Myring™, Mithra's combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA). The excellent results (re)confirm that Myring™ is bioequivalent to the branded version NuvaRing<sup>®</sup> (Merck).
- In May 2017, Mithra received European Good Manufacturing Approval (GMP) for the production line of Myring™ at the Mithra CDMO, allowing Mithra to file for marketing approval with the European agencies in July 2017. Myring™ is on track to receive European marketing approval in Q2/Q3 2018.
- Mithra's US partner Mayne Pharma is working on the FDA approval of Myring™, and aims to launch the product in H1 2019.

#### **Clinical Development of Tibelia<sup>®</sup>:**

- In November 2017, Mithra confirmed the extended shelf-life of 36 months of its complex therapeutic product Tibelia<sup>®</sup>, as compared to 24 months for other currently available tibolone-based products, including originator product Livial<sup>®</sup> (Merck). The extended shelf-life is a further validation of Mithra's expertise in developing Complex Therapeutics, and offers a competitive advantage to distributors and patients.

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<sup>2</sup> Transparency Market Research 2017; Datamonitor 2014

### Clinical Development of Zoreline®:

- Post-period, Mithra obtained positive top-line results for its 1-month PK/PD pilot study for Zoreline®, Mithra's product candidate for branded Zoladex® (AstraZeneca). Zoladex® is a biodegradable, injectable luteinizing hormone-releasing agonist, used to treat prostate cancer, breast cancer and benign gynecological disorders. The product exists as a 1- and a 3-month implant, containing 3.6 mg and 10.8 mg of goserelin, respectively.
- The Zoreline® PK study demonstrates the safety profile of the 1-month (3.6mg) implant as compared to Zoladex®, with results in line with regulatory requirements. Furthermore, the data collected in 58 patients also provide important information on the similar PD activity (efficacy) of the 1-month treatment in Zoladex® and Zoreline®.
- Mithra continues to work on the reformulation of the 3-month implant, with PK results expected in H2 2018, and is currently evaluating further development steps. Pending positive results for the 3-month product candidate, Mithra could move into a pivotal clinical PD study for both the 1- and 3-month formulation.
- Supported by the positive 1-month results, Mithra remains committed to finding a partner to co-develop and commercialize Zoreline®, in line with the Company's strategy to partner with leaders in Women's Health for its different product candidates.

### Preclinical development - Neuroprotection:

- In June, Mithra received Orphan Drug Designation (ODD) from EMA for E4 in neonatal encephalopathy (NE), based on the promising preclinical results obtained. The company intends to develop E4 to treat hypoxic ischemic encephalopathy (HIE), a serious and prevalent syndrome under the umbrella of NE causing significant mortality and morbidity in infants. HIE is a condition affecting approximately 30,000 new-borns each year in the European Union and the U.S<sup>3</sup>, and is a consequence of the reduction in the supply of blood or oxygen to the baby's brain before, during or shortly after birth. With approximately 25% of infants dying prior to discharge from the neonatal intensive care unit, HIE remains an important unmet medical need.
- Importantly, the results also highlight the potential of E4 to address additional indications, including pathologies beyond Women's Health.

### E4 (Esetrol): Patents & Publications update

- In January 2017, the US Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent covering the use of E4 as an emergency contraceptive. The patent specifically covers E4 as a potential new emergency contraception option when used alone. This new method differs from currently approved emergency contraceptives, which includes progestin only pills and combined estrogen-progestin pills. In December 2017, the same patent was granted in Eurasia.

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<sup>3</sup> Kurinczuk et al. Early Hum Dev 2010; 86: 329-338, 2010

- Mithra also strengthened its patent position in Australia, with a patent granted to protect E4's synthesis process until 2032 and a certificate of grant covering E4's use alone as emergency contraceptive.
- In June 2017, Mithra acquired the rights on an E4 patent for use in the treatment of HIE, for which an ODD was obtained from the European agency for development for neonatal encephalopathy. The patent is granted in several geographies, including Europe and the US.
- Mithra published its Phase IIb Estelle® data on well-being and body weight in the leading peer-reviewed journal *Contraception*<sup>4</sup>. The article reports on Estelle®'s high acceptability, user satisfaction and general well-being, in addition to favourable body weight control. These elements are key for user compliance and continuation, and hence of great importance for the eventual commercial success of Estelle®.

