



## ANNUAL RESULTS 2015

**Liège, Belgium 3 March 2016 – Regulated information –** Mithra Pharmaceuticals announced today its 2015 consolidated annual results.

*“2015 was another important year in the execution of our strategy. We are extremely pleased with Mithra’s development in 2015, which was a pivotal year for the company. We had several highlights in 2015 with the IPO, the acquisition of Estetrol and the recent acquisition of the remaining 50% of Novalon,” said François Fornieri CEO of Mithra, “In short, in 2015 Mithra became a public biotech-pharma company with a solid commercial basis and an interesting innovative portfolio based on, on the one hand, Estetrol and on the other its expertise in complex therapeutical entities, with a broad knowledge base in sustained release products based on polymer technology.”*

### **Esterol Acquisition**

**François Fornieri, CEO of Mithra Pharmaceuticals :** *“The highlight of the year has been the fact that we have been able to acquire all rights to Estetrol, which we believe could have extremely exciting applications in a broad range of indications. Beside its obvious potential in contraception and menopause, which formed the basis for our fund raising effort in 2015 with a 54.6 million EUR private capital round, we believe that this natural oestrogen also has broad potential in many other therapeutic areas.”*

### **IPO on Euronext**

**François Fornieri, CEO of Mithra Pharmaceuticals :** *“We realised a 79.3 million EUR IPO... Our solid balance sheet can continue to accommodate further sizeable expansion both through organic growth and through acquisitions and we will continue to seek deals where these can generate obvious value for Mithra and our shareholders.”*

### **Acquisition of the remaining 50% of Novalon**

**François Fornieri, CEO of Mithra Pharmaceuticals :** *“The acquisition of the remaining 50% of Novalon reinforces our know-how and expertise on polymers and controlled release products which will feed further developments and production in our CDMO.”*

### **CDMO**

**François Fornieri, CEO of Mithra Pharmaceuticals :** *“The CDMO forms an integral part of the Mithra Pharmaceuticals’ innovation and development strategy. The concept of the CDMO facility as set out by Mithra Pharmaceuticals provides the flexibility, however, to also support interested partners in their development and production of polymeric forms, implants, sterile injectables and tablets.”*

## Research & Development

**Steven Peters, CFO of Mithra Pharmaceuticals** : "Our 2015 results show our continued and increasing effort in R&D Investments as well as a solid commercial basis to support the launch of our foreign subsidiaries. Cash burn is being carefully controlled, as, given the level of financing required for each of our major projects, Mithra is currently in a "biotech-mode" in terms of R&D spending pattern. In that vein, we remain very attentive for any and all possibilities to enter into partnerships that would allow us to valorize elements of our portfolio which we are currently not actively pursuing, which would have the double benefit of supporting Mithra's main developments and allowing this exciting potential to be unlocked."

## Annual results 2015

### Consolidated Figures - Mithra

Thousands of Euro (€)	FY14 Actual	FY15 Actual
<b>CONSOLIDATED INCOME STATEMENT</b>		
<b>Gross profit</b>	<b>9.050</b>	<b>10.240</b>
Research and development expenses	(2.495)	(9.585)
General and administrative expenses	(6.088)	(7.074)
Selling expenses	(3.016)	(4.611)
Other operating income	383	321
<b>Total operating charges</b>	<b>(11.215)</b>	<b>(20.949)</b>
<b>REBITDA</b>	<b>(2.165)</b>	<b>(10.709)</b>
<b>Operating Result (EBIT*)</b>	<b>(2.928)</b>	<b>(14.267)</b>
<b>Net result for the period</b>	<b>(2.955)</b>	<b>(9.821)</b>
Cash & cash equivalents	1.678	96.794

- Gross profit increased by EUR 1.190k to EUR 10.240k, mainly resulting from the first license sale of Zoreline®. The performance in the Belux market was relatively stable in 2015. The company was able to partly compensate the price diminution by growing sales volumes. Further top line growth is coming from the German subsidiary which launched its first products in the second half of 2015.
- As expected, investments in Mithra's innovative product portfolio drive the increase in R&D expenses by EUR 7.091k to EUR 9.585k. Note that in the 2014 figures the development expenditure associated to the Estetrol projects were not included, as these were acquired in the beginning of 2015. The investments relating to Estelle® and Donesta® amount to EUR 7.991k or 83% of the total 2015 R&D expenditure.

- General and Administrative expenses increase by EUR 776k and amount to EUR 6.864k or a 16% increase which is largely explained by strengthening of management teams for the R&D teams in order to ensure the development plans of Estelle® and Donesta® projects, as well as administrative teams to assume the requirements related to a listed company.
- Selling expenses increase by EUR 1.595k to EUR 4.611k, which is primarily linked to the start-up of commercial operations in France and the launch of the German subsidiary.
- As a result the REBITDA shows a loss for 2015 of EUR 10.709k. The main driver for this loss is the increase in R&D expenditure related to our Estetrol portfolio in contraception and menopause.
- In addition to the operational expenses, Mithra incurred EUR 2.894k of exceptional expenses in 2015, which are mainly related to the IPO in June 2015 and other exceptional and non-recurring expenses.
- As of 31 December 2015 Mithra's cash and cash equivalent position amounts to EUR 96.794k, mainly resulting from the proceeds of the IPO in June 2015 amounting to EUR 79,3 million.

