



## MITHRA ANNOUNCES 2018 HALF YEAR RESULTS

Liège, Belgium, 25 September 2018 – 7:30 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces its financial results for the six-month period ending 30 June 2018, prepared in accordance with IFRS. The full interim report is available on the Investors sections of the website (<https://investors.mithra.com/en/>).

### Operational Highlights (including post-period end)

#### Clinical progress

- Positive top-line results for the Phase III Estelle® (E4 Freedom) 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. US/Canada study on track to report top-line results in Q1 2019
- Positive results from the Phase II hemostasis study of Estelle® were reported which corroborate earlier findings and delineate the unique safety profile of Estelle®
- Positive top-line results from the E4 Relief Phase II study for Donesta® for the treatment of Vasomotor Symptoms (VMS), in particular hot flushes relief, in post-menopausal women.
- Abbreviated New Drug Application (ANDA) filed with the US Food and Drug Administration (FDA) for vaginal ring for contraception, Myring™. Potential launch expected in H1 2019.
- Applied for additional patents to further strengthen and extend intellectual property estate for Estelle®, Donesta® and E4.

#### Licensing and supply agreements

- Exclusive license and supply agreement signed with Gedeon Richter to commercialize Estelle® in Europe and Russia (semi-exclusive license in Benelux)
- Exclusive license and supply agreement signed with Searchlight Pharma to commercialize Estelle® in Canada
- Exclusive license and supply agreement signed with Hyundai Pharm to commercialize Estelle® in South Korea
- Exclusive license and supply agreement signed with Alvogen for the commercialization of Myring™<sup>1</sup> in Russia
- Exclusive license and supply agreement signed with Orifarm for the commercialization of Myring™<sup>2</sup> in Denmark
- Mithra received its first Marketing Authorization (MA) for Myring™ in the United Kingdom

---

<sup>1</sup> Myring™ will be marketed under a different trademark name in Russia

<sup>2</sup> Myring™ will be marketed under a different trademark name in Denmark

- Exclusive license and supply agreement signed with Pei Li Pharm for the commercialization of Tibelia<sup>®3</sup> in Taiwan
- Exclusive license and supply agreement signed with Mediner for the commercialization of Tibelia<sup>®4</sup> in Hungary

### Financial Highlights (including post-period end)

- Revenues remain stable at EUR 12.6 million (H1 2017: EUR 12.7 million). Although stable, an increase of revenues was reported for license agreements thanks to Libbs for Estelle<sup>®</sup>; increase in revenues which was offset by decreased revenues for the Benelux business
- R&D expenditure decreased by 24% to EUR 19.4 million (H1 2017: EUR 25.5 million), reflecting end of investment in the Phase III Estelle<sup>®</sup> and Phase II Donesta<sup>®</sup> programs
- Raised EUR 77.5 million in gross proceeds by means of a private placement of 2,672,414 new shares through an accelerated bookbuild offering to fund clinical development of the Company's key assets
- Signed a comprehensive Belux partnership 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 license and supply agreements for a number of Mithra's products and product candidates developed in-house, including licenses for the commercialization in Belux of Tibelia<sup>®</sup>, Myring<sup>™</sup> and Estelle<sup>®</sup>
- Higher expected future revenues related to Estelle<sup>®</sup> captured in our business plan led to an increase of fair value for the contingent consideration reported for Estelle<sup>®</sup> (EUR 68,319k in June 2018 compared to EUR 41,811k in 2017); an IFRS adjustment in the fair values which was the main driver of the financial expenses of EUR 28,933k, a non-cash element in the income statement
- Cash at June 30 2018 of EUR 85.8 million, compared to EUR 36.2 million at the end of 2017

**François Fornieri, CEO of Mithra Women's Health commented:** *"Mithra made good progress in the first half of 2018 as we continue to focus on bringing our innovative E4-based oral contraceptive and hormone therapy products to market. The unique profile of Estelle<sup>®</sup> as a new generation oral contraceptive was underlined by a number of studies, including positive top-line results from the Europe/Russia Phase III. Its uniqueness was further recognised by the broad commercialization agreement recently signed with Gedeon Richter for Estelle in Europe and Russia. We look forward to the results from the North American Phase III trial early next year.*

