Regulated information

MITHRA ANNOUNCES 2017 HALF YEAR RESULTS

Liège, Belgium, 21 September 2017 – Mithra (Euronext Brussels: MITRA), a company specialized in women's health, today announces its financial results for the six-month period ending 30 June 2017, prepared in accordance with IFRS. The full interim report is available on the website in the Investors section (investors.mithra.com).

Operational Highlights (including post-period end)

- Estelle® oral contraceptive Phase III program on track – recruitment completed in Europe/Russia, as well as recruitment for an additional safety study and the initiation of a PK ethnobridging study
- Recruitment in final stages for Donesta® Phase II menopause study; on track to report top-line results in Q1 2018
- European Orphan Drug Designation in neonatal encephalopathy underlines potential of E4 beyond women's health, including neuroprotection
- Myring™ submitted for EU approval post period end – on track for launch in 2018; GMP approval received for production at Mithra CDMO
- Tibelia® received marketing authorization in France; exclusive agreement signed for Canada, where Tibelia® would be the first tibolone-based product in this market if approved
- Accelerated business development including license and supply agreement with Fuji Pharma for Donesta® in Japan and ASEAN markets; commercialization agreements with Mayne Pharma for Myring™ in the US and Gynial in Austria

Financial Highlights

- Revenues increased by 51.4% to EUR 12.7 million (H1 2016: EUR 8.4 million) thanks to license agreements with Fuji Pharma for Donesta® as well as with Mayne Pharma and Gynial for Myring™, with slightly increased revenues for the Benelux business
- R&D expenditure increased by 51.7% to EUR 25.5 million (H1 2016: EUR 16.8 million), reflecting targeted investment in the Phase III Estelle® and Phase II Donesta® programs
- Private placement of EUR 26.1 million in June supported by existing and new specialist life sciences investors, strengthening financial profile
- Cash at June 30 2017 of EUR 44.7 million, compared to EUR 45.8 million at the end of 2016

François Fornieri, CEO of Mithra, commented: *"I am pleased to report significant progress during the first six months of the year, both in terms of advancing our pipeline programs and delivering on Mithra's corporate objectives. Our advanced E4-based programs for Estelle® in contraception and Donesta® in menopause are progressing according to schedule, as are the Complex Therapeutics programs Myring™, Zoreline® and Tibelia®. Business development activities continued to accelerate, including partnerships with Fuji Pharma for Donesta® and Mayne Pharma for Myring™. These collaborations are an endorsement of the commercial potential of our products and further highlight Mithra's growing reputation in the increasingly attractive field of women's health.*

The Company also strengthened its financial position thanks to an oversubscribed private placement of EUR 26.1 million. The fundraising was supported by existing shareholders as well as new, specialized life sciences investors, demonstrating investor confidence in Mithra's strategy to become a fully-fledged biopharmaceutical company. The additional funding will be used to advance our lead clinical programs while also allowing the Company to pursue further business development opportunities to realize the full commercial potential of our pipeline programs. With a strengthened financial position, continued progress on all our key programs and accelerating partnering discussions, we look forward to the rest of 2017 with confidence."

Operational Review

E4 (Estetrol) unique natural estrogen platform

Estelle® - Phase III in contraception

In H1 2017, Mithra announced a number of key milestones for Estelle®, Mithra's combined oral contraceptive (COC) candidate, composed of 15 mg Estetrol (E4) and 3 mg drospirenone (DRSP). Estelle® is currently in Phase III studies (*E4 Freedom*) in the EU/Russia and the US/Canada, with top-line results expected in Q3 2018 and Q1 2019 respectively.

In February, recruitment was completed for the European Phase III study, with 1577 women aged 18-50 years enrolled, including 1350 aged 18-35 years. Post period end, Mithra announced in August that the first European study subject had successfully completed 13 cycles of Estelle® and the end of study physician visit.

In May, Mithra also initiated a pharmacokinetic (PK) ethnobridging study in Japanese women, which includes 96 subjects. Top-line results from the PK study are expected between Q4 2017 and Q1 2018. The study forms part of the partnership with Fuji Pharma for Estelle® in Japan & ASEAN.

An additional safety study into hemostatic, endocrine and metabolic parameters amongst 101 women also completed recruitment in June, with results expected in H1 2018. The study has the potential to corroborate earlier findings that indicate the potentially improved safety profile of Estelle® compared to current combined oral contraceptives (COCs).

