

REGULATED INFORMATION

MITHRA PHARMACEUTICALS ANNOUNCES ITS FIRST HALF 2016 FINANCIAL RESULTS AND OPERATIONAL PROGRESS

Liège, Belgium 1 September 2016, 07h30 – Mithra Pharmaceuticals, a leader in Women’s Health market, today announced its consolidated financial results for the six-month period ending 30 June 2016 prepared in accordance with article 13 of the Royal Decree of 14 November 2007. The full interim financial report (regulated information) is available on our website in the Investors section (investors.mithra.com).

François Fornieri, CEO of Mithra Pharmaceuticals, said: *"Over the first half of 2016, we made huge progress in our R&D programs and we strengthened significantly our pipeline. This commitment to research with high value potential, primarily focused on Estelle® and Donesta®, makes us simultaneously focus on business development, looking in a first stage for the best partners outside the EU or the US. In these latter markets we maintain our aim to partner at a later stage, when such partnering can offer an optimal return.*

The concrete interest of valuable potential partners, as well for these non-priority regions as for our non-priority products (as Myring or Tibolone), made the board decide to implement this BD-strategy everywhere; so the subsidiaries will be retargeted towards generating local partnering opportunities instead of efforts in building up local market presence.

I am convinced that this strategy positions Mithra for taking best advantage for the unique products we are developing!"

Steven Peters, CFO of Mithra Pharmaceuticals, said: *"The investments in our R&D programs, including starting up a phase II and a phase III trial, and the effect this has on cash management, gives us a typical biotech profile. But as Mithra has several high potential products, in several continents, and as we can combine deals with our future production capacity in our own CDMO*, we could monitor our financial situation by partnering step by step at the right time in the different regions. This adapted strategy with higher focus on business development work can finance our investments and keep the core long term value of our pipeline. Deals like the recent agreement with Fuji demonstrate the potential of this strategy."*

Operational Highlights

- In the development of Estelle[®], Mithra announced positive food effect results early 2016. The study demonstrated that the concomitant food intake with a single dose of Estelle in women resulted in a decrease for Estetrol and Drospirinone rate of absorption (cmax) while the extent of exposure (AUC) of both Estetrol and Drospirinone was not impacted. This study was mandatory before the introduction at the FDA of the IND for the US trial in June 2016. In July 2016 the European, Canadian and the US regulatory authorities have authorized the start of the extended phase III trial on both continents. Mithra announced that the first patient has been screened at the end of H1 2016 in an EU center.
- In the development of Donesta[®] the company has started its phase II dose finding study in Europe and has enrolled its first 5 patients. The main objective of these Phase II clinical trials regarding the Donesta[®] product candidate is to define the minimum effective dose to treat vasomotor menopausal symptoms, namely hot flushes. In total, 5 doses will be tested in this blinded study, among which one placebo. These doses will be tested on a panel of 225 women for 12 weeks of treatment.
- To strengthen its IP strategy, Mithra has filed a patent applications of its sublingual forms based on E4. This new potential patent can enlarge the patent protection period and avoids generic penetration. This good progress on the different E4 programs resulted in the meantime in a Loi signed with the Japanese women health market leader Fuji Pharma. Both parties have demonstrated in June 2016 their intention to conclude on a binding license and supply agreement for one or more indications on Estetrol before end of the year.
- In view of the construction of its CDMO, Mithra is entering a final stage, and will be completing the construction of its facility in the coming months, which will be within the expected timing and budget. An inauguration is foreseen by end of September. The CDMO will host different development and production programs, o.a. Mithra's owned complex long acting drugs, Zoreline[®] and Myring.
- For Zoreline[®], Mithra announced an update of the Zoreline[®] project and shared the final interim result of the pharmacodynamics study (PD) for the 3 month implant. This PD study results showed a non-responders level of more than 8 patients which was out of the specification for the trial. During this period also a pharmacokinetics has been started and results are expected by end of 2016.
- In view of the Myring development the company made good progress and started the production of its first technical and clinical batches. This event is expected within timing to make sure that the product can be launched at the moment of patent expiry of the original Nuvaring.
- Also on the registrations of its own Tibolone product, Tibelia[®], Mithra announced the green light it received for obtaining the European MA's. In the meantime 4 countries have granted an MA. Based on these results, Mithra announced the signature of a license and supply agreement with Gedeon Richter in 6 European countries.