*"Positive Phase IIb results were announced for our hormone therapy candidate, Donesta<sup>®</sup>, which demonstrated a statistically significant reduction in the frequency of hot flushes. Preparations for Phase III initiation are well under way. Myring<sup>™</sup> saw its first launches in Europe and is on track for launch in the US in 2019 following acceptance of the regulatory filing by the FDA.*

*"We further strengthened our financial position with a private placement and raised EUR 77,5 million. This strengthening will continue in the second half through the signed divestment of our Belux commercial portfolio to Ceres Pharma for up to EUR 40 million; and with significant upfront, milestone and sales-related royalty payments from the signed Gedeon Richter agreement for Estelle<sup>®</sup>. With a robust financial position, new partnering deals in key territories around the world and continued*

---

<sup>3</sup> Tibelia<sup>®</sup> will be marketed under a different trademark name in Taiwan

<sup>4</sup> Tibelia<sup>®</sup> will be marketed under a different trademark name in Hungary

*further progress on our key programs, we remain confident in our vision to transform women’s health through innovation.”*

## Operational review

### E4 (Esetrol) unique native estrogen platform and pipeline

#### *Estelle® - Phase III in contraception*

In H1 2018, Mithra announced a number of key milestones for Estelle®, Mithra’s combined oral contraceptive (COC) candidate, composed of 15 mg Esetrol (E4) and 3 mg drospirenone (DRSP).

Estelle® is currently in Phase III studies (E4 Freedom) in Europe/Russia and the US/Canada, and post period end we announced positive top-line results from the European and Russian leg of the study. The Company remains on track to report top-line results from the US/Canada Phase III study in Q1 2019.

In March, Mithra announced it had completed the minimum 10,000 cycles of Estelle® required for the US/Canada study. Mithra also completed recruitment for the European and Russian Phase III study, with 1,557 women aged 18-50 enrolled, including 1,350 aged 18-35.

Also in March, Mithra announced positive results from its Phase II hemostasis study of Estelle®. The study is an important sub-study running in parallel to the ongoing Phase III Estelle® (E4 Freedom) pivotal trials. The results were presented at the International Society of Gynecological Endocrinology Conference (ISGE) in Florence<sup>5</sup>. The aim of the study was to analyse a series of parameters that are widely accepted as surrogate markers of coagulation (blood clotting) and fibrinolysis (breakdown of clots). The markers help determine the risk profile of a novel COC (combined oral contraceptive) for deep venous thrombosis (DVT) and pulmonary embolism, which are well-documented side effects of certain commonly prescribed contraceptive pills.

LNG (levonogestrel) was included as a comparator as required by the regulatory agencies. This ‘second generation’ contraceptive option is known to have a limited impact on hemostasis parameters. Mithra elected to include Yaz® as an additional comparative arm, given the well-documented elevated DVT risk for current DRSP-based COCs relative to LNG-based products. As Estelle® also contains DRSP, a direct comparison with Yaz® is of great interest. Moreover, with peak sales EUR 1.2 billion, the Yaz® family still is the best-selling contraceptive pill in value, and Estelle®’s benchmark for commercialization.

Analysis across a range of parameters pointed to minimal changes in markers of coagulation and fibrinolysis even when compared to LNG (levonogestrel)-based COC, which was included as a comparator as a regulatory requirement. Moreover, the results indicated that the combination of DRSP (drospirenone)-based pill Estelle® with E4 did not lead to the higher hemostatic impact found with Yaz®. Yaz® is a direct competitor to Estelle® and the benchmark for Estelle®’s commercialization.

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.

Based on the positive data from the hemostasis Phase II sub-study, Mithra applied for an additional patent to further strengthen and extend the existing Estelle® and E4 intellectual property estate. If

---

<sup>5</sup> <http://isge2018.isgesociety.com/>

## PRESS RELEASE – REGULATED INFORMATION

granted, the patent would extend the existing E4 intellectual property estate, which comprises patents relating to the E4 synthesis process (until 2032) and E4 as a potential new emergency option.