### Mithra CDMO

- In May, the Mithra CDMO received European Good Manufacturing Approval (GMP) for the production line of Myring™. Thanks to the successful tech transfer and excellent results of the bioequivalence studies performed, the CDMO is set to produce Myring™ following regulatory approval in the EU and the US. In the EU, approval is possible in Q2/Q3 2018, with launch shortly thereafter, and US-partner Mayne Pharma aims to launch Myring™ in the US in H1 2019. With regard to the competitive landscape in the US, Myring™ should be well-positioned with a launch in the first half of 2019, which can be expected to have a positive effect on the volumes produced at the Mithra CDMO.
- The second and final phase of the CDMO construction is underway and on track to be completed in H1 2019 within the allocated budget (EUR 25.8 million). This second phase is dedicated to tablet manufacturing, and is supported by the Walloon region by a non-refundable investment grant.

### Business development

- In February 2017, Mithra granted an exclusive LSA to Mayne Pharma for the commercialization of Myring™ in the US. Mayne Pharma paid EUR 2.4 million upon signature, with further milestones of at least EUR 10 million following FDA approval. Currently, the US market for biocompatible contraceptive rings is worth USD 782.4 million<sup>5</sup>, which represents approximately 30% of the total global market by volume and 75% by value, making this a key territory for the commercialization of Myring™.
- Additional LSAs were signed for Myring™ with Gynial for Austria and with Adamed for the Czech Republic, underlining Mithra's know-how in polymer technology and its attractiveness to specialist players in Women's Health.
- Mithra will produce Myring™ at its CDMO, and as part of the long-term sourcing commitment of Mithra's partners, the Company already expanded its production capacity for Myring™.

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<sup>4</sup> <http://www.tandfonline.com/doi/full/10.1080/13625187.2017.1336532>

<sup>5</sup> IMS Health Q3 2017

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- In June, Mithra signed an exclusive LSA for the commercialization of Donesta® in Japan and ASEAN<sup>6</sup> with Fuji Pharma, the Japanese leader in Women's Health and Mithra's partner for Estelle® in these territories. The 20-year agreement is expected to generate low double-digit million development, regulatory and commercialization milestones. Mithra is also eligible for long-term supply revenues, as Donesta® will be produced at the Mithra CDMO. The Japanese and ASEAN HT market is still relatively small, valued at approximately EUR 48 million<sup>7</sup>. However, Fuji Pharma is fully committed to expanding the current market with Donesta®, given the potentially improved safety profile of E4 versus currently available HTs.
- Towards the end of 2017, Mithra also signed an important contract with the Brazilian leader in Women's Health, Libbs, for an exclusive 20-year commercialization license for Estelle® in Brazil. Mithra received a EUR 20 million down payment (50% of which is non-refundable), with EUR 14 million received upon signature of the contract and the remaining EUR 6 million payable in early 2018.

The contract also contains a manufacturing agreement enabling Libbs to produce Estelle® for the Brazilian market at its production facility in Sao Paulo (Brazil). Mithra will receive guaranteed annual recurring revenues based on minimum annual quantities (MAQ) and binding forecasts, and for sales exceeding these forecasts, a royalty rate of 40% on net sales will apply. Moreover, the contract includes a supply agreement for DRSP, giving Mithra an important alternative supply source for this key API. Libbs also plans to evaluate the possibility of supplying E4.

Over the duration of the contract, the agreement could generate several hundred million euros of revenues for Mithra.

