

mithco PHARMACEUTICALS

Annual Report 2016

Specialists in women's health Transforming options for women through innovation

# Contents

Business Section	
Our Mission	4
Mithra at a Glance	6
Achievements in 2016	10
Letter to Shareholders	14
Strategy & Outlook	16
R&D Projects	
Estetrol Estelle® Donesta® Myring™ Tibelia® Zoreline®	18 20 24 26 28 30
Mithra CDMO	32
About Women's Health	36
Financial Highlights 2016	38
Shareholder Structure	40
Financial Calendar 2017	41
Board of Directors	42
Our Executive Management Team	44
Corporate Governance and Financial Statements	
Report of the Board of Directors	52
Responsibility Statement	76
Auditor Report	77
Consolidated Financial Statements	79
Notes to the Consolidated Financial Statements	85





# Mithra at a glance

Estetrol (E4)

mithracdmo

Complex Therapeutics

Today, Mithra has two complementary platforms powered by a unique CDMO facility: its innovative E4-based pipeline, currently under investigation for use in contraception and menopause, and its portfolio of complex therapeutic solutions targeting improved, long-lasting delivery of trusted and established approaches to contraception, menopause and hormonal cancers.



#### E4: Mithra's native selective estrogen platform

Mithra's goal is to develop new and improved products that meet women's needs for better safety and convenience, bringing new ideas and options to a market characterized by lack of innovation in recent years. In particular, there is a growing opportunity for estrogen-based products which could offer an improved side effect profile over currently marketed products.

Mithra believes E4 has the potential to transform the women's health market, providing potential benefits over current estrogens in key areas including oral contraception and hormone therapy (HT). These potential benefits include a favorable VTE risk profile<sup>1</sup>, a lower breast pain and lower carcinogenic risk profile in the presence of E223, a favorable risk of drug-drug interaction4, a minimal increase of triglycerides<sup>5</sup>, excellent cycle control and improved spotting<sup>6</sup>, good user acceptability, body weight control, and general well-being7.

E4 is based on the natural estrogen produced by the human fetus, which passes through into maternal blood during pregnancy. Its pharmacodynamics and pharmacokinetics profile suggest a favorable effect on women's health. Its safety margin and tolerability also present an opportunity to investigate its use in other areas of women's health such as oncology, emergency contraception and osteoporosis, as well as in indications such as neuroprotection and wound healing.

Today, Mithra is focused on the development of two late-stage E4-based products, Estelle®, a 5th generation oral contraceptive, and Donesta®, a next-generation hormone therapy.



<sup>&</sup>lt;sup>1</sup> Kluft C et al., Contraception. 2016; <sup>2</sup> Gerard C et al., Oncotarget. 2015;6(19):17621-36,

Visser M et al., Horm Mol Biol Clin Invest. 2012;9:95-103; Visser M et al., Climacteric. 2008; 11 Suppl 1:64-8;

<sup>5</sup> Mawet M et al., Eur. J. Contracept. Reprod. Healthcare 2015:1-13; 6 Apter D. et al., Contraception. 2016;94(4):366-73;

Data on file

#### **Complex Therapeutics**

Mithra also has extensive expertise in the development of complex and innovative products using medical polymer technology. The company is leveraging this expertise to target improved, long-lasting delivery of trusted, established approaches to contraception, menopause and hormonal cancers.

Polymer technology allows prolonged drug delivery based on the use of polymer matrices. These enable a drug's active pharmaceutical ingredient (API) to be distributed at a predetermined rate over a period of time, maintaining controlled drug delivery with minimal side effects.

This technology platform enables Mithra to optimize drug treatment regimens and provides a unique combination of predetermined, safer release rates and durations. It also opens the way for Mithra to develop unique drug delivery approaches for new indications using the hormone formulation expertise and development and manufacturing capabilities at its dedicated CDMO research, development and specialist manufacturing center.

At present, Mithra has the following complex therapeutics under development:

#### Myring™

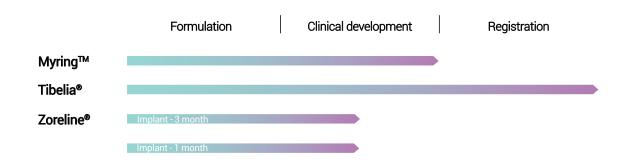
A contraceptive vaginal ring releasing a combination of hormones, made of Ethylene-vinyl-acetate copolymers

#### Tibelia®

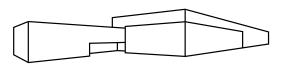
A therapeutic solution composed of tibolone, a synthetic steroid used for hormone therapy (HT) in menopause

#### Zoreline®

A biodegradable subcutaneous implant for prostate and breast cancer and benign gynecological indications.



### mithracdmo



#### Mithra CDMO

### An industry partner with expert research, development and manufacturing capabilities

Mithra CDMO, a 15 000 m² technology facility, forms an integral part of Mithra's innovation and development strategy. It represents a significant asset for the successful development, manufacturing and commercialization of its product portfolio.

This state-of-the-art facility will allow Mithra to develop and produce its product portfolio in-house, including complex therapeutics based on polymer technology as well as Estelle® and Donesta® tablets. It will enable Mithra to reduce reliance on external providers, retain its intellectual property and expertise in-house, and maintain a strong competitive position.

The platform will also provide its partners with a high

quality service covering most aspects of research, development and manufacturing of polymeric forms, implants, sterile injectables and tablets.

# Achievements in 2016

#### Innovation

In 2016, Mithra made significant progress across its innovative E4 (Estetrol) programs as well as its complex therapeutics.

With regard to its E4 pipeline, Mithra initiated Phase III trials in both Europa and North America for its oral contraceptive candidate, Estelle®, and also launched its European Phase II study for Donesta®, its next generation menopause therapy.

In August 2016, Mithra announced its first partnership agreement for Estelle® with Fuji Pharma, the Japanese leader in women's health, to commercialize Estelle® in Japan and ASEAN. This agreement not only underlines the unique potential of Estelle® and Mithra's partnership capabilities, but also marked the start of intensified business development activity which will be further accelerated in 2017. Post-period, Mithra already signed a term sheet with Fuji Pharma for Donesta®.

For its complex therapeutic solutions, Mithra received marketing authorizations (MA) in 12 European countries for its HT product, Tibelia®, with 8 licensing and supply agreements secured during the period. Also, importantly, its vaginal contraceptive ring Myring™ is on track for EU and US regulatory submission as of Q2 2017. In February 2017, Mithra was proud to announce an agreement with Mayne Pharma for the commercialization of Myring™ in the US.

In September, Mithra inaugurated its integrated specialist R&D and manufacturing facility in Liège, Belgium. Construction of Phase I of the project has been completed and will provide production capabilities for polymeric forms, implants and sterile injectables. The CDMO facility is currently producing validation batches of Myring™, and could receive GMP approval as early as Q2 2017. This would allow the company to ship its first commercial batches of Myring™ within the EU in 2017, a key milestone for the CDMO and for the Company as a whole.

The second and final phase of construction, which is dedicated to tablet manufacturing, is underway and on track to be completed in H1 2019 within the allocated budget (EUR 25.8 million).



#### Corporate

In 2016, Mithra further strengthened its management and Board of Directors.

Marc Coucke was appointed as Chairman of the Board and Koen Hoffman, Freya Loncin and Prof. Jean-Michel Foidart were appointed as Director. In addition, Christiane Malcorps was appointed a member of the Board of Mithra CDMO.

Post-period, Christophe Maréchal was appointed Chief Financial Officer and Michaël Dillen was named Chief Legal Officer.

The valuable strategic counsel and extensive experience of the Board and the strenghthened management team will help Mithra to achieve its objectives for 2017 and beyond.

Mithra's strategy and management were also recognized by two important awards in 2016. François Fornieri, CEO of Mithra, was named AstraZeneca Business Development Executive of the Year 2015 for leading three transformational deals in 2015, and Mithra was named as finalist at the Essenscia Innovation Awards 2016, a highly regarded industrial innovation award in Belgium, for its E4 development program.

In 2016, Mithra also launched *Gyn&Co*, a website focused on identifying and supporting the health needs of women. The website offers the company valuable insights into the real-life questions and concerns of women, which in turn helps to ensure that Mithra remains at the forefront of developing innovative therapeutics for women's health.

REVENUES OF OVER EUR 22.5 MILLION

OF WHICH LICENSE SALES ACCOUNT FOR EUR 5.7 MILLION

BALANCE SHEET TOTAL OVER EUR 172.7 MILLION AND A CASH POSITION OF EUR 45.8 MILLION

#### Commercial

Mithra continued to demonstrate its position as a leading player in the Benelux women's health market, with a market share in volume (cycles of treatment) of contraception of more than 45% in Belgium and more than 30% in the Netherlands. While pricing pressure led to lower revenues for the generic business (EUR 17 million vs EUR 18.8 million in 2015), total revenues increased to EUR 22.5 million (vs. EUR 20.4 million in 2015), thanks to the Fuji Pharma partnership for Estelle®.

EUR 34.3 MILLION
INVESTMENT IN R&D
DRIVEN BY E4-BASED
CLINICAL PIPELINE





# Letter to Shareholders

Dear Shareholders, colleagues and partners,

In 2016 and early 2017, we achieved a number of key milestones and accelerated Mithra's transformation into a leading R&D-focused women's health company.

Today, Mithra's business model is based around three key pillars. Our highly promising E4 portfolio, a new chemical entity product family that includes the lead clinical programs for Estelle® and Donesta®; our Complex Therapeutics business which includes Myring™, Tibelia® and Zoreline®; and our full spectrum research, development and complex manufacturing CDMO facility.

Mithra's commitment to improving options for women through innovative medical solutions addressing unmet medical needs remains as strong as ever. The women's health market is valued at EUR 35.6 billion worldwide, and is growing 3% year on year8. However, current contraception and menopause products continue to present women with quality of life and safety concerns, such as thrombotic events and increased cancer risks. Mithra has made great progress with its E4-based programs to provide a solution to these issues, and aims to bring to market products with an improved benefit/risk ratio.

E4 is a native estrogen acting selectively in tissues that has demonstrated significant potential and benefits over current standards of care in women's health and beyond. Following approvals from regulators in Europe and North America, Mithra initated key E4 studies during 2016, including the international Phase III Estelle® studies for contraception and the international Phase II Donesta® study for vasomotor symptoms in menopause.

Earlier in 2016, E4 mass balance and food studies were completed, and important pharmacokinetic and hemostasis studies were initiated later in the year to support our clinical program, while further benefitting E4's product characterization and differentiation.

Estelle's® strong Phase II results and favorable hemostatic profile data were published in the prestigious peer-reviewed journal Contraception<sup>9</sup>. In 2016, the journal also published an article<sup>10</sup> demonstrating the good bleeding pattern and cycle control observed with different E4 combinations, which are important in the Estelle project.

Furthermore, in 2016 Mithra continued to strengthen its IP portfolio for E4 in contraception and menopause with additional formulation patents filed, bringing the total number of patents to 26.

Critically, we also established EU- and US-based advisory boards made up of key opinion leaders for both Estelle® and Donesta® programs, which have further endorsed the major potential of E4 while providing additional strategic guidance on our clinical development programs.

The potential of E4 was also validated by the partnership signed with Fuji Pharma, the Japanese leader in women health, for the commercialization of Estelle® in Japan and ASEAN markets. Post-period, this was followed by a binding term sheet signed with Fuji Pharma to commercialize Donesta® in Japan and ASEAN.

With regard to complex therapeutics, Mithra obtained European regulatory approval for Tibelia® as well as marketing authorizations in 12 countries, with 8 license and supply agreements signed. In H2 2017, the Company expects to confirm the extended product shelf life of Tibelia®, from 24 to 36 months, which the Board believes will be an attractive commercial differentiator for current and potential partners.