In April, Mithra announced it had signed a binding Heads of Terms agreement with Searchlight Pharma, a rapidly growing Women's Health company, 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. 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 on 24 May 2018.

In June, Mithra announced it had signed a binding Heads of Terms agreement with Hyundai Pharm, a South Korean Women's Health leader, for an exclusive license to commercialize Estelle® in South Korea. Under the terms of the agreement 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. Post-period end, on 23 September 2018, Mithra finalized the exclusive licence and supply agreement.

Post period in August, 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 data support Estelle® as a novel; next-generation combined oral contraceptive for women with an improved benefit/risk profile. Topline results from the parallel Phase III study of Estelle® in the US/Canada are on track to be announced in Q1 2019.

The primary endpoint was contraceptive efficacy measured by the number of pregnancies per 100 women per 12 months of exposure (Pearl Index; PI) among the women aged 18-35 years old at study entry. Results showed a PI of 0.48 (confidence interval 0.15-1.11) during 13,688 cycles (1 cycle= 28 days), with reported sexual activity and in the absence of other contraceptive methods. The PI indicates a 99.5% efficacy rate over one year of use, exceeding the efficacy goals of the study. A PI and its difference with the upper limit of the confidence interval below 1 is a regulatory requirement of the European Medicines Agency (EMA)<sup>6</sup>.

Key secondary endpoints were also achieved including cycle control and bleeding profile, which are essential to women's compliance. An excellent regular bleeding pattern was shown, comparable to that of Ethinyl-Estradiol (EE) containing oral contraceptives.

The safety, acceptability and general well-being of the subjects (measured by two validated questionnaires) were also analyzed. Results from the MDQ (menstrual distress questionnaire) and QOL (quality of life) questionnaire showed that Estelle® is well tolerated by women, while their overall quality of life is maintained.

Moreover, the safety profile did not demonstrate unexpected events. The global safety assessment will be communicated in detail once the Phase III US/Canada study has been completed.

Post period, in September, Mithra and Gedeon Richter Plc. announced that they had entered into a landmark license and supply agreement to commercialize Estelle®<sup>7</sup> in Europe and Russia. Under the terms of the agreement Richter will make, upon signature of the contract, an upfront payment totaling 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. Potential additional sales-related milestones

---

<sup>6</sup> EMEA/CPMP/EWP/519/98 Rev 1

<sup>7</sup> Richter will commercialize the product under a different brand name.

will be payable to Mithra subsequent to the launch of the product. Moreover, Mithra will receive guaranteed annual recurring revenues based on minimum annual quantities (MAQ), in addition to tiered royalties from high single-digit to substantial double-digits on net sales.

### *Donesta® - Phase II in menopause*

In April, Mithra announced positive top-line results from the E4 Relief Phase II study of Donesta® for the treatment of Vasomotor Symptoms (VMS), in particular hot flushes relief, in post-menopausal women. Donesta® is Mithra's next-generation hormone therapy (HT) product candidate with oral administration of Estetrol (E4). The study successfully met its primary and key secondary objectives and confirmed Donesta® promising safety profile.

The results show that 15 mg E4 is highly efficacious for relieving some of the most bothersome and frequent symptoms of menopause, while offering a promising safety profile. This highlights the potential of Donesta® as a unique next-generation hormone therapy and provides a solid foundation for the next stage of clinical development. If approved, Donesta® could offer a true novel and differentiated therapy with an improved benefit/risk profile for women globally confronted with a range of menopausal symptoms.

Based on the positive data from the Phase IIb dose-finding study, Mithra applied for an additional patent to further strengthen and extend the existing Donesta® intellectual property estate. If granted, the patent would further extend the existing Donesta® intellectual property estate.

In May, Mithra announced additional positive efficacy and safety data from the Phase IIb study for Donesta®. 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<sup>8</sup>.