In June, Phase IIb results on body weight and well-being were published in the peer-reviewed *European Journal of Contraception and Reproductive Health Care* [1]. The favorable body weight control observed in the FIESTA study could potentially be a key advantage of Estelle®, as research shows that this could play an important role in treatment compliance and continuation of COCs[2]. The article is a

[1] Article available online at http://www.tandfonline.com/doi/full/10.1080/13625187.2017.1336532

[2] Bitzer J, Paoletti AM. 2009. Clin Drug Investig.; 29(2):73-8.

validation of the scientific community's support for Estelle's® potential, and underlines the need for an innovative, improved combined oral contraceptive for women.

After the end of the reporting period, in August, recruitment was completed for a PK substudy in the US, to determine the impact of demographic characteristics (including race, BMI and smoking) on the absorption, distribution and excretion of Estelle®. The FDA increasingly requires contraceptive study entry criteria to be more reflective of the real-world target population, and this PK substudy should provide valuable insights into the use of Estelle® in various subpopulations.

Donesta® - Phase II in menopause

In June, Mithra signed an exclusive License & Supply agreement for Donesta®, its next generation hormone therapy candidate, with Fuji Pharma, the Japanese leader in women's health and Mithra's partner for Estelle®. Mithra is eligible for a low double-digit downpayment, pending certain development, regulatory and commercialization milestones, EUR 1.5 million of which was recognized in H1 2017. Moreover, the 20-year agreement is also expected to generate long-term supply revenues at the Mithra CDMO.

Recruitment for the Phase II dose-finding study is expected to be finalized in coming weeks, with at least 225 patients randomized over five treatment groups, including placebo. Mithra remains on track to report top-line results in Q1 2018.

E4 platform

In June, Mithra received orphan drug designation (ODD) from the European EMA for the treatment of life-threatening neonatal encephalopathy, based on promising preclinical data and the large unmet medical need. Results show the potential of E4 to address indications beyond women's health, including in neuroprotection.

The IP position was also strengthened in January, with a patent granted in the US in emergency contraception for E4 alone. In Australia, after the end of the reporting period in July, the Australian Patent Office (IP Australia) granted a patent for the E4 synthesis manufacturing process until 2032 (which the company also holds for other territories such as the US, Europe and Hong Kong) and for the use of E4 as an emergency contraceptive. In addition, an Australian patent for E4 in neuroprotection was received. Mithra already holds this patent in additional territories such as Europe and the US.

Complex Therapeutics

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

In May, Mithra received Good Manufacturing Practice (GMP) approval for the European production of Myring™ at Mithra's integrated R&D and manufacturing CDMO facility, a necessary step before the product can be launched in Europe after expiry of the patent of the originator product, Nuvaring®, in April 2018. The approval provides further validation of Mithra's manufacturing and development capabilities at its state-of-the-art CDMO.

After the end of the reporting period in July, Mithra submitted Myring™ for European market approval, in line with previously announced timelines. Myring™ is on track to be launched in Europe from Q2 2018.

In February, an exclusive long-term agreement was signed with Mayne Pharma, the second-largest supplier of oral contraceptives in the US market, covering commercialization in the US. Mithra

received EUR 2.4 million upon signature, and under the agreement will receive milestone payments of at least EUR 10 million on Abbreviated New Drug Application (ANDA) approval from the FDA and on the commercial launch of the product. As the US accounts for over 75% of the revenues of more than USD 900 million generated by the originator product, Nuvaring®, this is a key territory for Myring™.

Mayne Pharma is expected to submit the US marketing authorization application in Q4 2017, with approval possible in H2 2018 and launch shortly thereafter.

In May, Mithra signed its first European licensing agreement for Myring™ with Gynial for the Austrian market.

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

French marketing approval for Tibelia® was received in May, completing the decentralized procedure with marketing authorizations now granted in 15 European countries. With launches in three countries, and three more to follow in the coming months, Tibelia® is expected to become an additional revenue driver for Mithra.

An exclusive agreement for Tibelia® in Canada was signed in June with an undisclosed Canadian partner. Tibelia® would be the first tibolone-based Hormone Therapy product available in Canada. The marketing authorization process is on track, with a potential marketing authorisation anticipated between Q3 2018 & H1 2019.

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

For Zoreline®, Mithra expects to report on the PK results of the 1-month implant in H2 2017, while PK results of the 3-month formulation upgrade also are on track to report in the second half of 2017.

Mithra remains committed to finding a partner for co-development and commercialization, in line with the company's strategy to partner with leaders in women's health for its different product candidates.

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 41% in Belgium and over 30% in the Netherlands for contraception products.