Based on Datamonitor 2014.

g Kluft C, Zimmerman Y, Mawet M, et al. Reduced haemostatic effects with drospirenone-based oral contraceptives containing estetrol versus ethinyl estradiol. Contraception 2016; 95: 140-147

Mithra's contraceptive vaginal ring, Myring™, gained further traction in 2016 with the successful manufacturing of the clinical batches and completion of bioequivalence studies in Europe and the US, which is an essential part of the regulatory filing process. Post-period, Mithra was pleased to announce a deal with Mayne Pharma (ASX: MYX) for the exclusive license to Myring™ in the US. The US vaginal ring market is estimated to be worth USD 780 million and represents 75% of the global market in terms of value, making this a key territory for the commercialization of Myring™.

All Mithra projects can today be housed in our integrated research, development and manufacturing facility (CDM0) inaugurated in September 2016, ahead of schedule. This facility will operate as a pharmaceutical ecosystem for our own projects and for partners interested in leveraging our expertise on a contract basis and for co-development. Thanks to the agreement signed with Mayne Pharma in February 2017, Mithra expects to produce Myring™ at its CDMO, and as part of Mayne Pharma's long-term exclusive sourcing commitment, Mithra is considering the expansion of its production capacity for Myring™ within the Mithra CDMO.

#### 2017 outlook

While the well-established commercial business in the Benelux will continue to generate revenues, additional revenue from business development operations is anticipated in 2017 for the complex therapeutics as well as the E4 programs. As the Estelle® and Donesta® studies progress, the Company is committed to accelerating partnering discussions in both the EU and North America for these two lead programs.

Other news expected in 2017 includes the GMP accreditation of the Mithra CDMO, with audits by the FDA to follow. Obtaining a first accreditation will be a major step forward for the Mithra CDMO, opening the way to follow-on accreditations for its different activities.

Plans to file for regulatory approval for Myring $^{\text{m}}$  in the US and the EU in Q2 2017 should further accelerate business development interest for this product.

Pharmacokinetic studies for E4 alone, as well as for the E4/Drospirenone combination (Estelle®), will continue in 2017 and the clinical evaluation of the QT interval (early QT study) analyzing the cardiovascular pro-arrhythmic potential of E4 is also expected. All of these studies should further contribute to the safety profile of Estelle® and of E4 in general.

We are very much looking forward to the outcome of these upcoming events and remain confident in the clinical development progress of our proprietary programs.

2017 promises to be another exciting year at Mithra, in which the Company resolutely pursues its mission to transform women's health by offering new choices through innovation.

Marc Coucke

François Fornieri



#### Strategy

Mithra's mission is to help transform women's health by offering new choices through innovation. With a particular focus on fertility, contraception and menopause, our goal is to develop, manufacture and commercialize products that meet women's needs for better safety and convenience. In 2017 the Company will continue to focus on its lead assets and look to pursue strategic partnerships for both the E4 pipeline as well as the complex therapeutics.

Commercially, Mithra aims to retain its leadership position in the Benelux contraceptive market throughout 2017, while further leveraging commercial partnerships in other regions. As communicated, the Company decided to put the subsidiaries in France and Germany on hold and to seek external distribution partners in these countries. The Company is also confident that its commercial experience will continue to provide value as it aims to maximize the market potential of upcoming products.



Building on the progress in 2016, Mithra is looking forward to further preparing the commercialization of its lead contraceptive product candidate Estelle®, working to select a suitable partner for the Phase III Donesta® study, and filing for marketing approval of its vaginal contraceptive, Myring™, in both Europe and the US in Q2 2017. The company believes that these developments, along with its innovative research, development and manufacturing facility in Liège, will further strengthen its position as a leading international player in women's health.

Following discussions with its international scientific boards as well as its Board of Directors, the Company now plans to partner its E4-based programs for territories including Europe and the US. Hence, for both Estelle® and Donesta®, Mithra is currently identifying potential partners and discussions are expected to ramp up in 2017. For Estelle®, partnership discussions should be seen in the context of the preparation for the commercial launch of Mithra's lead contraceptive product candidate. The partnering strategy for Donesta®'s Phase III trial will reduce upfront expenditure while maximizing product opportunities by working with well-established partners on the Phase III design, regulatory approvals and commercialization.

The later-stage E4-based programs Estelle® (Phase III) and Donesta® (Phase II) currently hold the greatest value. However, the Board believes that early-stage non-core indications for E4 in neuroprotection and wound healing may also provide significant value and interesting partnering opportunities in the future, demonstrating the broad clinical potential of E4.

With regard to complex therapeutics, an important milestone will be the submission of Myring™ for marketing approval in Europe and the US in 2017, following the successful completion of bioequivalence studies with Nuvaring®.

Updates on Zoreline®'s 1-month and 3-month implant are expected in H2 2017, and Mithra remains committed to finding a partner for co-development and commercialization.

The significant investment in the development of Mithra's advanced pipeline, especially the E4-based products, is expected to continue in 2017. Mithra is confident that it can accelerate its partnership discussions in view of the significant potential of its programs to transform options for women in the large and fast-growing segments of safe contraceptives and HT solutions.

# Estetrol

#### E4 – The first NEST™: Native Estrogen Acting Selectively in Tissues

The unmet medical need for an estrogen with an improved benefit/risk profile remains strong. In light of the preclinical and clinical research to date, E4 (Estetrol) could play that role. E4 is a natural estrogen that is produced by the human fetus passing in maternal blood at relatively high levels during pregnancy. Recent E4 research indicates potential advantages over existing estrogens on the market.

> Thanks to its favourable pharmacodynamic and pharmacokinetic profile, its tolerability and its safety margin, E4 potentially represents a major breakthrough in various therapeutic fields like contraception and menopause.

Mithra possesses 26 patent families to date, ranging from E4 synthesis to its use in a broad range of indications such as cancer treatment (breast and prostate cancer, in particular), dermatology (e.g. wound healing) and musculoskeletal pain.

#### The potential benefits of E4

- Favorable VTE risk profile<sup>11</sup>
- Lower breast pain and lower carcinogenic risk profile in the presence of E212,13
- Favorable risk of drug-drug interaction<sup>14</sup>
- Minimal increase of triglycerides<sup>15</sup>
- Excellent cycle control and improved spotting<sup>16</sup>, good user acceptability, body weight control, and general well-being<sup>17</sup>

<sup>11</sup> Kluft C et al., Contraception. 2016; 12 Gerard C et al., Oncotarget. 2015;6(19):17621-36; 13 Visser M et al., Horm Mol Biol Clin Invest. 2012;9:95-103; 14 Visser M et al., Climacteric. 2008;11 Suppl 1:64-8; 15 Mawet M et al., Eur. J. Contracept. Reprod. Healthcare 2015:1-13;

Apter D. et al., Contraception. 2016;94(4):366-73;

We are bringing potentially better therapeutic options to Women

Maud Jost, Estetrol Project Leader

#### **Advisory boards**

In 2016, Mithra has set up 2 scientific committees, composed of European and North American experts in gynecology, to support the next development steps of its products candidates based on E4, Estelle® and Donesta®, in Europe and North America.

The committees are also advising Mithra on the clinical relevance and the added value of Estetrol in the contraception and menopause fields, and they are working with Mithra to confront development plans with market needs.

#### Further strengthening E4's IP

Mithra obtained further patents to protect E4's synthesis process in additional territories such as Europe, Mexico, Hong Kong and Chile. The optimisation of the E4 synthesis will significantly drive down costs, while limiting the environmental print of the synthesis.

The Company has also filed patent applications for sublingual forms of E4-based products and formulations. These additional formulation patent filings reinforce Mithra's IP position and could offer a protection period running until 2036.

Post period-end, the US Patent and Trademark Office (USPTO) issued a Notice of Allowance for US Application Serial Number 14/238,310, a patent which covers 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.

//

I would say E4 is a revolution for healthcare but it is the result of a progressive and natural process of evolution. E4 has been carefully selected by Mother Nature over millions of years, and it most probably has a very important role and greater therapeutic potential in comparison to many synthetic molecules that are developed by the industry. Together with the E4 preclinical and safety studies performed to date, this unique and differentiating aspect of E4 means that we have great confidence with respect to the positive outcome of the trials. , ,

Prof Jean-Michel Foidart

# Estelle®

Estelle® is a combined oral contraceptive product candidate composed of 15 mg Estetrol (E4) and 3 mg Drospirenone (DRSP). The Estelle® program has now completed recruitment for its Phase III clinical trial in Europe and Russia, while Phase III recruitment is still ongoing in the United States. The study details can be found on Clinicaltrial.gov database under the name *E4 Freedom*: MIT-Es0001-C302 (US/Canada) NCT02817841 and MIT-Es0001-C301 (EU/RU) NCT02817828.



## The European Phase III study design (MIT-Es0001-C301)

The European Phase III Estelle® study design is an open-label single-arm study that enrolled at least 1550 subjects aged 18-50 years of whom 1350 subjects are aged 18-35 years.

The objectives of the study are to evaluate the contraceptive's efficacy, cycle control, and the general safety and acceptability of the 15mg E4/3mg DRSP combination oral contraceptive pill in healthy women aged 18-50 years old.

The study is taking place in 69 centers across Europe and Russia, and will involve the participation of the study ubjects over a period of 12 months (13 cycles, 1 cycle = 28 days).

#### Primary outcome

 Contraceptive efficacy in the 18-35 year old population based on the Pearl Index<sup>18</sup> (PI)

#### Secondary outcomes

- Contraceptive efficacy in the 18-50 year old population based on the PI and life table analysis
- · Cycle control and bleeding profile
- Safety and tolerability
- Subject's well being (measured by two questionnaires)
- Endometrial safety (in a subset of subjects)

# The North American Phase III study design (MIT-Es0001-C302)

The North American Phase III Estelle® study design is an open-label single-arm study that is expected to enroll at least 2000 subjects aged 16-50 years of whom 1800 subjects are aged 16-35 years.

The objectives of the study are almost identical to those of the European study. However, the North American study will not include the endometrial surveillance. Instead it will specifically study the impact of covariates of the North American study population, in particular the age and body mass index (BMI).

The study is taking place in approximately 67 centers across the United States and Canada over a period of 12 months.

#### **Primary outcome**

 Contraceptive efficacy in the 16-35 year old population based on the Pearl Index<sup>19</sup> (PI)

#### Secondary outcomes

- Contraceptive efficacy in the 16-50 year old population based on the PI and life table analysis
- Cycle control and bleeding pattern
- Safety and tolerability
- Subject's well-being (measured by two questionnaires)
- · Population PK sub-study

<sup>18.19</sup> A standardized measurement of contraceptive methods calculated as the number of contraceptive failures per 100 women divided by the years of exposure.

### Estelle® key program developments in 2016

- Mithra initiated Phase III studies in the US and Canada as well as in Europe and Russia for its lead compound, Estelle<sup>®</sup>.
- In April 2016, Mithra announced top-line food effect study results for Estelle®, a mandatory first step before commencing the Phase III trial. In July 2016, the start of the Phase III clinical trial of Estelle® was approved by regulators in the US and Canada.
- Top line results of the Phase I study evaluating the effect of single, multiple and supratherapeutic oral doses of E4/DRSP combinations (up to 5 times the therapeutic dose) on safety, tolerability and PK parameters showed a good tolerability in all combinations and complete PK data.
- The first subjects in the European study, which is taking place in Sweden, Poland, Norway, Belgium, Finland, Germany, Hungary, Czech Republic and Russia, were screened in June 2016, and in September 2016 patient enrollment started for the US study.