In June, Mithra presented the Phase IIb study results for Donesta® at the 16<sup>th</sup> World Congress on Menopause in Vancouver, Canada.

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 introduction of new treatment options that provide a safer alternative to currently available therapies<sup>9</sup>.

## **Complex Therapeutics**

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

In March, Mithra announced that the Abbreviated New Drug Application (ANDA) for its vaginal ring for contraception, Myring™<sup>10</sup>, had been accepted for filing by the US Food and Drug Administration (FDA). The ANDA was submitted by Mithra's partner for the US commercialization of the vaginal ring, Mayne Pharma (ASX:MYX). The acceptance by the FDA was an important regulatory step, as it reconfirms the pathway towards launch of the product candidate expected in H1 2019.

---

<sup>8</sup> 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)

<sup>9</sup> Transparency Market Research 2017

<sup>10</sup> Mayne Pharma will market Myring™ under a different trademark name in the US

## PRESS RELEASE – REGULATED INFORMATION

Myring™ is an intra-vaginal hormonal contraceptive delivery device combining etonogestrel and ethinyl estradiol over a 3-week period, and is developed to be fully bioequivalent to Merck's NuvaRing®. NuvaRing® had total US sales of approximately USD 830 million for the 12 month period ending 31 January 2018<sup>11</sup>. The US market represents over 75% of the annual global sales of NuvaRing®, making this a key territory for the product. NuvaRing® went off patent in April 2018, and no generic version has been approved in the US to date.

The exclusive long-term license and supply agreement with Mayne Pharma was first announced in 2017. 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 US FDA through to commercial launch of the product. Following launch, Mithra anticipates important financial contributions from the production of the vaginal ring at Mithra's CDMO facility. Based on recent market intelligence, Mayne Pharma is well placed to be among the first to enter the US market, which would potentially entitle Mithra to additional milestone payments.

In March, Mithra announced it had granted an exclusive license and supply agreement to Alvogen for the commercialization of Myring™<sup>12</sup> in Russia. This agreement follows previous partnerships with Mayne Pharma, Gynial and Adamed for the US, Austria and the Czech Republic, respectively. Under the terms of the agreement, following Marketing Authorization (MA), Alvogen will have the right to sell the contraceptive vaginal ring in Russia, a market worth approximately EUR 13 million<sup>13</sup>. Alvogen is a key player in women's health in Russia and Central and Eastern Europe. In addition to a down payment and milestone payment, Mithra anticipates revenues following commercial launch, as Mithra will exclusively manufacture and supply the product to Alvogen from its CDMO facility.

In June, Mithra announced an exclusive license and supply agreement with Orifarm for the commercialization of Myring™<sup>14</sup> in Denmark. The Danish market is worth approximately EUR 0.75 million<sup>15</sup>. Orifarm is a Danish fast-growing supplier to the Nordic countries with an established business among pharmacies and hospitals. The launch of the vaginal ring in Denmark will enable Orifarm to grow its footprint in Women's Health in its key market. In addition to down payments and milestone payments, Mithra will receive revenues for the exclusive manufacturing and supply of Myring™ to Orifarm.

Post period, in July, 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<sup>16</sup> with no generic competition on the market as yet. The ring will also be produced at Mithra's CDMO.

Under the same decentralized procedure, MAs for Latvia and Hungary were also granted, with additional MAs expected in Europe (Croatia, the Czech Republic, Poland, Slovakia and Slovenia) as well as the US in H2 2018/early 2019.

---

<sup>11</sup> According to IQVIA, as provided by Mayne Pharma

<sup>12</sup> Myring™ will be marketed under a different trademark name in Russia

<sup>13</sup> NuvaRing® (Merck) sales IMS Analytics Q3 2017

<sup>14</sup> Myring™ will be marketed under a different trademark name in Denmark

<sup>15</sup> Estimation provided by Orifarm (no IMS available)

<sup>16</sup> CAGR (2013-2017): +6.6%

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

In July, Mithra announced an exclusive license and supply agreement with Mediner for the commercialization of Tibelia®<sup>17</sup> in Hungary, a market worth approximately EUR 0.6 million<sup>18</sup>. Mediner is a Hungarian-based company offering a broad portfolio of in-licensed products to its home market, with a key focus on gynecology. In addition to license fees, Mithra is eligible for annual revenues over the duration of the 10-year contract.