Post period-end, Mithra further strengthened its market position by signing a contract with Procare 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, an unmet medical need. As of Q1 2018, the product will 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 Review

Income statement

Thousands of Euro	*30 June 2017*	*30 June 2016*
INCOME STATEMENT		
Revenues	**12.662**	**8.362**
Cost of sales	**(4.630)**	**(4.420)**
Gross profit	**8.032**	**3.942**
Research and development expenses	(25.502)	(16.829)
General and administrative expenses	(3.990)	(3.829)
Selling expenses	(2.357)	(4.521)
Other operating income	602	198
Total operating expenses	**(31.248)**	**(24.981)**
Operating Profit / (Loss) / REBITDA	**(23.215)**	**(21.039)**
Amortization costs	**(1.201)**	**(479)**
EBIT	**(24.416)**	**(21.518)**
Financial result	**4.342**	**(1.031)**
Share of profit/(loss) of associates	(76)	(22)
Profit / (Loss) before taxes	**(20.150)**	**(22.571)**
Income taxes	**1.358**	**2.977**
Net Profit / (Loss) for the period	**(18.792)**	**(19.595)**

The Group made a net loss of EUR 18.792k for the first half of 2017, compared to a net loss of EUR 19.595k for the first six months of 2016.

The Revenues of the Group increased in the first half of 2017 by 51.4% to EUR 12.662k (H1 2016: EUR 8.362k). The increase is mainly owing to license revenues from the first partnership agreements for Myring™ (with Mayne Pharma and Gynial; EUR 2.400k) and Donesta® (with Fuji Pharma; EUR 1.500k); increased sales in the Benelux markets (EUR 678k); and by a drop in sales in Germany (EUR 154k).

Cost of Sales remained largely stable, driving the increase in Gross Profit to EUR 8.032k from EUR 3.942k.

Total Operating Expenses of the Group have increased by 25% from EUR 24.981k in H1 2016 to EUR 31.248k in H1 2017. Research and development expenses (excluding payroll costs) increased in the first half 2017 by 51.7% to EUR 25.502k (H1 2016: EUR 16.829k). This increase is primarily due to increased R&D activity for the Phase III studies of Estelle® and the Phase II study of Donesta®.

This is partially compensated by decreased selling expenses, from EUR 4.521k to EUR 2.357k, which is mainly driven by reduced commercial operations in France and Germany, as the subsidiaries in these countries were put on hold in the second semester of 2016.

These effects resulted in a negative REBITDA of EUR 23.215k in 2017 compared to EUR 21.039k in 2016.

The net financial income of EUR 4.342k is mainly the result of the IFRS adjustment in the fair value of the contingent liabilities and the government advances (EUR 4.808k), in addition to finance costs of EUR 783k.

Cash flow statement

Thousands of Euro	*30 June 2017*	*30 June 2016*
Operating Loss	**(24.416)**	**(21.518)**
CASH FLOWS FROM OPERATING ACTIVITIES		
Depreciation and amortization	1.201	479
Share-based compensation	374	364
Taxes paid	(26)	(15)
Subtotal	**(22.868)**	**(20.690)**
Changes in Working Capital		
Increase/(decrease) in Trade payables and other current liabilities	2.135	6.122
(Increase)/decrease in trade and other receivables	(3.909)	766
(Increase)/decrease in inventories	1.057	(765)
(Increase)/decrease in other		
Net cash provided by/(used in) operating activities	**(23.585)**	**(14.567)**
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of tangible assets	(38.092)	(4.711)
Proceeds from sale of tangible assets	-	7
Purchase of intangible assets	-	(2.187)
Prepayments	-	-
Acquisition of a subsidiary net of cash acquired	-	-
Investment in associates	-	-
Investment in other assets	(2)	(6)
Net cash provided by/(used in) investing activities	**(38.094)**	**(6.897)**
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on financial loans	-	(17.027)
Proceeds from financial loans	35.586	7.746
Interests paid and other financial charges	(312)	(192)
Interest and other financial income received	-	41
Dividends paid to owners	-	-
Proceeds from issuance of shares (net of issue costs)	25.398	-
Net cash provided by/(used in) financing activities	**60.673**	**(9.433)**
Net increase/(decrease) in cash & cash equivalents	**(1.005)**	**(30.897)**
Cash & cash equivalents at beginning of year	**45.750**	**96.794**
Cash and cash equivalents at end of period	**44.745**	**65.897**

At EUR 44.7 million, the current cash position is little changed compared to 31 December 2016 (EUR 45.8 million), despite significant investments in the advanced clinical pipeline. This is due to the Private Placement of EUR 26.1 million closed on 23 June 2017, which strengthened Mithra's financial profile, and to the revenues that have already been recognized for the partnership agreements closed in H1 2017 (EUR 3.9 million).

Business development activity will continue to accelerate in the near term, with a particular focus on partnerships for Estelle® in coming months, where discussions with several potential partners are currently advancing, both in Europe and other major markets.

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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 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 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.

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