# Estelle® post period results and prospects for 2017

- Post period, Mithra announced in February 2017 that it completed recruitment into the European arm of its Phase III study, with 1709 subjects screened, of which at least 1550 are expected to qualify for enrollment into the study.
- The Phase III Estelle® studies are expected to report top line results between Q3 2018 and Q1 2019.
- In 2017, we expect the evaluation of the QT assessment for Estelle® as well as the results of completed pharmacokinetic profile for E4 alone (MIT-Es0001-C102).

<sup>&</sup>lt;sup>20</sup> Apter D, Zimmerman Y, Beekman L, et al. Bleeding pattern and cycle control with estetrol-containing combined oral contraceptives: results from a phase II, randomised, dose-finding study (FIESTA). Contraception 2016; 94: 366-73.

<sup>21</sup> Kluft C, Zimmerman Y, Mawet M, et al. Reduced haemostatic effects with drospirenone-based oral contraceptives containing estetrol versus ethinyl estradiol. Contraception 2016; 95: 140-147

#### **Expected newsflow**

#### H2 2017

completion of pharmacokinetic profile with results from study (MIT-Es0001-C102) with E4 alone expected

#### H1 2018

Results of hemostasis study

#### H2 2018

Complementary data on ovarian function inhibition

#### Prestigious peer-reviewed Estelle® publications

In 2016, two additional scientific articles were published in the peer-reviewed journal *Contraception*. The first article is based on the results of the E4 Fiesta Phase II study. This study showed that of the four treatment modalities investigated, the 15 mg of E4/DRSP combination has the most favorable bleeding pattern and cycle control and is the preferred combination for further Phase III clinical development<sup>20</sup>.

The second article is a scientific paper highlighting the reduced hemostatic effects of the E4/DRSP combination, namely the Estelle® product candidate developed by Mithra, in a comparative study with another combined oral contraceptive. The published results suggest a low procoagulant effect of the E4/DRSP combination, which should be clinically verified for low antithrombotic side effects<sup>21</sup>.



# Donesta®



#### Primary outcome:

To define the minimum effective dose by evaluating changes in frequency and severity
of moderate to severe VMS (hot flushes). In total five doses will be tested in this blinded
study, including placebo

#### Secondary outcomes:

- To evaluate the effects of different doses on vulvovaginal atrophy, on vaginal maturation index and on vaginal pH
- To evaluate additional secondary endpoints, including evaluation of bone parameters, lipid & glucose metabolism, hemostatic laboratory variables, PK and women satisfaction
- · To evaluate safety, including change in endometrial thickness

#### Key program developments in 2016

Following discussions with regulatory agencies as well as recommendations from its international clinical advisory boards, the Company decided to expand the protocol for the study and amend patient exclusion criteria.

The amended study protocols is expected to generate significant additional safety and efficacy data and provide a stronger platform for the Phase III program. In particular, the protocol includes specific steps related to endometrial safety to rule out endometrial hyperplasia and subject exclusion criteria based on lipid levels. Importantly, in addition to assessing the effect of E4 on reduction of hot flushes, the protocol will evaluate a series of important parameters, including bone metrics and patient satisfaction. It will also provide a detailed understanding of key safety issues including the E4 coagulation profile and lipid and glucose metabolism.

In September 2016, Mithra contracted another CRO, Synteract HCR Inc., with specific expertise in women's health, to support patient recruitment and site management for the Phase II study. The change of CRO is boosting recruitment, thanks to the addition of new sites and new motivational tools for investigators.

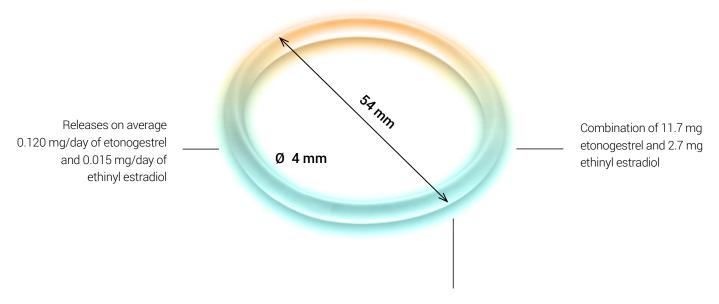
#### **Prospects for 2017**

Post-period, Mithra's scientific advisory boards in both Europe and North America provided further support for the amended Phase II study protocol and for further development and commercialization of Donesta®. Moreover, data show that the EUR 6 billion HT market is fast-growing, positioning Mithra well for partnering discussions following the Phase II Donesta® study. IMS Health data show a CAGR of 10.3% for the global menopause market over 2012-2016. According to Datamonitor<sup>22</sup>, the market could reach EUR 12.4 billion in the years ahead.

In order to maximize the global potential of Donesta® and spread development costs and risks, the Board has decided to seek development partners as early as Phase III. Mithra is strongly committed to accelerating its business development efforts to detect the best possible partners for different geographies, including the US and the EU.

<sup>&</sup>lt;sup>22</sup> Datamonitor 2014.

# $Myring^{TM}$



Ethylene vinylacetate copolymers

Myring<sup>™</sup> is a flexible contraceptive vaginal ring made of ethylene vinylacetate copolymers, and contains a combination of 11.7 mg etonogestrel and 2.7 mg ethinyl estradiol. When placed in the vagina, each ring releases on average 0.120 mg/day of etonogestrel and 0.015 mg/day of ethinyl estradiol over a three-week period of use, in line with the original vaginal ring, Nuvaring<sup>®</sup>.

The ring remains in place for three weeks, after which it is removed for a one-week break. Then, there usually is withdrawal bleeding, and a new ring is inserted one week after the last ring was removed.

Myring<sup>™</sup> has been shown to be bioequivalent to the Nuvaring<sup>®</sup> vaginal ring, which remains under patent protection until April 2018 in the US and Europe.

#### Key program developments in 2016

In March 2016, Mithra announced the completion of the formulation development for Myring™.

In December 2016 and January 2017, Mithra announced the results of two bioequivalence studies, which demonstrated that Myring™ is bioequivalent to the branded European and US version of NuvaRing®.

Production of the first technical and clinical batches by the Mithra CDMO started in October 2016. Following the successful completion of the initial technical batches, Mithra transferred manufacturing to the CDMO.

In September 2016, Mithra submitted an application for the manufacturing authorization for Myring™ at its production facility to the Federal Agency for Medicines and Health Products in Belgium (AFMPS).

### Post period news and prospects for 2017

Post period, Mithra announced an agreement for the exclusive licensing of Myring™ and its commercialization in the US with Mayne Pharma, the second-largest supplier of oral contraceptives in the US market. As part of the agreement, Mayne Pharma paid EUR 2.4 million upon signature and will pay further milestones of at least EUR 10.0 million following approval by the US FDA. Currently, the US market for biocompatible contraceptive rings is worth USD 780 million, which represents approximately 30% of the total global market by volume and over 75% by value, making this a key territory for the commercialization of Myring™ <sup>23</sup>.

Importantly, Mithra will produce Myring™ at its CDMO, and given Mayne Pharma's long-term exclusive sourcing commitment, Mithra is considering the expansion of its production capacity for Myring™.

AFMPS's GMP audit of Mithra CDMO took place in February 2017, and Mithra expects to announce a further update regarding its findings in Q2 2017. Receiving of GMP approval will enable Mithra to ship its first commercial batches of Myring™ into the EU.

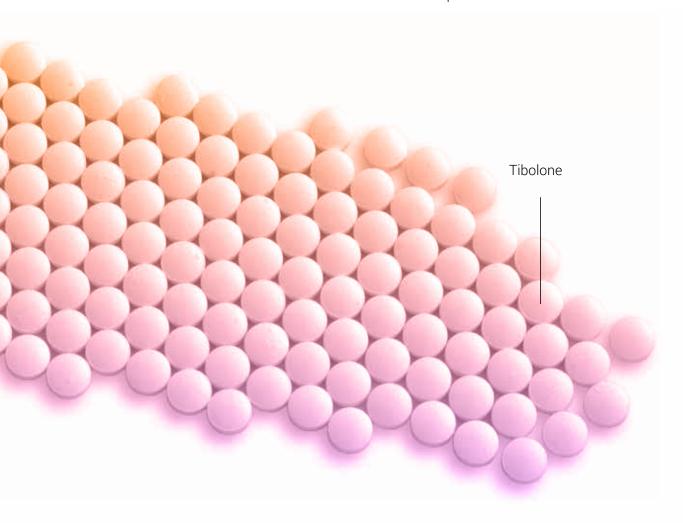
Mithra intends to file for marketing approval for Myring™ in both Europe and the United States as of Q2 2017.

Formulation Clinical development Registration

# Tibelia®

Tibelia® is a therapeutic solution developed by Mithra and composed of tibolone, a synthetic steroid for use in hormone therapy.

Tibelia® targets two indications of the original product, Livial®: treatment of estrogen deficiency symptoms in postmenopausal women and prevention of osteoporosis in postmenopausal women at high risk of fractures who are intolerant of, or contraindicated for, other medicinal products approved for the prevention of osteoporosis.



# Key program developments in 2016

In December 2016, Mithra announced that it obtained Marketing Authorizations (MA) for the commercialization of Tibelia® for use in hormone therapy in the UK, Belgium, Holland, Luxembourg, Spain, Portugal, Germany, Hungary, Poland, Norway, Sweden and Finland.

Mithra also signed eight License and Supply Agreements for Tibelia® in a number of territories in and outside of Europe. These agreements represent a double digit deal size.

#### Prospects for 2017

In January 2017, Mithra obtained additional MAs for Greece and Italy. A French authorization is pending. The Company also expects to sign additional agreements in other territories, and the product will be launched in Sweden, Finland and Italy during 2017.

Trends analysis indicate a potential shelf-life of 36 months for Tibelia® compared to 24 months for competitor products, based on improved formulation stability. An evaluation of the 36-month shelf life is planned for H2 2017.

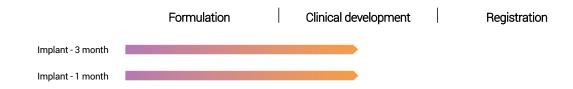
Formulation Clinical development Registration

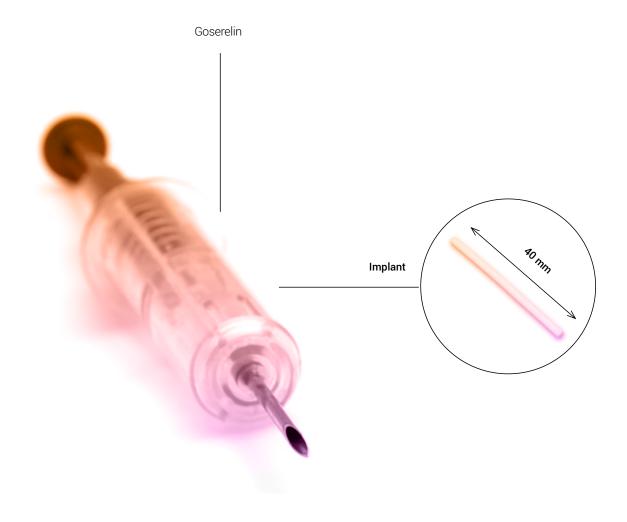
# Zoreline®

Zoreline® is a biodegradable, subcutaneous implant for prostate and breast cancer and benign gynecological conditions (endometriosis, uterine fibroids).

Mithra is developing both a one-month implant, containing 3.6 mg of goserelin, for combined therapies in breast cancer, and a three-month implant with 10.8 mg of goserelin, to be used in the field of prostate cancer.

The one-month implant for breast cancer represents a market value of EUR 202 million, while the market for the three-month implant for prostate cancer is worth EUR 404 million<sup>24</sup>.