**Post period**, in September, Mithra announced an exclusive license and supply agreement with Pei Li Pharm for the commercialization of Tibelia®<sup>19</sup> in Taiwan, a menopause market worth approximately EUR 4.1 million<sup>20</sup>.

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

In Q1 2018, Mithra received the positive results of 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 3-month implant, containing 3.6 mg and 10.8 mg of goserelin, respectively.

The Zoreline® PK study demonstrated the safety profile of the 1-month (3.6mg) implant compared to Zoladex®, with results in line with regulatory requirements. Furthermore, the data collected in 58 patients also provides important information on the similar PD activity (efficacy) of the 1-month treatment in Zoladex® and Zoreline®.

Mithra is continuing to work on the reformulation of the 3-month implant, with PK results on track for Q4 2018, and is currently evaluating further steps for development. Pending positive results of the 3-month product candidate.

Mithra could potentially move into a pivotal clinical PD study for both the 1- and 3-month formulations.

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.

## **Business Update**

In May, Mithra announced it had closed a contract with Midas Pharma for the development of a sterile injectable product at Mithra's CDMO in Belgium. Midas Pharma, based in Germany, is a full-service provider and a leader in the sourcing and supply of intermediates, Active Pharmaceutical Ingredients, Finished Dosage Forms and dossiers for finished products. The company is present in 10 countries and works with generic pharma players, big pharma companies as well as biotech firms. Financial terms of the contract were not disclosed. Following the umbrella agreement signed with GSP in 2017, this new contract with a highly regarded partner in the field is a further endorsement of the Mithra CDMO.

---

<sup>17</sup> Tibelia® will be marketed under a different name by Mediner

<sup>18</sup> IMS Health 2017. CAGR in volume (2013-2017): +5%

<sup>19</sup> Tibelia® will be marketed under a different name by Pei Li Pharm

<sup>20</sup> IMS Health 2017



## PRESS RELEASE – REGULATED INFORMATION

In May, Mithra raised EUR 77.5 million in gross proceeds by means of a private placement of 2,672,414 new shares through an accelerated bookbuild offering. Mithra intends to use the net proceeds of the Private Placement to:

- Fund optimal clinical development for the Company's key assets:
  - Financing of the post-Phase III regulatory steps for the oral contraceptive Estelle<sup>®</sup>
  - Initiation of the Phase III development program for Donesta<sup>®</sup>, Mithra's VMS product candidate, with the rapid advancement of the preparatory/bridging studies followed by the initiation of recruitment for the Donesta Phase III trials. In order to maximize the market potential of Donesta, Mithra intends to launch both an E4 monotherapy trial and a combination trial (E4 + progesterin)
- Give the Company increased strategic and financial flexibility to further progress partnering discussions for the commercialization of Estelle and (co)development of Donesta<sup>®</sup>
- Fund general corporate purposes.

Post period, in July, Mithra announced that it had signed a comprehensive Belux partnership 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 license and supply agreements for a number of Mithra's products and product candidates developed in-house, including licenses<sup>21</sup> for the commercialization in Belux of Tibelia<sup>®</sup>, Myring<sup>™</sup> and Estelle<sup>®</sup>.

Under the terms of the agreement, Mithra received an immediate payment of EUR 20 million. Pending certain sales milestones, Mithra is eligible to receive an additional EUR 20 million in earn-outs over the next five years. In addition, to the extent that Mithra remains responsible for the co-marketing of certain products, Ceres Pharma will pay a low double-digit service fee on net sales.