- Mithra signed an exclusive agreement for Tibelia® in Canada with an undisclosed partner. The marketing authorization process with Health Canada is presently ongoing. Since Tibelia® would be the first tibolone-based Hormone Therapy product on the Canadian market, the product would be launched as a new treatment option. Currently, Tibelia® is on the market in the UK, Finland, Sweden, the Netherlands, Spain and Italy, with two additional launches planned in the course of 2018.
- In December, Mithra signed its first injectables contract for the Mithra CDMO with GSP, a leading player in generic healthcare products. The umbrella agreement comprises the development and production of four products. Importantly, since the products are designed to receive GMP accreditation, they should allow for European and US GMP approval of injectable section at the Mithra CDMO. This should open the door to additional injectables partnerships.
- Also in December, Mithra successfully disposed of its French affiliate. Product marketing authorizations were transferred to Laboratoire CCD, a French-based Women's Health player, while at the same time a share purchase agreement for Mithra France was concluded with Theramex, whereby Theramex will take over the subsidiary, including its pharmaceutical license. Financial details of the agreements were not disclosed. The sale of the French subsidiary fits into Mithra's strategy to maximize the value of its non-core assets, and to fully focus on the development and partnering of its key E4-based programs.

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<sup>6</sup> Association of Southeast Asian Nations : Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam

<sup>7</sup> IMS Health Q3 2017

## CORPORATE

- Christiane Malcorps (representative of P4MANAGEMENT BVBA), Global Head of Facility Excellence & Country Manager Belgium at Solvay, replaced Mr Philippe Suinen (permanent representative of P. Suinen SPRL) as a member of Mithra's remuneration committee. Mr. Suinen remains a member of Mithra's audit committee. Ms. Malcorps has been a member of Mithra's Board of Directors (Mithra SA) and a member of the Board of Mithra's CDMO since 2016.
- In February, Mithra announced the appointment of Christophe Maréchal as Chief Financial Officer. Before joining Mithra, Mr. Maréchal was Director, Group Treasury and Credit Risk Manager, at Hamon Group (Euronext Brussels: HAMO), an engineering and contracting company. He has more than 20 years of financial experience in the international industrial, telecommunications, manufacturing and banking industries, including M&A, operational and financial strategy, and tactical initiatives to drive long term business growth.
- Also in February, Michaël Dillen was appointed as Chief Legal Officer. Mr. Dillen has 10 years of experience in various legal positions, predominantly focused on the healthcare sector. Mr. Dillen started his career as a lawyer, where he developed a legal practice focused on corporate and commercial advice for private and institutional clients in the life sciences industry. Before joining Mithra in 2017 as Chief Legal Officer he worked for Terumo, a Japanese listed medical devices company. Here, he acted as senior counsel responsible for covering legal services in the EMEA region.
- Sofie Van Gijssel also joined Mithra in February 2017, when she was appointed Investor Relations Officer and Member of the Executive Team. Previously, Ms. Van Gijssel was Co-CEO of the New York branch of KBC Securities USA. In this role, Ms. Van Gijssel mainly focused on Institutional Equity Sales for the Benelux Biotech & Healthcare sector, including for corporate transactions such as IPOs and Private Placements.
- In June 2017, Mithra successfully raised EUR 26.1 million in an oversubscribed private placement. The operation received the strong continued support of existing shareholders as well as the interest of international and local specialist healthcare investors. The proceeds of the transaction strengthened Mithra's cash position, positioning the company well to deliver on the further development of the E4 programs and accelerate business development efforts.
- Triggered by the capital increase, the warrant plan initiated on March 2, 2015, was exercised. An additional 724,350 ordinary shares have been issued for an amount of EUR 2,478,594 as the result of the exercise of 439 subscription rights (warrants). As a result of the transaction, Mithra now has 34,967,081 outstanding shares carrying voting rights. The outstanding warrants remain exercisable as from 1 January 2019.
- Mithra was ranked 3rd in a regional survey organized by Randstad, the global leader in the human resources industry. The survey evaluates the attractiveness of companies established in the greater Liège area, and Mithra obtained top scores for "cutting edge technology" and "financial health". This regional ranking reflects Mithra's ability to continue to attract the best talent and skills needed to support its growth and development.

- Mithra was also nominated for the sustainable partnership awards organized by SHIFT ([www.sustainablepartnerships.be](http://www.sustainablepartnerships.be)) for the development of its interactive web platform dedicated to Women's Health and to the improvement of the interaction between Health Care Professionals & patients ([www.gynandco.info](http://www.gynandco.info)).

## Benelux Business

Mithra continued to demonstrate its position as a leading player in the Benelux women's health market, with a market share (in number of cycles) of more than 40% in Belgium and approximately 30% in the Netherlands for contraception products.