#### Key highlights in 2016 and prospects for 2017

In March 2016, Mithra announced that the PD study results for the 3-month implant showed that more than eight patients failed to respond to the current formulation. The PK study, which compares the safety profile with the originator product, Zoladex®, is currently in its final stages and the full clinical study report is expected in Q2 2017.

For the 1-month implant, the PK study is currently ongoing and the clinical study report is expected in H2 2017.

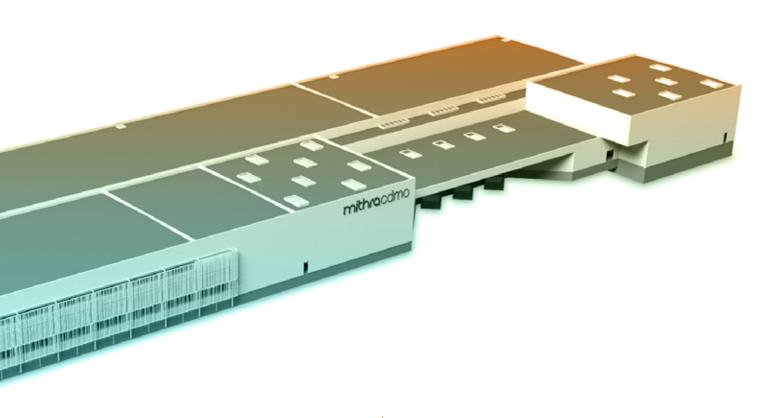
Mithra remains committed to finding a partner to co-develop and commercialize Zoreline®, in line with the Company's strategy to partner with leaders in women's health for its different product candidates.





# Mithra CDMO

Fully integrated ecosystem for state-of-the-art research, development & manufacturing



On September 30 2016, Mithra celebrated the opening of its CDMO facility, specialized in polymeric forms, sterile injectables and hormonal tablets.

#### Phase '

Polymeric forms - Implants - Sterile injectables Completed by 2016

#### Phase 2

#### **Hormonal Tablets**

Completed by 2019

#### The strategic rationale for operating an in-house CDMO<sup>25</sup>

Maintaining its own CDMO facility enables Mithra to directly support the research, development and manufacturing of its product candidates, and to keep its expertise in-house for its key polymer technology and E4-based products.

It also allows Mithra to operate independently from third parties when developing and manufacturing its own therapeutic solutions.

Furthermore, the facility offers third-party opportunities for the development and production of polymeric forms, sterile injectables and hormonal tablets. There is a growing interest in such capabilities, as larger companies engage in outsourcing to de-risk their supply chain and use contract manufacturing sites.

In 2016, Mithra signed a 20-year exclusive license and supply agreement for Estelle® with Fuji Pharma, which includes an exclusive supply obligation for the duration of the agreement. In the future, this could provide the Mithra CDMO with a steady flow of production work for E4-based products, and an important source of revenue. A term sheet for Mithra's product candidate in menopause, Donesta®, signed early 2017, also comprises an exclusive supply obligation for the duration of the contract.

Under the agreement with Mayne Pharma for the exclusive license for Myring™ in the US, Mithra will produce Myring™ at its CDMO, and Mithra is hence considering production capacity for Myring™.

#### Full range of services

#### 1. Drug Delivery Services

- Pharmaceutical development
- Clinical supply manufacturing
- Stability studies
- · Contract manufacturing
- Logistics and supply chain

#### 2. Supporting services

- Quality assurance
- Regulatory services

#### Major milestone in 2016

In September 2016, Mithra announced the completion of Phase I (for polymeric forms, implants and sterile injectables) and the official opening of its CDMO. The second and final phase of construction is on track to be completed in H1 2019 within the allocated budget (EUR 25.8 million). This phase is dedicated to tablet manufacturing and is supported by the Walloon region through a non-refundable grant.

<sup>&</sup>lt;sup>25</sup> Contract Development Manufacturing Organization



# About Women's Health

In March 2016, Mithra launched *Gyn&Co*, a website focused on identifying and supporting the health needs of women. The aim is to keep a finger at the pulse of women's questions and concerns and to ensure that Mithra remains at the forefront of developing innovative products in women's health.

This website provides information on women's health throughout their life by using a range of interactive media and tools. Every stage of a woman's life brings changes and questions and sometimes triggers fear and anxiety. *Gyn&co* addresses issues like puberty, menstruation, contraception, pregnancy, infertility, menopause, hygiene and gynecological conditions. A wide range of experts have contributed to *Gyn&co* and agreed to respond to questions within their specialism, providing women with a reliable source of information and making them better informed.

# Qualitative surveys to listen to women's needs

Since its creation, Mithra Pharmaceuticals has been inspired by women and has been consistently committed to improving women's lives through innovative products that are accessible to all women.

In 2015, Mithra decided to conduct a unique global study to gain a better understanding of women's health needs. This unprecedented qualitative study involved 870 women aged 16-68 in four different countries (Brazil, Germany, France and Belgium), offering them the opportunity to share their experiences and concerns. Over 40,000 posts and comments were gathered in just three weeks.



www.gynandco.be

# Financial Highlights

#### Figures presented below are management figures

Thousands of EUR (€)	FY16 Actual	FY15 Actual
Revenues	22.468	20.435
Cost of sales	(9.029)	(10.195)
Gross Profit	13.439	10.240
Research and development expenses	(34.137)	(9.585)
General and administrative expenses	(7.394)	(7.074)
Selling expenses	(7.510)	(4.611)
Other operating income / expenses	677	321
Total operating charges	(48.364)	(20.949)
REBITDA <sup>26</sup>	(34.926)	(10.709)
Non recurring costs	_	(2.894)
	(1.050)	` ,
Depreciations & amortisations	(1.050)	(664)
EBIT	(35.976)	(14.267)
Financial result	(4.660)	2.410
Share of (loss)/profit of associates		(2.758)
Result before taxes	(40.635)	(14.615)
Income taxes	5.548	4.794
	,	/a- a- a- a-
Net result for the period	(35.087)	(9.821)

<sup>&</sup>lt;sup>26</sup> Recurring EBITDA

Gross profit increased by EUR 3.199k to EUR 13.439k, mainly thanks to the first major partnership agreement for Estelle® with Fuji Pharma. The performance in the Belux market slightly declined in 2016, but Mithra was able to partly compensate the price decrease by growing sales volumes.

Investments in Mithra's innovative product portfolio (mainly the start of the Phase III studies for Estelle® and Phase II study for Donesta®) have driven the increase in R&D expenses by EUR 24.5k to EUR 34.14k.

General and Administrative expenses increased by EUR 320k and amount to EUR 7.394k due to the further strengthening of the R&D management team for the E4-based programs.

Selling expenses increased by EUR 2.899k to EUR 7.510k, mainly driven by commercial operations in France and Germany.

As a result of the increase in R&D expenditure for the E4 programs in contraception and menopause, the REBITDA shows a loss for 2016 of EUR 34.926k.

The net financial income in 2015 was the net result of a gain realized on the set-up acquisition of Novalon (see financial note 9.5.3) and financial expenses related to the changes in fair value of the contingent liability for the Estetra acquisition. In 2016, there was a strong increase in the fair value accounting of Estetra earn-outs (as explained in the financial note 9.16.3), so a liability on the balance sheet, which had to be recognized in the income statement as financial expenses (so a loss in earnings).

The income taxes in 2015 and 2016 are still the result of temporary differences and tax losses carried forward, and this is hence a non-cash item.



# Shareholder Structure François Fornieri<sup>27</sup> 32,61% **Free Float** 26,77% Marc Coucke<sup>28</sup> 16,49% Meusinvest SA 16,09% OGEO Fund OFP 4,76% Bart Versluys<sup>29</sup> 3,28%

<sup>&</sup>lt;sup>27</sup> François Fornieri formerly also held his shareholding partially through Mithra Participations (a société civile de droit commun) of which he is the director, but which was resolved on 21 December 2016. As disclosed previously, François Fornieri also holds warrants entitling him to subscribe 1,211,100 additional shares of Mithra.

<sup>&</sup>lt;sup>28</sup> Marc Coucke holds his shareholding partially through Alychlo NV and Mylecke Management Art & Invest NV, which he both controls.

<sup>&</sup>lt;sup>29</sup> Bart Versluys holds his shareholding through Scorpiaux BVBA and Versluys Bouwgroep BVBA, which he both controls.

18 April 2017

Annual Report 2016 (available online)

18 May 2017

Ordinary General Shareholders' Meeting

21 September 2017

Half Year 2017 Results

# Financial Calendar 2017

# Board of Directors

#### Marc Coucke,

Chairman, Non-executive Director

#### François Fornieri

Executive Director

#### Jean-Michel Foidart

**Executive Director** 

# Philippe Suinen Independent Director

# **Jacques Platieau** Independent Director

#### Koen Hoffman

Independent Director

#### Marc Beyens

Non-executive Director

#### Guy Debruyne

Non-executive Director

#### Gaëtan Servais

Non-executive Director

#### Freya Loncin

Non-executive Director

# Christiane Malcorps Non-executive Director

#### **Eric Van Traelen**

Company Secretary



# Our Executive Management Team



François Fornieri Chief Executive Officer

Mr François Fornieri has almost 30 years of pharmaceutical experience with a strong focus on women's health. He obtained a degree in Chemistry and is the founder and CEO of the Company.

François previously worked for Bayer-Schering and was also co-founder of Uteron Pharma, which was sold to Watson/Actavis (NYSE: ACT) in early 2013.

François has been elected 2011 *Manager of the year* by the Belgian business magazine Trends/Tendances.



Christophe Maréchal
Chief Financial Officer

Mr Christophe Maréchal was Director, Group Treasury and Credit Risk Management, at Hamon Group (Euronext Brussels: HAMO), an engineering and contracting company. He has more than 20 years of international financial experience in the industrial, telecommunications, manufacturing and banking industries, including M&A, operational and financial strategy, and tactical initiatives to drive long-term business growth.

Before joining Hamon Group in 2006, Mr Maréchal held a number of positions at France Telecom Group in Paris, London and Brussels, including Deputy Group Treasurer. He holds a Masters in Business Administration from the University of Liège, Belgium, and studied econometrics at the Katholieke Universiteit Brabant, Tilburg, Netherlands.

#### Michaël Dillen

Chief Legal Officer

Mr. Michaël Dillen has 10 years of experience in various legal positions, predominantly oriented towards the healthcare sector. Michaël initiated his career as a lawyer, where he developed a legal practice focused on corporate and commercial advisory towards 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.

Michaël holds a masters degree in law, LL.M. degrees in both health law and business law (University of Antwerp and Queen Mary and Westfield College, University of London), as well as a masters degree in business (Solvay Business School).



#### Jean-Michel Foidart

President of the Scientific advisory board

Prof Jean-Michel Foidart co-founded Mithra Pharmaceuticals SA and Uteron Pharma SA.

Through his membership of international research centers as well as his academic and industry career, he has extensive knowledge of reproductive medicine.

He trained in Gynecology at the University of Liège where he also obtained a PhD in cell biology and biochemistry. He is the former head of the Gynecology and Obstetrics department at the University of Liège, the general secretary of the European Society of Gynaecology (ESG) and member of multiple editorial boards of international peer-reviewed journals.

Prof Foidart was awarded the *Bologne-Lemaire Prize* from Institut Destrée (Walloon of the year) in 2011.



## **Valérie Gordenne** *Chief Scientific Officer*

Ms Valérie Gordenne has over 18 years of experience in the pharma industry with a strong focus on R&D, (non)clinical trials, regulatory affairs and manufacturing. She holds a Master Degree in Pharmaceutical Sciences (Industrial Pharmacist) from the University of Liège.