For Mithra, the sale of the branded generics business realized the value of an increasingly non-core asset, as the Company continues to become a fully-focused innovative biopharma company. More particularly, following the successful results from the Phase IIb study of Donesta<sup>®</sup> (menopause) and with the pivotal Estelle<sup>®</sup> Phase III studies (contraception) drawing to an end, the agreement enables Mithra to focus on these two potential blockbusters.

---

<sup>21</sup> Semi-exclusive license on Estelle, exclusive license on Myring, semi-exclusive license on Tibelia, exclusive license on Daphne, in Belux



## Financial Review

### Income statement

#### CONTINUING OPERATIONS

| <i>Thousands of Euro</i>                      | <i>30 June<br/>2018</i> | <i>30 June<br/>2017</i> |
|---|-------------------------|-------------------------|
| <b>INCOME STATEMENT</b>                       |                         |                         |
| <b>Revenues</b>                               | <b>6,718</b>            | <b>5,477</b>            |
| <b>Cost of sales</b>                          | <b>(687)</b>            | <b>(1,366)</b>          |
| <b>Gross profit</b>                           | <b>6,031</b>            | <b>4,111</b>            |
| Research and development expenses             | (18,342)                | (25,502)                |
| General and administrative expenses           | (4,377)                 | (3,990)                 |
| Selling expenses                              | (761)                   | (966)                   |
| Other operating income                        | 4,413                   | 602                     |
| <b>Total operating expenses</b>               | <b>(19,067)</b>         | <b>(29,856)</b>         |
| <b>Operating Profit / (Loss) / REBITDA*</b>   | <b>(13,037)</b>         | <b>(25,745)</b>         |
| <b>Depreciation and amortization expenses</b> | <b>(1,363)</b>          | <b>(1,201)</b>          |
| <b>EBIT</b>                                   | <b>(14,401)</b>         | <b>(26,946)</b>         |
| <b>Financial result</b>                       | <b>(28,933)</b>         | <b>4,342</b>            |
| Share of profit/(loss) of associates          | -                       | (76)                    |
| <b>Loss before taxes</b>                      | <b>(43,334)</b>         | <b>(22,680)</b>         |
| <b>Income taxes</b>                           | <b>7,800</b>            | <b>2,218</b>            |
| <b>Net Loss for the period</b>                | <b>(35,534)</b>         | <b>(20,462)</b>         |

#### DISCONTINUED OPERATIONS

| <i>Thousands of Euro</i>                 |             | <i>30 June<br/>2018</i> | <i>30 June<br/>2017</i> |
|--|-------------|-------------------------|-------------------------|
| <b>CONSOLIDATED INCOME STATEMENT</b>     |             |                         |                         |
|  | Notes       |                         |                         |
| <b>Revenues</b>                          | <b>6.18</b> | <b>5,906</b>            | <b>7,184</b>            |
| <b>Cost of sales</b>                     |             | <b>(2,933)</b>          | <b>(3,264)</b>          |
| <b>Gross profit</b>                      |             | <b>2,973</b>            | <b>3,921</b>            |
| Selling expenses                         |             | (1,458)                 | (1,391)                 |
| <b>Total operating expenses</b>          |             | <b>(1,458)</b>          | <b>(1,391)</b>          |
| <b>Operating Profit / (Loss) /EBITDA</b> |             | <b>1,516</b>            | <b>2,530</b>            |
| Depreciation and amortization expenses   |             | -                       | -                       |
| <b>EBIT</b>                              |             | <b>1,516</b>            | <b>2,530</b>            |
| <b>Financial result</b>                  |             | <b>0</b>                | <b>0</b>                |
| <b>Profit before taxes</b>               |             | <b>1,516</b>            | <b>2,530</b>            |
| <b>Income taxes</b>                      |             | <b>(429)</b>            | <b>(860)</b>            |
| <b>Net Profit for the period</b>         |             | <b>1,087</b>            | <b>1,670</b>            |