In July, Mithra further strengthened its market position by signing a contract with Procure for the exclusive distribution of Papilocare® in Belgium and Luxembourg. Papilocare® is a therapy for the prevention and treatment of Human Papillomavirus (HPV) dependent lesions, for which no treatment was previously available.

Towards the end of 2017, Mithra also launched Laclimella®, a novel hormonal treatment for menopausal symptoms composed of 1 mg estradiol valerate and 2 mg dienogest.

As of 2018, both products form part of Mithra's growing portfolio of higher-margin, specialized products in Women's Health, to complement Mithra's existing marketed branded generics and to leverage the existing commercial infrastructure.

FINANCIAL RESULTS

**Consolidated Income Statement**

<i>Thousands of Euro (€)</i>	Year ended 31 December	
	2017	2016
<b>CONSOLIDATED INCOME STATEMENT</b>		
<b>Revenues</b>	<b>46,252</b>	<b>22,468</b>
<b>Cost of sales</b>	<b>(9,095)</b>	<b>(9,029)</b>
<b>Gross profit</b>	<b>37,158</b>	<b>13,439</b>
Research and development expenses	(48,185)	(34,299)
General and administrative expenses	(8,697)	(8,226)
Selling expenses	(4,695)	(7,567)
Other operating income	3,338	677
<b>Total operating expenses</b>	<b>(58,239)</b>	<b>(49,414)</b>
<b>Operating profit / (loss)</b>	<b>(21,081)</b>	<b>(35,976)</b>
Financial income	377	165
Financial expense	(25,722)	(4,793)
<b>Financial result</b>	<b>(25,345)</b>	<b>(4,627)</b>
Share of (loss)/profit of associates and joint ventures accounted for using the equity method		(32)
<b>Loss before taxes</b>	<b>(46,426)</b>	<b>(40,635)</b>
<b>Income taxes</b>	<b>11,421</b>	<b>5,548</b>
<b>Net loss for the year</b>	<b>(35,006)</b>	<b>(35,087)</b>
<b>Attributable to</b>		
Owners of the parent	(35,006)	(35,087)
Non-controlling interest		
<b>Profit / (Loss) per share</b>		
Basic earnings per share (euro)	(1.37)	(1.13)
Diluted earnings per share (euro)	(1.37)	(1.13)

**IFRS Consolidated Statement of financial position**

<i>Thousands of Euro (€)</i>	As at 31 December	
	2017	2016
<b>ASSETS</b>		
Property, plant and equipment	59,519	16,961
Goodwill	5,233	5,233
Other Intangible assets	80,385	79,130
Investments in associates	0	165
Deferred income tax assets	22,718	12,193
Other non-current assets	2,644	1,139
<b>Non-current assets</b>	<b>170,500</b>	<b>114,820</b>
Inventories	4,141	4,170
Trade & other receivables	33,881	7,955
Other Short Term deposits	-	43,600
Cash & cash equivalents	36,190	2,150
<b>Current assets</b>	<b>74,212</b>	<b>57,876</b>
<b>TOTAL ASSETS</b>	<b>244,712</b>	<b>172,696</b>

<i>Thousands of Euro (€)</i>	As at 31 December	
	2017	2016
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
Share capital	25,036	22,613
Share premium	148,279	122,830
Retained earnings	(86,433)	(52,384)
Translation differences		(44)
<b>Equity attributable to equity holders</b>	<b>86,882</b>	<b>93,015</b>
Subordinated loans	11,158	6,431
Bank borrowings	37,578	1,061
Refundable government advances	7,785	8,255
Other loans	46,727	32,495
Provisions	266	266
Deferred tax liabilities	2,099	3,469
<b>Non-current liabilities</b>	<b>105,612</b>	<b>51,977</b>
Current portion of financial loan	167	945
Short term other financial liabilities	16,070	6,010
Trade payables and other current liabilities	24,174	15,682
Corporate tax payable	(4)	73
Accrued charges & Deferred revenue	11,811	4,995
<b>Current liabilities</b>	<b>52,217</b>	<b>27,705</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>244,712</b>	<b>172,696</b>