She started her career in Research and Development for a medium size pharmaceutical company called SMB Technology as Project Manager and later, she became Qualified Person for a manufacturing site dedicated to investigational medicinal products.

In 2004 she joined Mithra as Qualified Person where her responsibilities also included Regulatory Affairs for the pre- and post-marketing portfolio. Between 2008 and 2012 she acted as General Manager of Odyssea Pharma SA, the site dedicated to hormonal intrauterine system Levosert® which is now a subsidiary of Actavis (NYSE: ACT). Following the acquisition of Uteron Pharma by Watson/Actavis (NYSE: ACT), she returned to Mithra as Chief Scientific Officer.

Responsibilities at Mithra include R&D for the Company's portfolio, from discovery to marketing authorization.



**Jan Van der Auwera** *Chief Marketing Officer* 

Mr Jan Van der Auwera has over 30 years of experience in the pharma industry.

Before joining Mithra as Head of Marketing in 2012, Jan was business unit manager & business development manager of Pharmexx for 10 years. In this position he played a key role in the growth of Pharmexx in the Benelux market. Jan started his career as a sales representative with Serono and Schering.

Jan holds Master Degrees in Physical Education from the University of Brussels and in Marketing from the University of Antwerp.





**Rudi Meurs** *Chief Production Officer* 

Mr Rudi Meurs has over 30 years of operational experience, notably in the pharma industry, with focus on manufacturing and manufacturing engineering.

He holds a Master Degree in Sciences from the KU Leuven.

He started his career at Van Hool and LAG International, both manufacturers of industrial vehicles. In 1993, he joined Bosal International, a first tier supplier of exhaust systems for the automotive industry. Based at the headquarters in Belgium, he was responsible for the industrialization of OE-projects for OEM customers in Europe. In 1996, he started at Tenneco Automotive, a global US based supplier of shock absorbers and exhaust systems where he was promoted in 1998 as plant manager for the green field plant in Ghent. In 2006, he joined Merck as Plant Director. During his tenure at Merck, he developed strong manufacturing and operational knowledge specific to the pharma industry.

Rudi joined Mithra in 2014 as Head of Mithra Contract Development and Manufacturing Organization (CDMO).

#### Julie Dessart

Chief Communication Officer

Ms Julie Dessart has 10 years of experience in economical journalism, both in press and audiovisual media. She followed more than 80 Belgian companies in more than 25 countries to report on their exportation plans.

Before joining Mithra as Head of Communication in 2013, Julie Dessart was the owner of Sunzi SPRLU, a small company specialised in audiovisual strategy, which develops audiovisual concepts and corporate movies for companies. Julie Dessart started her career as a freelance journalist and debate moderator working for RH Tribune magazine, Finance Management magazine, WAW magazine, RTBF, TV5 Monde, UCM, A.W.E.X and other private and public clients.

She holds a Master Degree in Communication from the University of Louvain la Neuve and a Master Degree of European Political Sciences from the University of Brussels.





**Jean-Manuel Fontaine**Head of external affairs, Public Relations Officer

Mr Jean-Manuel Fontaine has over 18 years of experience in the pharma industry in manufacturing, supply chain and commercial positions.

He started his career at Pfizer in supply chain and manufacturing where he ensured ERP implementation and integration of Pfizer's Belgium manufacturing site. In 2001 he joined Lundbeck where he held various positions in sales & marketing in Belgium and France, notably for Cipralex®. In 2010, Jean-Manuel joined UCB's global marketing team as associate director, developing global campaign for the brand and driving business alignment across EU regions.

In 2013, Jean-Manuel joined Mithra to lead successively business development and public relations.

Jean-Manuel holds a Master in Pharmaceutical Sciences and MBA from Cornell University.



**Sofie Van Gijsel** *Investor Relations Officer* 

Ms Sofie Van Gijsel joined Mithra Pharmaceuticals in February 2017 as Investor Relations Officer.

Before joining Mithra, Ms. Van Gijsel was Co-CEO of the New York branch of KBC Securities USA.

In this role, Ms. Van Gijsel mainly focused on Equity Sales for the Benelux Biotech & Healthcare sector, including for corporate transactions such as IPOs. Ms. Van Gijsel holds a Master in Linguistics of Trinity College (Dublin) and a PhD in Linguistics from the University of Leuven (Belgium), as well as the Series 7.63 and 24 FINRA licenses.

Corporate
Governance
and Financial
Statements

1. R	Report of the board of directors	52
1.1.	Analysis of results / operations	52
1.2.	Balance sheet analysis	52
1.3.	Cash flow analysis	53
1.4.	Corporate governance statement	53
1.5.	Statements required by art. 34 of the royal decree of 14 November 2007	65
1.6.	Transactions within the authorized capital	67
1.7.	Acquisition of own Securities	67
1.8.	Use of financial instruments by the Group as per art. 96 of the Belgian Companies' code	67
1.9.	Circumstances that could considerably affect the development of the Group	67
1.10	O. Research and development	71
1.11	1. Conflicting interests of directors (Art. 523 of the Belgian Companies Code)	71
1.12	2. Independence and expertise of at least one member of the audit committee	73
1.13	3. Justification of the valuation rules	74
1.14	4. Appropriation of results	74
1.15	5. Important events subsequent to the accounting reference date	74
1.16	6. Grant of discharge to the directors and the statutory auditor	75
2. R	Responsibility statement	76
3. A	uditor report	77
3.1. end	Statutory auditor's report to the general meeting of the company Mithra Pharmaceuticals S.A. led December 31st, 2016	,
4. C	Consolidated Income Statement	79
5. S	statement of comprehensive income	80
6. C	Consolidated Balance Sheet	81
7. C	Consolidated statements of changes in Equity	83
8. C	Consolidated Cash Flow statement	84
9. N	lotes to the consolidated financial statements	85
9.1.	General Information	85
9.2.	Summary of Significant Accounting Policies	85
9.3.	Financial Risk Management	92
9.4.	Critical Accounting Estimates and Judgements	94
9.5.	Business combinations and asset deals	95
9.6.	Segment Information	99
9.7.	Intangible Fixed Assets	100
9.8.	Property, plant and equipment	101
9.9.	Goodwill	102
9.10	O. Investments in associates	102
9.1	1. Inventories	103
9.12	2. Trade Receivables and other current assets	103
9.13	3. Other short term investments	103

9.14.	Cash and cash equivalents	104
9.15.	Share capital	104
9.16.	Borrowings	105
9.17.	Trade payables and other current liabilities	108
9.18.	Financial instruments	108
9.19.	Revenue and other operating income	110
9.20.	Expenses by nature	111
9.21.	Employee benefit expenses	111
9.22.	Retirement benefit schemes	112
9.23.	Financial income and expenses	112
9.24.	Income tax expense	113
9.25.	Result per share	114
9.26.	Share-based payments	115
9.27.	Contingencies and arbitrations	115
9.28.	Commitments	116
9.29.	Related party transactions	116
9.30.	Events after the balance sheet date	118
9.31.	Mithra Pharmaceuticals companies consolidation scope	119
9.32.	Disclosure audit fees	120
9.33.	Condensed statutory financial statements of Mithra SA	121

### 1. Report of the board of directors

#### 1.1. Analysis of results / operations

#### Total income

Mithra's revenues increased almost 10% from EUR 20.4 million to EUR 22.5 million. The main reason for the increase in revenues was the deal with Japanese market leader Fuji Pharma for EUR 5.5 million (the 2015 results included EUR 1.8 million for a Zoreline<sup>®</sup> agreement with GSP). With regard to the generic business, Mithra gained market share and volume, but due to pricing pressure in the contraceptive market, revenues for this segment were EUR 16.7 million, some EUR 1.9 million lower than in 2015.

Gross margin for 2016 increased by EUR 3.2 million from EUR 10.2 million to EUR 13.4 million. The increase of 31% is due to the deal with Fuji Pharma (EUR 5.5 million) while in 2015 the gross margin included the Zoreline<sup>®</sup> deal with GSP for an amount of EUR 1.8 million.

#### R&D expenses

R&D investments rose from EUR 9.5 million to EUR 34.3 million, which amounts to an increase of EUR 24.8 million. This is mainly due to development expenses related to the Phase III of Estelle® and the Phase II of Donesta®, as well as API investments in E4 (EUR 21.4 million in 2016). Investments in Myring™, Zoreline® and Tibolone® accounted for EUR 7.6 million. The remainder of the R&D costs relate to payroll and consultancy expenses, and more specifically to start-up expenses at the level of the CDMO.

#### G&A expenses

G&A expenses are well controlled and have been lowered by EUR 2.1 million from EUR 10.3 million in 2015 to EUR 8.2 million in 2016. The difference is mainly attributable to the exceptional and one-time listing costs in 2015.

#### Selling expenses

Selling expenses increased in 2016 due to investments in the subsidiaries in Germany, Brazil and France. However, in the course of 2016, the Company decided to put the subsidiaries on hold and to seek external distribution partners in these countries. As a result, the selling structure decreased by the end of 2016, and expenses for these territories came to EUR 3.3 million on 31 December 2016.

#### Financial result

The financial result for 2016 amounts to EUR -4.6 million which was mostly driven by changes in fair value on existing earn outs, mainly for Estelle<sup>®</sup>.

The loss of the period before taxes amounts to EUR 40.6 million. This is an increase of EUR 26 million compared to 2015, driven by R&D expenses in 2016.

The tax result of the year shows a profit of EUR 5.5 million. This is a deferred tax asset to be offset against future taxable income. Taking this tax profit into consideration, the net loss for 2016 was EUR 35.1 million.

#### 1.2. Balance sheet analysis

As of 31 December 2016, the balance sheets showed a total of EUR 114.8 million in non-current assets, the largest part of which are other intangible assets (EUR 79.1 million). These intangible assets are the result of the acquired assets and represent the fair value of the assets, aside from Donesta®, which was acquired at purchase cost of EUR 8 million. The fair value mainly relates to Estelle® for an amount of EUR 30.7 million and to Zoreline® for an amount of EUR 24.4 million.

In the non current assets we note a considerable increase in tangible fixed assets (EUR 16.96 million at the end of 2016 vs. EUR 3.57 million in 2015). The increase relates to the investments at the level of the CDMO where Mithra is preparing the production of  $Myring^{M}$ .

Current assets at the end of 2016 represent a value of EUR 57.8 million, the bulk of which is the company's cash position of EUR 45.8 million on 31 December 2016.

The equity position at the end of the year decreased from EUR 127.4 million in 2015 to EUR 93.0 million in 2016. The decrease is primarily related to the loss booked in 2016.

Non-current liabilities increased to EUR 51.9 million at the end of 2016, compared to EUR 43.6 million in 2015, primarily due to the financing obtained for the CDMO facility as well as an increase of the fair value of the earn out for Estetra. Other loans of EUR 32.5 million represent the fair value debt towards the former owners of Estelle<sup>®</sup> for EUR 22.4 million and the former owners of Zoreline<sup>®</sup> for EUR 6 million.

The reduction in current liabilities to EUR 27.7 million (from EUR 34.5 million in 2015) is primarily attributable to the reimbursement of the short-term financing, compensated for by an increased deferred revenue position related to the Fuji agreement. (Note that this relates to the conditional part of the Fuji deal, which is currently not yet recognised as revenue.)