## PRESS RELEASE – REGULATED INFORMATION

### GROUP TOTAL (INCLUDING DISCONTINUED OPERATIONS)

| <i>Thousands of Euro</i>               | <i>30 June<br/>2018</i> | <i>30 June<br/>2017</i> |
|--|-------------------------|-------------------------|
| <b>CONSOLIDATED INCOME STATEMENT</b>   |                         |                         |
| Revenues                               | 12,624                  | 12,662                  |
| Operating Profit / (Loss)/ EBITDA      | (11,522)                | (23,215)                |
| Depreciation and amortization expenses | (1,363)                 | (1,201)                 |
| EBIT                                   | (12,885)                | (24,416)                |
| Financial result                       | (28,933)                | 4,342                   |
| Loss before taxes                      | (41,818)                | (20,150)                |
| Income taxes                           | 7,371                   | 1,358                   |
| Net Loss for the period                | (34,448)                | (18,792)                |

In the Financial highlights section, we use a REBITDA reference where the result of the discontinued operations have been excluded. For this reason, as for the section Interim condensed consolidated financial statements, we have isolated the discontinued operations related to the sale of the Benelux activities to Ceres Pharma. For more details please refer to Notes 6.18 Discontinued Operations.

The Group made a net loss of EUR 34,448k for the first half of 2018, compared to a net loss of EUR 18,792k for the first six months of 2017.

The Revenues of the Group remain stable in the first half of 2018 at EUR 12,624k (H1 2017: EUR 12,662k). Although stable, we see an increase of the license revenues (EUR 1,785k) related to the partnership agreements from EUR 3,900k in H1 2017 to EUR 5,685k in H2 2018 (mainly for Estelle® with Libbs for EUR 5,000k and with Searchlight for EUR 500k); and a decrease of sales in the Benelux markets (EUR 1,737k), mainly due to brand switches, a later launch than expected for Laclimella and Papilocare, and the termination of contract for some distributed products. We also reported a further drop in sales in Germany and France (EUR 64k). We remind that the French activities were sold in December 2017; and the German company is on hold and reported an insignificant amount of sales revenues as we don't develop a sales and distribution organization anymore.

Cost of Sales decreased by EUR 1,010k, driving the increase in Gross Profit from EUR 8,032k to EUR 9,004k.

Total Operating Expenses of the Group have decreased by 34% from EUR 31,248k in H1 2017 to EUR 20,524k in H1 2018. Research and development expenses (excluding payroll costs) decreased in the first half 2018 by 28% to EUR 18,342k (H1 2017: EUR 25,502k). This decrease is primarily due to decreased R&D activity for the Phase III studies of Estelle® and the Phase II study of Donesta® both nearing completion. R&D expenses for Donesta® should increase in the second semester 2018 in light of Phase III study expenses.

This decrease in R&D expenses together with an increase in Other operating income, from EUR 602k to EUR 4,413k, which is mainly explained by tax credit 2018 estimations and by refundable government advances recognition mechanism, resulted in an improved negative EBITDA of EUR 12,885k in 2018 compared to EUR 23,215k in 2017.

## PRESS RELEASE – REGULATED INFORMATION

Higher expected future revenues related to Estelle<sup>®</sup> captured in our business plan led to an increase of fair value for the contingent consideration payable reported for Estelle<sup>®</sup> (EUR 68,319k in June 2018 compared to EUR 41,811k in 2017); an IFRS adjustment in the fair values which was the main driver of the net financial expenses of EUR 28,933k, a non-cash element in the income statement; together with the amortized cost of government advances and interest payables.

\* REBITDA is an alternative performance measure calculated by excluding the non-recurring items from EBITDA from our consolidated statement of income prepared in accordance with IFRS. We consider one-off items and exceptional items as non-recurring items. For more details please refer to Notes 6.19 Alternative Performance measure.