- Finally, on top of the steady progress in the development plans, Mithra continues to confirm its market leadership position in Contraception in Belgium (in number of cycles). For June 2016 the company published its best selling month (based on IMS sales data) ever.

Events after 30 June 2016

- Mithra Pharmaceuticals announced the appointment of Marc Coucke as chairman of the Board of Directors. Other changes also occurred in the Board of Directors of Mithra Pharmaceuticals: Koen Hoffman, CEO of Value Square and former CEO of KBC Securities, was appointed independent director and will become chairman of the audit committee of Mithra; Freya Loncin, General Counsel Alychlo, was appointed new non-executive director; Professor Jean-Michel Foidart, co-founder of Mithra and current co-chairman of the Scientific Committee of Mithra Pharmaceuticals, was appointed non-executive director.
- Only two months after its LOI with Fuji Pharma, Mithra signed its first major partnership agreement for Estelle. This partnership is in line with Mithra's strategy to partner out its lead Estetrol-based products for territories outside of the EU and US. Fuji Pharma obtained the rights to commercialize Estelle®, Mithra's oral contraceptive product candidate based on Estetrol, in Japan and ASEAN, representing a total market of EUR 330 million. The 20-year partnership agreements, which include exclusive supply by Mithra from its CDMO, generate upfront milestones of up to EUR 26 million, of which EUR 10 million is paid at signature.

Selected First Half 2015 Financial Results

<i>In thousand of Euro</i>	H1 2016	H2 2015
Gross profit	3,942	3,604
Research and Development expenses	(16,829)	(2,833)
General and administrative expenses	(3,829)	(3,553)
Selling expenses	(4,521)	(1,427)
Total operating charges	(24,981)	(7,621)
Operating Profit / (Loss) / REBIDTA	(21,040)	(4,017)
EBIT	(21,518)	(6,811)
Net Profit / (Loss) for the period	(19,595)	(6,264)
Cash and cash equivalent at end of period	65,897	96,794

The Group made a net loss of EUR 19.595k for the first half of 2016, compared to a net loss of EUR 6.264k for the first six months of 2015.

The Revenues of the Group decrease by EUR 53k from EUR 8.415k to EUR 8.362k. The decrease is mainly explained by a drop in sales in the Netherlands (EUR 376k) which was partly compensated by increased sales in the Belux (EUR 109k) markets.

First licence sales for Tibolone as well as the shift towards the Belux and German market drive the increase in gross margin from 43% to 47%.

The operational expenses of the Group have increased with EUR 17.360k from EUR 7.621 in 2015 to EUR 24.981k in 2016. The main driver for this increase is the ramp-up in expenditure (excluding payroll costs) for the Estetrol contraception and menopause projects as well as the costs related to the launch of the CDMO.

The increase in G&A expenses is primarily due to changes in the group structure and the expansion of the management and back office team to support the further growth.

The costs associated to the launch of the German and French sales organizations drive the increase in selling costs by EUR 3.094k.

These effects resulted in a REBITDA of - EUR 21.040k in 2016 compared to EUR 4.017k in 2015.

During 2015 non-recurring costs amounted to EUR 2,511k, mainly composed of the costs related to the IPO in 2015. During 2016 no exceptional costs were booked.

The finance costs primarily includes the costs related to the IFRS adjustment in fair value of the milestone payments for Estetra, contractual obligations of Novalon and fair values of the government advances.

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About Mithra

Mithra Pharmaceuticals SA, founded in 1999 as a spin-off of the University of Liège by Mr. François Fornieri and Prof. dr. Jean-Michel Foidart, is a pharmaceutical company focused on Women's Health. Mithra's mission is to support and assist women at every stage of their life, thereby improving their overall quality of life. As such the Company aims to become a worldwide leader in women's health by developing, manufacturing and commercialising proprietary, innovative and differentiated drugs and complex therapeutical entities in four therapeutic fields of women's health, fertility and contraception, menopause and osteoporosis, vaginal infections and cancers.

Mithra has a total headcount of approximately 85 staff members and 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.