#### 1.3. Cash flow analysis

Full year cash flow amounted to EUR -51 million, which is composed of:

- Operating cash flows: EUR -24.7 million. The negative EBIT of EUR -35.9 million, the withholding taxes on the Fuji deal of EUR -1 million and the fair value impact on the refundable government advances of EUR -1.3 million are partly offset by an increase in trade payables (+ EUR 7.2 million), deferred revenues of the Fuji deal (+ EUR 4.5 million), depreciations (+ EUR 1 million) and a decrease in the Trade receivables and other receivables. For the sake of the cash flow analysis, the decrease of EUR -8.5 million in Other debts under the Trade payables & other current liabilities (see note 9.17) has been positioned under Business combinations transactions in the Investing cash flows
- Investing cash flows: EUR -24.6 million. The cash flows for the business combinations refer to the payment of EUR 8.5 million to GSP during H2 2016. Investments in tangible assets are predominately related to capex for the CDMO (EUR 13.2 million) while investments in intangible assets mainly include the products bought as part of the GSP deal.
- Financing cash flows: EUR -1.8 million. Reimbursement of financing mainly include the reimbursement of a short-term bridge financing of EUR 16.9 million as well as the normal reimbursements on existing financing facilities. Proceeds from financing primarily refer to the CDMO financing.

#### 1.4. Corporate governance statement

#### Reference code

The Corporate Governance of the Company is organized pursuant to the Belgian Companies Code (BCC), the Company's Articles of Association and the Company's Corporate Governance Charter (CGC).

The Company's CGC was adopted by the Extraordinary Shareholders Meeting of 8 June 2015 and has become effective upon completion of the offering and listing of the shares of the Company. It was drafted in accordance with the recommendations set out in the Belgian Corporate Governance Code, which was issued on 9 December 2004 by the Belgian Corporate Governance Committee and as amended on 12 March 2009, pursuant to Article 96, §2, section 1, 1 of the BCC and the Royal Decree of 6 June 2010 with regard to the appointment of the Corporate governance Code to be complied with by listed companies.

The 2009 Belgian Corporate Governance Code (BCGC) is available on the internet site of the Belgian Corporate Governance Committee (<a href="https://www.corporategovernancecommittee.be">www.corporategovernancecommittee.be</a>).

The CGC will be updated as required in the case of any change made to the Company's corporate governance policy. No update took place during the last financial year.

The Company's CGC, together with the articles of association of the Company, are available on the Company's website (<a href="www.mithra.com">www.mithra.com</a>), mentioning the date of the most recent update, in a clearly recognizable part of the Company's website under the heading "Investors", separate from the commercial information.

The Company being a listed company since 30 June 2015, the implementation of the principles of the Code and the BCGC was made, and the revised organization of the Company was implemented, gradually over the financial year. The Company's Board of Directors complies with the BCGC, and believes that certain deviations from its provisions were justified in view of the Company's particular situation.

These deviations include the following:

- Provision 2.1 BCGC: gender diversity. Since the IPO, the Board was mainly composed of men. The Company commits to build a diverse list of candidates for new positions in the future pursuant to Article 518bis of the BCC.
- Provision 5.2 BCGC: the Company decided not to appoint a formal internal auditor because of the size of the Company. However, the Audit Committee regularly evaluates the need for this function and/or commissions external parties to conduct specific internal audit missions and report back to the Audit Committee.

#### Capital & shares

On 31 December 2016, the share capital of Mithra amounted to EUR 22,789,993.24 as per Belgian GAAP and consists of 31,129,756 ordinary shares. All shares are equal and common (each having the same rights), and are fully paid up. The shares do not have a nominal value, but reflect the same fraction of the Company's share capital, which is denominated in euro. Each share entitles its holder to one vote. The total number of voting rights as at 31 December 2016 was 31,129,756.

The number of existing shares and the number of voting rights remain unchanged at 31 December 2016 and on the date of this report. No changes in the number of shares or voting rights have taken place in 2016.

The Company's shares are admitted to trading on the regulated market of Euronext Brussels, under the ticker "MITRA"

#### Other capital-related events of importance in 2016:

• There has been no other capital related event in 2016.

#### Shareholders & shareholder structure

#### Shareholders structure

Based on the transparency declarations the Company has received, the significant shareholders of the Company (i.e. above 3% of the outstanding voting rights) as at 31 December 2016 are:

Shareholder	Address	Number of voting rights	% of voting rights
François Fornieri <sup>1</sup>		10,150,800	32.61%
Marc Coucke <sup>2</sup>		5,133,124	16.49%
Meusinvest SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,008,766	16.09%
Ogeo Fund OFP	Boulevard Piercot, 46, B-4000 Liège, Belgium	1,481,700	4.76%
Bart Versluys <sup>3</sup>		1,020,200	3.28%
Free float		7,975,166	25.61%

- François Fornieri formerly also held his shareholding partially through Mithra Participations (a société civile de droit commun) of which he is the director, but which was resolved on 21 December 2016 As disclosed previously, François Fornieri also holds warrants entitling him to subscribe 1,211,100 additional shares of Mithra.
- 2. Marc Coucke holds his shareholding partially through Alychlo NV and Mylecke Management Art & Invest NV, which he both controls.
- 3. Bart Versluys holds his shareholding through Scorpiaux BVBA and Versluys Bouwgroep BVBA, which he both controls.

All percentages are calculated on the basis of the current total number of voting rights.

The most recent transparency declarations are available on the company's website www.mithra.com.

#### Shareholders' arrangements

To the Board's best knowledge, no shareholders' agreement exists among shareholders of the Company with respect to the Company.

The lock-up arrangements with KBC Bank Securities and ING Belgium NV (i.e. the Joint Bookrunners of the IPO) for a period of 12 months as from 30 June 2015 expired at the end of the said period and the standstill obligation regarding the sale or issuance of shares and similar financial instruments, subject to certain exceptions, covering a period of 365 days as from 30 June 2015, agreed on within the IPO of the Company also expired at the end of the said period. See Mithra's prospectus for more detailed information.

#### **Board of Directors**

#### Composition of the board

The Board of Directors currently consists of 12 members (with a minimum set out in the Articles of Association of three), 3 of which are Executive Directors (as member of the Executive Management Team) and 9 of which are non-executive Directors, including 3 independent Directors.

The roles and responsibilities of the Board, its composition, structure and organization are described in detail in Mithra's Corporate Governance Charter (available on Mithra's website). This Corporate Governance Charter specifies the criteria that directors must satisfy to qualify as independent directors.

Directors are appointed for a maximum term of four years, which is renewable.

#### The composition of Mithra's Board of directors is currently as follows:

Name	Position	Term 1	Nature of Mandate	Board of Directors Committee Membership	Attendance² to 2016 Board meetings
YIMA SPRL (permanent representative: Mr François Fornieri)	Managing director	2019	Executive	-	6/6
Mr François Fornieri	Director	2019	Executive	-	6/6
Mr Marc Beyens	Director	2019	Non-executive	-	4/6
CG CUBE S.A. (permanent representative: Mr Guy Debruyne)	Director	2019	Non-executive		6/6
Meusinvest SA (permanent representative: Mr Gaëtan Servais)	Director	2019	Non-executive	Audit Committee	6/6
EVA CONSULTING SPRL (permanent representative Mr Jean-Michel Foidart)	Director	2019 <sup>3</sup>	Executive		2/2
P4MANAGEMENT SPRL (permanent representative: Ms Christiane Malcorps)	Director	2019 <sup>3</sup>	Non-executive	-	
Alychlo NV (permanent representative: Mr Marc Coucke)	Director	2019	President Non-executive	Nomination and Remuneration Committee (Chair)	6/6

Name	Position	Term 1	Nature of Mandate	Board of Directors Committee Membership	Attendance <sup>2</sup> to 2016 Board meetings
Aubisque BVBA (permanent representative Ms Freya Loncin)	Director	2019 <sup>1</sup>	Non-executive	-	2/2
Ahok BVBA (permanent representative Mr Koen Hoffman)	Director	2019 <sup>3</sup>	Independent	Audit Committee (Chair)	2/2
P.SUINEN SPRL-S (permanent representative: Mr Philippe Suinen)	Director	2019	Independent	Audit Committee Nomination and Remuneration Committee	6/6
Mr. Jacques Platieau	Director	2019	Independent	Nomination and Remuneration Committee	6/6

- 1. The term of the mandate of the Director will expire immediately after the Annual Shareholders Meeting held in the year set forth next to the Director's name. Current directors were appointed at the Extraordinary Shareholders Meeting held on 8 June 2015, unless specified otherwise above.
- 2. The number of meetings that could be attended by each director is due to the nomination of new directors during the financial year.
- 3. EVA CONSULTING SPRL, AUBISQU BVBA and AHOK BVBA have been appointed temporarily as directors on 24/08/16, and P4MANAGEMENT SPRL on 24/02/17. Their final appointment will be put on the agenda of the next Shareholders Meeting.
- 4. BDS MANAGEMENT BVBA fulfilled a mandate of Director until 22/08/16 and attended 4 meetings of the Board of Directors. INVESTPARTNER SCRL fulfilled a mandate of Director until 24/08/16 and attended 0 meeting of the Board of Directors. H J Tijmen COELINGH BENNINK fulfilled a mandate of Director until 22/11/16 and attended 4 meetings of the Board of Directors. Mr Jean Sequaris died on 8/7/16 and fulfilled a mandate of Directoruntil such a date. He attended 2 meetings of the Board of Directors. Ms Christiane Malcorps fulfilled a mandate of Director from 22/11/16 until 24/02/17, date from which she has been replaced by her management company P4MANAGEMENT BVBA.

Mr. Fornieri acts both as Director and as permanent representative of YIMA SPRL and he effectively controls two votes at the meetings of the Board of Directors.

More detailed information on the Board's responsibilities, duties, composition and operation can be found on Mithra's website in the Corporate Governance Charter.

#### **Activity report**

In 2016, six Board meetings have been held (in case two distinct meetings take place successively, only one is taken into account hereinabove).

These Board meetings were mainly related to the financial results and financial reporting, including the half-year and annual accounts and budget, the Company's strategy, progress, important agreements or (expected) acquisitions, and continuous evaluation of the structure of the Company. Furthermore, Partenaire Conseil SPRL (permanent representative Eric Van Traelen) was appointed as Compliance Officer.

#### Performance evaluation of the board

Led by the Chair and assisted by the Nomination and Remuneration Committee (and possibly also by external experts) the Board conducts, every 3 years, a self-evaluation in respect of its size, composition, performance and those of its committees, as well as in respect of its interaction with the Executive Management. The evaluation shall have the following objectives:

- Assessing how the Board or the relevant Committee operates;
- Checking that the important issues are suitably prepared and discussed;
- Evaluating the actual contribution of each Director's work, the Director's presence at Board and Committee meetings and his constructive involvement in discussions and decision-making;
- Checking the Board's or Committee's current composition against the Board's or Committee's desired composition.

• The non-executive Directors annually assess their interaction with the Executive Management Team. In this respect, non-executive Directors meet at least once a year in absence of the CEO and the other executive Directors, if any. No formal Board decision can be taken at such meeting.

There is a periodic evaluation of the contribution of each Director aimed at adapting the composition of the Board to take account of changing circumstances. At the time of their re-election, the Directors' commitments and contributions are evaluated within the Board, and the Board ensures that any appointment or re-election allows an appropriate balance of skills, knowledge and experience to be maintained on the Board. The same applies at the time of appointment or re-election of the Chairs (of the Board and of the Board Committees).

The Board acts on the results of the performance evaluation by recognizing its strengths and addressing its weaknesses. Where appropriate, this will involve proposing new members for appointment, proposing not to reelect existing members or taking any measure deemed appropriate for the effective operation of the Board.

#### Audit committee

Although the Company currently does not qualify as a "large" listed company (as defined in Article 526*bis* of the BCC), the Board of Directors has voluntarily set up an Audit Committee, in line with the BCGC.

More detailed information on the Audit Committee's responsibilities can be found in the CGC, which can be found on Mithra's website.