### Cash flow statement

#### GROUP TOTAL (INCLUDING DISCONTINUED OPERATIONS)

| <i>Thousands of Euro</i>  |       | <i>30 June<br/>2018</i> | <i>30 June<br/>2017</i> |
|---|-------|-------------------------|-------------------------|
| <b>CASH FLOWS FROM OPERATING ACTIVITIES</b>                         |       |                         |                         |
| <b>Operating Loss</b>   |       | <b>(12,885)</b>         | <b>(24,416)</b>         |
| Depreciation and amortization                                       |       | 1,363                   | 1,201                   |
| Development costs capitalization                                    | 6.7.  | (3,424)                 | -                       |
| Tax credit  | 6.5.  | (597)                   | -                       |
| Share-based compensation  | 6.14. | 217                     | 374                     |
| Taxes paid  |       | -                       | (26)                    |
| <b>Subtotal</b>   |       | <b>(15,325)</b>         | <b>(22,868)</b>         |
| <b>Changes in Working Capital</b>                                   |       |                         |                         |
| Increase/(decrease) in Trade payables and other current liabilities | 6.12. | (14,142)                | 2,135                   |
| (Increase)/decrease in trade receivables and other receivables      | 6.10. | 16,066                  | (3,909)                 |
| (Increase)/decrease in inventories                                  |       | (2,534)                 | 1,057                   |
| Increase/(decrease) in other deferred revenue and others            |       | (4,681)                 | -                       |
| <b>Net cash provided by/(used in) operating activities</b>          |       | <b>(20,617)</b>         | <b>(23,585)</b>         |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES</b>                         |       |                         |                         |
| Payment for acquisition of tangible fixed assets                    | 6.8.  | (776)                   | (4,862)                 |
| Proceeds from sale of tangible assets                               |       | -                       | -                       |
| Payment for acquisition of intangible fixed assets                  | 6.7.  | (219)                   | -                       |
| Contingent liabilities payments                                     |       | (3,190)                 | -                       |
| Investment in other assets  |       | -                       | (2)                     |
| <b>Net cash provided by/(used in) investing activities</b>          |       | <b>(4,185)</b>          | <b>(4,863)</b>          |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES</b>                         |       |                         |                         |
| Payments on financial loans   | 6.12. | (303)                   | -                       |
| Proceeds from financial loans & government advances                 | 6.12. | 903                     | 2,355                   |
| Interests paid  |       | (1,427)                 | (312)                   |
| Proceeds from issuance of shares (net of issue costs)               | 6.11  | 75,196                  | 25,398                  |
| <b>Net cash provided by/(used in) financing activities</b>          |       | <b>74,370</b>           | <b>27,442</b>           |
| <b>Net increase/(decrease) in cash &amp; cash equivalents</b>       |       | <b>49,568</b>           | <b>(1,005)</b>          |
| <b>Cash &amp; cash equivalents at beginning of year</b>             |       | <b>36,190</b>           | <b>45,750</b>           |
| <b>Cash and cash equivalents at end of period</b>                   |       | <b>85,757</b>           | <b>44,745</b>           |

**CONTINUING OPERATIONS**

| <i>Thousands of Euro</i>  | <i>30 June<br/>2018</i> | <i>30 June<br/>2017</i> |
|---|-------------------------|-------------------------|
| Cash flow from operating activities                                 | (22,133)                | (26,115)                |
| Cash flow from investing activities                                 | (4,185)                 | (4,862)                 |
| Cash flow from financing activities                                 | 74,370                  | 27,442                  |
| <b>Cash flow from continuing operations (net increase/decrease)</b> | <b>48,052</b>           | <b>(3,536)</b>          |

For additional information, please refer to Note 6.18 Discontinued operations.

At EUR 85.8 million, Mithra’s current cash position has significantly improved compared to 31 December 2017 (EUR 36.2 million), despite significant investments in the advanced clinical pipeline. This is due to the Private Placement of EUR 77.5 million closed on 30 May 2018, which strengthened Mithra’s financial profile, and to the revenues that have been collected over H1 2018 for the partnership agreements (EUR 6 million from Libbs).

\*\*\*\*\*

**For more information, please contact:**

**Investor Relations & Press**

François Fornieri, CEO

Jean-Manuel Fontaine, PRO

[investorrelations@mithra.com](mailto:investorrelations@mithra.com) / +32 4 349 28 22

**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 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 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.*