## R&D Highlights

- In order to validate the current Development Plans of its two innovative Estetrol-based products Estelle® and Donesta® and before starting the enrolment of a more complete R&D team, Mithra mandated a renowned international organization to perform an extensive external assessment. This audit showed that the processes of Estelle and Donesta projects are well designed and that Phase II and III clinical trials can start.
- In 2015, Mithra Pharmaceuticals announces the last patient enrolment in the pharmacodynamics & pharmacokinetics studies of the Zoreline® implant 10.8 mg
  - The 142 patients needed have now been enrolled
  - Studies conducted by Mithra among oncologists and gynecologists showed that goserelin in one-month use are linked to breast cancer in combined therapies.

## Operational highlights

- In February 2015, Mithra announced a financing round of EUR 54,6 million led by Marc Coucke and other investors, such as Bart Versluys<sup>1</sup>, SRIW, various family offices and existing investors in the Company. Mithra raised additional EUR 79,3 million through the proceeds of its IPO.
- In 2015, Mithra strengthens its R&D portfolio by acquiring:
  - 4 innovative projects from Actavis Belgium (former Uteron Pharma): Estelle<sup>®</sup>, Colvir<sup>™</sup>, Alyssa<sup>™</sup> et Vaginate<sup>™</sup>
  - All rights in respect of Estetrol (in addition to the rights to Estetrol in the field of oral contraceptives with the project Estelle<sup>®</sup>) from Pantarhei Bioscience (for example, Donesta<sup>®</sup>).
  - All worldwide and property rights on Myring et Zoreline<sup>®</sup> (Mithra acquires 50 % of Novalon SA (in addition to the 50 % it already owns) for a total amount of EUR 9,4 million. Mithra now owns 100% of Novalon).
- One year after laying the first stone of its CDMO, Mithra Pharmaceuticals provides an update on this huge construction. The progress of the construction suggests more promising perspectives than expected:
  - The CDMO's construction is about 3 month ahead of schedule.
  - Expenses related to the Phase I completion are below the initial budget.
  - Mithra found the necessary funding for the Phase II completion.
- In Belgium, Mithra remains leader on the oral contraception market with 45,24% of market shares (in number of blisters) in 2015, accounting for a 1,4% increase compared to 2014. Mithra ranks far ahead of Bayer Schering, Sandoz, MSD, TEVA and Pfizer.
- In the Netherlands as well, Mithra dominates the oral contraception market with 32% of market shares (in volume in counting units) in 2015, compared to 27% in volume in 2014 (tenders market) en matière de contraception, accounting for a 5% increase.
- En 2015, Mithra takes concrete actions in its affiliates
  - 1<sup>st</sup> September 2015, Mithra Pharmaceuticals launched its first products in Germany, Mithra Pharmaceuticals GmbH, with two first brands, MIDIEN<sup>®</sup> (EE/DNG) and MIDESIA<sup>®</sup> (DESO Mono), two modern, state-of-the-art contraceptives. Products containing (EE/DNG) represent 21% of the contraception market, accounting for 50% of the 'progestin-only' market and products containing (DESO mono) represent 6% of contraception market. Mithra Deutschland focuses on innovation as well by signing an exclusive Licensing & Supply Agreement with Giellepi Spa (Italy) for

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<sup>1</sup> In January 2016, Bart Versluys operates a net purchase of shares and now has 3,17% of the voting rights in Mithra Pharmaceuticals

marketing an oral product with Lactobacillus Mix for the indication “Bacterial Vaginosis” in Germany.

- In July 2015, Mithra Pharmaceuticals signs a Dossier Acquisition and Supply Agreement with Famy Care, one of the largest manufacturers of contraceptive pills. Under the terms of this Agreement, Mithra Pharmaceuticals acquires the marketing authorizations for two products in France: Milevoni® 20/100 (Ethinylestradiol (0.02 mg)/Levonorgestrel (0.1 mg)) and Milevoni® 30/150 (Ethinylestradiol (0.03 mg)/Levonorgestrel (0.15 mg)). The commercialization of these products on the French territory should start Q4 2016.
- In 2015, Mithra conducted a market study in order to understand Brazilian market trends 5 OTX products (2 from Mithra’s R&D) will be ready to enter the market in 2016, representing altogether a total market of ca. EUR 200 million.
- Globally, Mithra signed 4 new contracts for a total amount of EUR 845,977 on several years. With Tibolone, last development project of Mithra, this amount could reach EUR 1,745,977 during 2016.

### Highlights after 31 December 2015

- Strengthening of the R&D team
  - Appointment of an Estetrol Development Programs Director
  - Appointment of a Clinical Development Director
- In February 2016, Mithra enrolls the first patient of the comparative pharmacokinetic trial. The objective is to compare the formulation of the three-month implant with the formulation of the equivalent product.

The entire report is available on the website <http://investors.mithra.com>

### Pictures

For pictures of François Fornieri, please click here on the following link:

<http://www.mithra.com/logo-et-charte-graphique/>

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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](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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