The Chair of the Audit Committee report to the Board subsequent to each Committee meeting on its activities, conclusions, recommendations and resolutions. The Chair of the Audit Committee, on an annual basis, reports to the Board on the Audit Committee's performance.

#### Composition

The Audit Committee is composed of three members, which are exclusively non-executive Directors. Two of its members are independent Directors.

At least one of its members has the necessary expertise with regard accounting and auditing and, if possible, a majority of its members are independent Directors. The Board of Directors ensures that the Audit Committee has the necessary and sufficient expertise with regards to accounting, audit and finance, in order to fulfill its role in an adequate manner. The Chair of the Audit Committee is not the Chair of the Board of Directors. The CEO and CFO can attend the meetings of the Audit Committee in an advisory and non-voting capacity. At least twice a year, the Audit Committee meets the Statutory Auditor in order to discuss questions regarding its mandate, the audit procedure and, in particular, the potential weaknesses identified in the control.

The following Directors are members of the Audit Committee: AHOK BVBA (permanent representative: Mr Koen Hoffman) (Chair), P.SUINEN SPRL-S (permanent representative: Mr Philippe Suinen) and MEUSINVEST SA (permanent representative: M. Gaëtan Servais). AHOK BVBA (permanent representative: Mr Koen Hoffman) and P. SUINEN SPRL-S (permanent representative: Mr Philippe Suinen) are both independent Directors.

#### **Activity report**

The Audit Committee met five times in 2016. The statutory auditor was present at two of these five meetings.

The main topics discussed were the interim half-year and annual financial information and figures, the budget, the statutory auditor's external audit, internal control, risk management and compliance.

Attendance was as follows: AHOK BVBA (permanent representative: Mr. Koen Hoffman): 1/1, P.SUINEN SPRL-S (permanent representative Mr. Philippe Suinen): 5/5, MEUSINVEST SA (permanent representative: Mr. Gaëtan Servais): 1/1. Mr. Jean Sequaris sadly passed away on 8/7/16 and attended 2/3 meetings. BDS Management BVBA (permanent representative: Ms Barbara De Saedeleer: fulfilled a mandate of Director until 22/08/16 and attended 1/3 meetings. MEUSNVEST SA (permanent representative: Mr. Gaëtan Servais) has been designated as member of the Audit Committee on 24/08/16.

#### Nomination and remuneration committee

Although the Company did not qualify as a "large" listed company (as defined in Article 526quater of the BCC), the Board of Directors has voluntarily set up a Remuneration Committee, in line with the BCGC. As the Remuneration Committee also performs the task of a nomination committee, it is called the Nomination and Remuneration Committee.

The role of the nomination and remuneration committee is to make recommendations to the Board of Directors with regard to the (re-)election of directors and the appointment of the CEO and the executive managers, and to make proposals to the board on the remuneration policy for directors, the CEO and the executive managers.

The committee has also specific tasks. These are further described in the Company's CGC and Article 526quater of the Companies Code. In principle, the committee will meet at least two (2) times per year.

#### Composition

The Nomination and Remuneration is composed of three members, which are exclusively non-executive Directors. Two of its members are independent Directors.

The Nomination and Remuneration Committee has the necessary expertise in terms of the remuneration policy, which is evidenced by the experience and previous roles of its members.

The following Directors are members of the Nomination and Remuneration Committee: ALYCHLO NV (permanent representative: Mr Marc Coucke) (Chair), P. SUINEN SPRL-S (permanent representative: Mr Philippe Suinen) and Mr Jacques Platieau. P. SUINEN SPRL-S (permanent representative: Mr Philippe Suinen) and Mr Jacques Platieau are independent Directors.

The CEO is invited to attend the meetings of the Nomination and Remuneration Committee in an advisory and non-voting capacity. He does not attend discussions concerning his own remuneration.

The Chair of the Nomination & Remuneration Committee report to the Board subsequent to each Committee meeting on its activities, conclusions, recommendations and resolutions. The Chair of the Nomination & Remuneration Committee shall, on an annual basis, report to the Board on the Nomination & Remuneration Committee's performance. Every 3 years, the Nomination & Remuneration Committee reviews its terms of reference and its own effectiveness and recommends any necessary changes to the Board.

#### **Activity report**

The Nomination & Remuneration Committee met three times in 2016.

The main topics discussed were the preparation of the remuneration report, performance of the CEO and other members of the Executive Management Team, their remuneration, the composition of the Executive Management Team, and the assessment whether the contractual conditions giving right to bonuses to the CEO were met.

Attendance was as follows: ALYCHLO NV (permanent representative: Mr. Marc Coucke): 1/1, P.SUINEN SPRL-S (permanent representative Mr. Philippe Suinen): 3/3, Mr. Jacques Platieau: 1/1. Mr. Jean Sequaris died on 08/07/16 and attended 2/2 meetings. INVESTPARTNER SCRL (permanent representative: Marc Foidart) fulfilled a mandate of Director until 24/08/16 and attended 2/2 meetings. ALYCHLO NV (permanent representative: Mr. Marc Coucke) and Mr. Jacques Platieau have been designated as members of the Nomination & Remuneration Committee on 24/08/16.

#### Executive committee

The Board of Directors of Mithra has set up an Executive Management Team. The Executive Management Team is an advisory committee to the Board of Directors, which does not constitute a management committee ("comité de direction") under Article 524bis of the BCC.

The Executive Management Team's mission is to discuss and consult with the Board and advise the Board on the day-to-day management of the Company in accordance with the Company's values, strategy, general policy and budget, as determined by the Board.

The Executive Management Team shall, in preparation for each meeting of the Board, prepare a report to the Board on the day-to-day management of the Company, to be presented by the CEO to the Board. Such report shall contain a summary of all material resolutions discussed in the Executive Management Team over the relevant period.

More detailed information in the Executive Management Team's responsibilities can be found in the CGC, which can be found on Mithra's website.

#### Composition

At least all executive Directors are member of the Executive Management Team. The Executive Management Team is currently composed of ten members: the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Legal Officer (CLO), Chief Communication Officer (CCO), Public Relations Officer (PRO), Chief Production Officer (CPO), Chief Scientific Officer (CSO), the Chief Marketing Officer (CMO), the Investor Relations Officer (IRO), and the President of the Scientific Advisory Board. The Executive Management Team is chaired by the CEO of the Company. Furthermore, the Chair may invite additional personnel to attend a meeting of the Executive Management Team.

The current members of the Executive Committee are listed in the table below.

Name	Function
YIMA SPRL (permanent representative: Mr François Fornieri)	Chief Executive Officer, Chief Business Development Officer (Chair)
EVA CONSULTING SPRL (permanent representative: Mr. Jean-Michel Foidart)	Chair of the Scientific Advisory Board
CMM&C SPRL (Mr Christophe Maréchal)	Chief Financial Officer (CFO)
MIDICO BVBA (Mr Michaël Dillen)	Chief Legal Officer (CLO)
Sunzi SPRL (Ms Julie Dessart)	Chief Communication Officer (CCO)
Novafontis SPRL (Mr Jean-Manuel Fontaine)	Public Relations Officer (PRO)
Mr Rudi Meurs	Chief Production Officer (CPO)
Alius Modi SPRL (Mrs Valérie Gordenne)	Chief Scientific Officer (CSO)
Travel And Communication Consultancy ("TACC") BVBA (Mr Jan Van der Auwera)	Chief Marketing Officer (CMO)
Mrs Sofie Van Gijsel	Investor Relations Officer (IRO)

<sup>1.</sup> The scientific structure having been modified in an important manner, the Board replaced on 22/11/2016 the Scientific Committee by a Scientific Advisory Board not governed by the CGC.

During 2016 and up to the date of this report, the following changes occurred in the composition of the Executive management team:

ELITHO BVBA (Mr Michael Truyen) resigned from its function as Chief Legal Officer (CLO) and was replaced by MIDICO BVBA (Mr Michael Dillen) on 1 February 2017. VESTECO BVBA (Mr Steven Peters) resigned from its function as Chief Financial Officer (CFO) on 31 October 2016 and was replaced by CMM&C SPRL (Mr Christophe Maréchal) on 23 February 2017. EVA CONSULTING (Mr. Jean-Michel Foidart) became executive Director as from 1 January 2017. Mrs. Sofie Van Gijsel has been designated Company's Investor Relations Officer (IRO) on 6 February 2017.

#### **Activity report**

The Executive Management Team met regularly and at least once every month. The CEO reported and advised the Board on this day-to-day management at every Board meeting.

#### Remuneration report

#### Directors

#### Procedure applied in 2016 in order to create a remuneration policy and to determine the individual remuneration

The Nomination and Remuneration Committee recommends the level of remuneration for Directors, including the Chairman of the Board, which is subject to approval by the Board and, subsequently, by the Annual Shareholders Meeting.

The Nomination and Remuneration Committee benchmarks the Directors' compensation against peer companies. The level of remuneration should be sufficient to attract, retain and motivate Directors who match the profile determined by the Board.

Apart from their remuneration, all Directors will be entitled to a reimbursement of out-of-pocket expenses actually incurred as a result of their participation in meetings of the Board of Directors.

The level of remuneration of the Directors was determined at the occasion of the Company's Initial Public Offering on 8 June 2015 and explained in the Prospectus issued by the Company in that context. It has not been modified since then. The remuneration of the Directors will be disclosed to the Company's shareholders in accordance with the applicable laws and regulations.

The Directors' mandate may be terminated *ad nutum* (at any time) without any form of compensation. There are no employment or service agreements that provide for notice periods or indemnities between the Company and the members of the Board of Directors, who are not a member of the Executive Management Team.

Without prejudice to the powers granted by law to the Shareholders Meeting, the Board will set and revises at regular intervals the rules and the level of compensation for Directors executing a special mandate or having a seat in one of the committees, as well as the rules for reimbursement of the Directors' business-related out-of-pocket expenses.

Only non-executive Directors shall receive a fixed remuneration in consideration of their membership of the Board and the Committees of which they are members. Regarding the members of the Board of Directors that are members of the Executive Management Team, please see under the heading "Executive Management Team" on the Company's website.

Independent directors will not receive, in principle, any performance related remuneration, nor will any options or warrants be granted to them.

The Board may upon recommendation of the Nomination and Remuneration Committee propose to the Shareholders Meeting to deviate from the latter principle and grant warrants in order to attract and retain highly qualified independent Directors.

Executive Management Team members receive no additional compensation when invited to the Board.

#### Remuneration policy applied during 2016

The remuneration package for the non-executive Directors (whether or not independent) approved by the Shareholders Meeting of 8 June 2015 is made up of a fixed annual fee of EUR 20,000. The fee is supplemented with a fixed annual fee of EUR 5,000 for membership of each committee of the Board of Directors, and an additional fixed annual fee of EUR 20,000 for the Chairman of the Board. Changes to these fees will be submitted to the Shareholders Meeting for approval.

There is no performance related remuneration for non-executive Directors.

Apart from the above remuneration for non-executive Directors (whether or not independent), all Directors will be entitled to a reimbursement of out-of-pocket expenses actually incurred as a result of participation in meetings of the Board of Directors.

The total amount of the remunerations and the benefits paid in 2016, to the non-executive Directors (in such capacity) was EUR 255.835 (gross, excluding VAT), split as follows:

Name	Nature	Remuneration as Director	as Member of a committee	As Chair of the Board
Marc Beyens	Non-exec	20.000		
CG Cube	Non-exec	20.000		
CEFMA Consult	Non-exec	5.000		
Meusinvest	Non-exec	20.000	1.780,82	
Investpartner	Non-exec	12.986,30	3.246,58	
Prof. Coelingh Bennink	Non-exec	17.917,81	4.479,45	
Alychlo	Non-exec - Chair	20.000	1.780,82	7.123,29
BDS Management	Non-exec	12.822	3.205	12.822
Jean Sequaris	Independent	10.410,96	5.205,48	
P. Suinen	Independent	20.000	10.000	
Jacques Platieau	Independent	20.000	1.780,82	
Ahok	Independent	7.068,49	1.767,12	
Eva Consulting	Non-exec	7.123,29		
Aubisque	Non-exec	7.123,29		
Christiane Malcorps	Non-exec	1.360		

The table below provides an overview of the shares and warrants held by the current members of the Board.