**Consolidated statement of cash flows**

<i>Thousands of Euro (€)</i>	Year ended 31 December	
	2017	2016
<b>Cash Flow from operating activities</b>		
<b>Operating result</b>	<b>(21,081)</b>	<b>(35,976)</b>
Depreciation, amortisation and impairment	2,156	1,050
Contingent liabilities payments	-	(1,264)
Development costs capitalization	(3,860)	-
Tax credit	(2,406)	-
Share based payments	1,020	728
Taxes paid	(85)	(1,096)
<b>Subtotal</b>	<b>(24,256)</b>	<b>(36,557)</b>
<b>Changes in working capital</b>		
Increase/ (decrease) in Trade payables and other current liabilities	8,493	11,689
(Increase) / decrease in Trade receivables and other receivables	(25,925)	1,543
(Increase) / decrease in Inventories	29	(1,374)
Increase/(decrease) in deferred revenue and others	6,739	23
<b>Net cash provided by/ (used in) operating activities</b>	<b>(34,921)</b>	<b>(24,676)</b>
<b>Cash Flow from investing activities</b>		
Business combinations	-	(8,500)
Payment for acquisition of tangible fixed assets	(45,434)	(13,795)
Proceeds from sale of tangible assets	-	36
Payment for acquisition of intangible fixed assets	(1,255)	(2,309)
Disposal of assets	312	-
Investment in other non-current assets	-	(6)
<b>Net cash provided by/ (used in) investing activities</b>	<b>(46,377)</b>	<b>(24,574)</b>
<b>Cash Flow from financing activities</b>		
Payments on financial loan	(574)	(17,148)
Proceeds from financial loan & government advances	45,695	15,628
Interest paid	(1,271)	(274)
Proceeds from issuance of shares (net of issue costs)	27,887	-
<b>Net cash provided by/ (used in) financing activities</b>	<b>71,738</b>	<b>(1,794)</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>-9,560</b>	<b>-51,044</b>
Cash & cash equivalents at beginning of the year	45,750	96,794
<b>Cash &amp; cash equivalents at end of the year</b>	<b>36,190</b>	<b>45,750</b>

**PROFIT AND LOSS**

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- While IFRS 15 is normally applicable for accounting periods beginning on or after 1 January 2018, management has early adopted the Standard for the preparation of the 2017 financial statements. The Group has conducted a detailed analysis of its contracts and concluded that adoption of IFRS 15 does not affect revenues that were reported for 2016 and the half year ended June 30, 2017. The Group has accordingly decided to apply retrospectively to each prior reporting period.
- Net sales encompass revenue recognized resulting from transferring control over 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, and 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 106% from EUR 22.5 million to EUR 46.3 million. The main reasons for the increase in revenue were the Donesta<sup>®</sup> deal with Japanese market leader Fuji Pharma for which EUR 4 million was recognized, the Estelle<sup>®</sup> deal with Libbs for EUR 15 million and the commercialization deal with Mayne Pharma for Myring<sup>™</sup> in the US for EUR 10 million. In total, and including additional smaller deals, Mithra recognized EUR 29.4 million in licensing agreements revenue in 2017, compared to EUR 5.5 million in 2016. 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 Benelux business, Mithra's revenues were EUR 16.8 million in 2017, virtually unchanged from 2016.
- Gross margin for 2017 increased by EUR 23.8 million from EUR 13.4 million in 2016 to EUR 37.2 million in 2017. The increase of 177% is due to the licensing agreement deals referred to above. As a reminder, the gross margin in 2016 reflected the Estelle<sup>®</sup> deal with Fuji Pharma (EUR 5.5 million of total gross margin of EUR 13.4 million). The gross margin on the Benelux business was EUR 7.7 million in 2017, compared to EUR 7.9 million in 2016.
- R&D expenses increased by EUR 13.9 million from EUR 34.3 million in 2016 to EUR 48.2 million in 2017. This is mainly related to the Phase III of Estelle<sup>®</sup> (EUR 23.7 million in 2017) and the Phase II of Donesta<sup>®</sup> (EUR 5.5 million in 2017), as well as API costs in E4 (EUR 1.5 million in 2017). R&D expenses for Myring<sup>™</sup>, Zoreline<sup>®</sup> and Tibelia<sup>®</sup> amounted to EUR 4.1 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.
- G&A expenses are well controlled and have slightly increased by 0.4 million from EUR 8.3 million in 2016 to EUR 8.7 million in 2017.

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- Selling expenses have significantly decreased in 2017, mainly driven by reduced commercial operations in France and Germany, and thanks to the sale of Mithra's French subsidiary in early December 2017. As a result, selling expenses came to EUR 4.7 million at 31 December 2017, down from EUR 7.6 million.
- Operating income at EUR 3.3 million is mainly the result of R&D investments that may allow the Group to benefit from tax credits.
- REBITDA comes out to EUR -18.1 million in 2017 compared to EUR -34.9 million in 2016. EBIT was EUR -21 million in 2017, compared to EUR -35.9 million in 2016.
- The financial loss for 2017 amounts to EUR 25.3 million and is driven by changes in the fair value of contingent liabilities (earn outs) payables and in the refundable government advances, which are non-cash elements. Regarding the contingent liabilities, this reflects the higher probability of success of our clinical trials and management's higher estimate for future sales revenues.
- Although the fair values impacts are significant over 2017, the loss for the period before taxes amounts to EUR 46.4 million, which is an increase of only EUR 5.8 million compared to 2016 thanks to a much better REBITDA in 2017 compared to 2016.
- The Group recorded a tax credit of EUR 11.4 million for the year. This is a deferred tax asset to be offset against future taxable income. Taking this tax credit into consideration, the net loss for 2017 was EUR 35 million (loss of EUR 35.1 million for 2016).

#### STATEMENT OF FINANCIAL POSITION

- As of 31 December 2017, the Statement of financial position sheets shows a total of EUR 170.5 million in non-current assets, the largest part of which are Other intangible assets (EUR 80.4 million). These Other intangible assets are the result of acquired assets as part of a business combination. Note that Donesta<sup>®</sup> qualifies as an asset deal, for EUR 8 million. The fair value mainly relates to Estelle<sup>®</sup> for an amount of EUR 30.6 million, to Zoreline<sup>®</sup> for an amount of EUR 24.4 million, and to Myring<sup>™</sup> for an amount of EUR 11.4 million. Other intangible assets consist mainly of a portfolio of acquired product rights and market access fees. Over 2017, EUR 1.6 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 42.6 million additional net book value of tangible fixed assets (EUR 59.5 million at the end of 2017 vs. EUR 16.9 million in 2016). The increase relates to the construction of the first phase of the new production facility for the manufacturing of pharmaceutical products (Mithra CDMO), where Mithra is preparing the production of Myring<sup>™</sup>.
- Current assets at the end of 2017 represent a value of EUR 74.2 million. The cash position accounts for EUR 36.2 million on 31 December 2017 and the Trade & other receivables for EUR 33.9 million. The Trade & other receivables section is significant because of a EUR 6 million milestone invoice to Libbs due and received in January 2018. Furthermore, EUR 4.9 million has been invoiced to GSP late December 2017 for

the Injectable contracts and milestone on the development of Zoreline. The Trade & other receivables includes also, in light of the IFRS 15, unbilled revenue accounted for EUR 10.1 million related to licensing revenue. Finally, the Trade & other receivables section comprises of EUR 5.3 million of recoverable VAT that relates to the recognition of tangible fixed assets by Mithra CDMO.

- The equity position at the end of the year has decreased from EUR 93.0 million in 2016 to EUR 86.9 million in 2017. The decrease is the net result of the loss booked in 2017 as well as the private placement and the warrant exercise.
- Non-current liabilities increased to EUR 105.6 million at the end of 2017, compared to EUR 52 million in 2016, primarily due to the leases (+EUR 34 million) and Subordinated financing (+EUR 4.7 million) for the CDMO facility, as well as an increase of the fair values of the contingent considerations payables (+EUR 14.2 million) which are reported under Other loans.
- The current liabilities increased to EUR 55.3 million at the end of 2017, compared to EUR 27.7 million in 2016. The increase reported under Short term Other financial liabilities is attributable to an increase of the fair values of some contingent considerations payable (+EUR 6.4 million) and refundable government advances (+EUR 0.5 million), as well as an increase of bank borrowings granted for the financing of the Mithra CDMO facility (+EUR 3.5 million). The increase of the current liabilities is also the result of an increase in the Trade payables and other current liabilities (+EUR 8.5 million) and in the Accrued charges & deferred income (+EUR 6.9 million). The increase in Deferred income is the result of the Estelle® deal with Libbs for which Mithra still had a EUR 6 million invoice in the trade receivables, EUR 1 million of which has been recognized as revenue (EUR 5 million deferred licensing agreements revenues), and EUR 4.9 million invoiced late December to GSP for the Injectable contracts and milestone on Zoreline development that have been fully deferred. The section Deferred income is also reporting an amount of EUR 3 million for an investment grant from the Walloon Region which appears as a reduction of the deferred income on the statement of financial position.

## CASH FLOW

Full year cash flow amounted to EUR -9.6 million, which is composed of:

- *Operating cash flow:* The cash used for operating activities amounts to EUR -34.9 million for the full year 2017. The EBIT of EUR -21.1 million has been adjusted for the non-cash items amounting in net to EUR 13.8 million. These non-cash items relate to depreciation, tax credits, share based payments and development costs capitalizations. Working capital is also impacting the cash used for operating activities amounts as a result of an increase in Trade & other receivables (EUR 25.9 million) which is partially offset by an increase of Trade & other Payables (EUR 8.5 million) and Deferred revenue (EUR 6.7 million).
- *Investing cash flows:* EUR -46.4 Million. The purchase of tangible assets relates predominately to property, plant & equipment acquired at the Mithra CDMO facility (EUR 45.7 million).
- *Financing cash flows:* EUR 71.7 million. Proceeds from financing primarily refer to the entering into force of the CDMO phase 1 leases (EUR 34 million) and drawdowns on

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straight loans facilities granted to Mithra CDMO. Proceeds from issuance of shares refer to the Private Placement of EUR 25.4 million closed on 23 June 2017, which strengthened Mithra's financial profile; and the issue of an additional 724,350 ordinary shares for an amount of EUR 2.5 million as a result of the exercise of 439 subscription rights (warrants).

## Outlook

Building on the progress made in 2017, Mithra is looking forward to substantial news flow in 2018. In early March, Mithra will present more details of its hemostasis study for Estelle<sup>®</sup>, including at the ISGE conference on March 8. The results will further delineate the unique safety profile of Mithra's contraceptive candidate when compared to currently available products. Towards the end of Q1/early Q2, top-line Phase II dose-finding results for Donesta<sup>®</sup>, Mithra's novel menopause product candidate, are expected. Furthermore, results of the first pivotal Estelle<sup>®</sup> study in the EU & Russia will be available in Q3 2018, with the US/Canada Phase III results to follow in Q1 2019. At the same time, Mithra continues its work on additional indications for E4, including in neuroprotection.

For Myring<sup>™</sup>, European approval can already be expected in Q2/Q3 2018, with Mayne Pharma making significant progress for the US approval and launch, which is expected in H1 2019.

In 2018, Mithra also expects to further accelerate its business development efforts for the E4 blockbuster candidates in the key geographies of EU and US as well as for the Complex Therapeutics, following important contracts signed with leaders in Women's Health in the course of 2017.

The company is confident that these developments, along with the accelerating activity at its innovative research, development and manufacturing facility in Liège (Mithra CDMO), will further solidify Mithra's position as a leading international player in Women's Health.

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**About Mithra**

Mithra (Euronext: MITRA) is dedicated to providing innovation and choice in women's health, with a particular focus on fertility, contraception and menopause. Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience. Its two lead development candidates - a fifth generation oral contraceptive, Estelle®, and a next generation hormone therapy, Donesta®- are built on Mithra's unique natural 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 Mithra CDMO. Mithra was founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. Dr. Jean-Michel Foidart and is headquartered in Liège, Belgium.

Further information can be found at: [www.mithra.com](http://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.*

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