Share-Warrantholder	Shares	%	Warrants	%	Shares and Warrants	%
YIMA SPRL (permanent representative: Mr François Fornieri) (CEO)	0	0.00%	0	0.00%	0	0.00%
Mr François Fornieri (permanent representative of YIMA SPRL) (together with YIMA SPRL)	10,150,800	32.61%	1,211,100	67.40%	11,361,900	34.51%
Marc Beyens	0	0.00%	0	0.00%	0	0.00%
G CUBE S.A. (permanent representative: Guy Debruyne)	343,200	1.10%	0	0.00%	343,200	1.04%
<b>Guy Debruyne</b> (permanent representative of CG Cube S.A.) (together with CG Cube S.A.)	0	0.00%	0	0.00%	0	0.00%
AHOK BVBA (permanent representative : Mr Koen Hoffman)	0	0.00%	0	0.00%	0	0.00%
Koen Hoffman (permanent representative of Ahok BVBA) (together with Ahok BVBA)	0	0.00%	0	0.00%	0	0.00%
Meusinvest SA (permanent representative: Gaëtan Servais)	5,008,766	16.09%	0	0.00%	5,008,766	15,21%
Gaëtan Servais (permanent representative of Meusinvest SA)	0	0.00%	0	0.00%	0	0.00%
Aubisque BVBA (permanent representative : Ms Freya Loncin)	0	0.00%	0	0.00%	0	0.00%
Freya Loncin (permanent representative of Aubisque BVBA) (together with Aubisque BVBA)	0	0.00%	0	0.00%	0	0.00%
Marc Coucke (permanent representative of Alychlo NV) (Marc Coucke together with Alychlo NV and Mylecke Management, Art & Invest NV)	5,133,124	16.49%	0	0.00%	5,133,124	15 .59%
Eva Consulting SPRL (permanent representative : Jean-Michel Foidart)	0	0.00%	0	0.00%	0	0.00%
Mr Jean-Michel Foidart (permanent representative of Eva Consulting SPRL) (together with Eva Consulting SPRL)	0	0.00%	0	0.00%	0	0.00%
Christiane Malcorps	0	0.00%	0	0.00%	0	0.00%
P.SUINEN SPRL-S (permanent representative: Mr Philippe Suinen)	0	0.00%	0	0.00%	0	0.00%
Philippe Suinen (permanent representative of P.SUINEN SPRL-S) (together with P.SUINEN SPRL-S)	0	0.00%	0	0.00%	0	0.00%
Jacques Platieau	0	0.00%	0	0.00%	0	0.00%
Subtotal	20,635,890	66.29%	1,211,100	67.40%	21,803,657	70.04%

#### Executive management team

#### Procedure applied in 2016 in order to create a remuneration policy and to determine the individual remuneration

The remuneration of the members of the Executive Management Team is determined by the Board of Directors upon recommendation of the Nomination and Remuneration Committee and subsequent to the CEO's recommendation to this Committee (except for his own remuneration). Mithra Pharmaceuticals strives to be competitive in the European market.

#### Remuneration policy applied during 2016

The level and structure of the remuneration of the members of the Executive Management Team is such that qualified and expert professionals can be recruited, retained and motivated taking into account the nature and scope of their individual responsibilities.

The remuneration of the members of the Executive Management Team currently consists of the following elements:

- each member of the Executive Management Team is entitled to a basic fixed remuneration designed to fit responsibilities, relevant experience and competences, in line with market rates for equivalent positions;
- each member of the Executive Management Team currently participates in, and/or in the future may be
  offered the possibility to participate in a stock based incentive scheme in accordance with the
  recommendations set by the Nomination and Remuneration Committee, upon the recommendation by the
  CEO to such committee (except in respect of his own remuneration) and after (in respect of future stock
  based incentive schemes) prior shareholder approval of the scheme itself by way of a resolution at the
  Annual Shareholders Meeting;
- each member of the Executive Management Team is entitled to a number of fringe benefits (to the exception, however, of those managers engaged on the basis of service agreements), which may include participating in a defined contribution pension or retirement scheme, disability insurance and life insurance, a company car, and/or a lump-sum expense allowance according to general Company policy.

In view of the recent listing (in the middle of 2015) of the Company, a short and long term performance based remuneration and incentive scheme is an hypothesis which is just talked about within the Nomination and Remuneration Committee. Such scheme is to be based on objectives which will, in accordance with Article 520*bis* of the BCC, be pre-determined in an explicit decision by the Board of Directors and will be chosen so as to link rewards to corporate and individual performance, thereby aligning on an annual basis the interests of a member of the Executive Management Team with the interests of the Company and its shareholders and benchmarked with the practices in the sector.

Schemes under which members of the Executive Management Team are remunerated in shares, warrants or any other rights to acquire shares, shall be subject to prior shareholder approval by way of a resolution taken by the General Meeting of Shareholders. The approval shall relate to the scheme itself and not to the grant to individuals of share-based benefits under the scheme. Such schemes shall include appropriate vesting periods.

The amount of remunerations and benefits paid in 2016 to the CEO and the other members of the Executive Management Team, (gross, excluding VAT and share-related payments) is shown in the table below, with its breakdown:

Thousands of Euro (€)	Total	Of which CEO
Basic Remuneration	2,508	805
Variable Remuneration (*)	-	-
Group Insurance (pension, invalidity, life)	4	-
Other insurance (car, cell phone, hospitalization)	20	-
Total	2,533	805

The table below provides an overview of the shares and warrants held by the current members of the Executive Management Team, including the Executive Director (i.e., the CEO).

Share- / Warrantholder	Shares	%	Warrants	%	Shares and Warrants	%
YIMA SPRL (permanent representative: François Fornieri) (CEO) (together with François Fornieri)	0	0.00%	0	0.00%	0	0.00%
Mr François Fornieri (permanent representative of YIMA SPRL) (together with YIMA SPRL)	10,150,800	32.61%	1,211,100	67.40%	11,361,900	34.51%
Mr. Christophe Maréchal (representative of and together with CMM&C SPRL BVBA)	0	0.00%	0	0.00%	0	0.00%
Mr. Jean-Michel Foidart (representative of and together with Eva Consulting SPRL)	0	0.00%	0	0.00%	0	0.00%
Ms. Julie Dessart (representative of and together with Sunzi SPRL)	10,922	0.04%	24,750	1.38%	35,672	0.11%
Mr. Jean-Manuel Fontaine (representative of and together with Novafontis SAS)	4,642	0.01%	24,750	1.38%	29,392	0.09%
Mr. Rudi Meurs	21,376	0.07%	49,500	2.75%	70,876	0.22%
Ms. Valérie Gordenne (representative of and together with Alius Modi SPRL)	8,550	0.03%	74,250	4.13%	82,800	0.25%
Mr. Jan Van der Auwera (representative of and together with TACC BVBA)	16,500	0.05%	0	0.00%	16,500	0.05%
Mr. Michaël Dillen (representative of and together with Midico)BVBA)	0	0.00%	0	0.00%	0	0.00%
Subtotal	10,212,790	32,80%	1,384,350	77.04%	11,597,140	35,22%
Total	31,129,756	100.00%	1,796,850	100.00%	32,926,606	100.00%

The Company put into place a stock option plan under which warrants ("droits de souscription") were granted to employees, consultants or Directors of the Company.

Upon proposal of the Board of Directors, the Extraordinary Shareholders Meeting of the Company of 2 March 2015 approved the issuance of warrants giving right to 1,796,850 Shares, which, on a fully-diluted basis, represent 5.56% additional Shares.

These warrants have been granted free of charge. All warrants have been accepted by the relevant beneficiaries. Each warrant entitles its holder to subscribe for 1,650 Shares of the Company at a subscription price of EUR 5,646.00 per 1,650 Shares (a part of which corresponding to the par value of the existing Shares on the day the warrants are exercised will be allocated to the share capital, the balance will be booked as an issue premium).

These warrants can be exercised in principle as from 1 January 2019, and have a term of 8 years as from their grant. Upon expiration of the 8 years term, they become null and void. On the date hereof, all warrants remain outstanding.

Currently, eight members of the Executive Management Team are engaged on the basis of a service agreement and two members of the Executive Management Team on the basis of an employment agreement, all of which can be terminated at any time, subject to certain pre-agreed notice periods, which may, at the discretion of the Company, be replaced by a corresponding compensatory payment.

The service agreement with the CEO, YIMA SPRL, sets out a notice period (or notice indemnity *in lieu* of notice period) of 12 months.

#### Claw-back provisions

There are no provisions allowing the Company to reclaim any variable remuneration paid to executive management based on incorrect financial information.

#### Miscellaneous

In general, the company has no intention to compensate in a subjective or discretionary manner.

#### Most important characteristics of internal control

The Executive Management Team should lead the Company within the framework of prudent and effective control, which enables to assess and manage risks. The Executive Management Team should develop and maintain adequate internal control systems so as to offer a reasonable assurance concerning the realization of the goals, the reliability of the financial information, the observance of applicable laws and regulations and to enable the execution of internal control procedures. The Audit Committee assists the Board of Directors in the execution of its task to control the Executive Management Team.

#### **Control Environment**

The Executive Management Team has organized the internal control environment, which is monitored by the Audit Committee. The Audit Committee decided not to create an internal audit role, since the scope of the business does not justify a full-time role.

The role of the Audit Committee shall be to assist the Board in fulfilling its monitoring responsibilities, as stipulated in the Company's CGC. These responsibilities include the financial reporting process, the system of internal control and risk management (including the Company's process for monitoring compliance with laws and regulations) and the external audit process.

#### Statutory auditor

BDO Réviseurs d'Entreprises SCRL, with registered office at Rue de Waucomont, Battice 51, 4651 Herve, Belgium, member of the Institut des Réviseurs d'Entreprises/Instituut der Bedrijfsrevisoren, represented by Felix Fank, auditor, has been appointed as Statutory Auditor of the Company on 8 June 2015 for a term of three years ending immediately after the Shareholders Meeting to be held in 2018 that will have deliberated and resolved on the financial statements for the financial year ended on 31 December 2017. BDO Réviseurs d'Entreprises SCRL is a member of the Belgian Institute of Certified Auditors ("Institut des Réviseurs d'Entreprises") (membership number B00023).

# 1.5. Statements required by art. 34 of the royal decree of 14 November 2007

According to article 34 of the Belgian Royal Decree of 14 November 2007, Mithra hereby discloses the following items:

#### Restrictions, either legal or prescribed by the articles of association, on voting rights

Pursuant to the BCC, to attend or be represented at the general meeting and exercise her/his voting right, a shareholder must have carried out the accounting registration of his/her shares no later than the fourteenth day before the general meeting at 24:00h Belgian time (the "Registration Date"), either by registering them in the Company's register of nominative shares, or by registering them in the accounts of a licensed account holder or a settlement institution, the number of shares held on the day of the meeting being disregarded.

The shareholder must also inform the Company of her/his desire to attend the general meeting no later than the sixth day before the general meeting.

## Rules governing the appointment and replacement of board members and the amendment of the issuer's articles of association

The Articles of Association provide that the number of Directors of the Company, who may be natural persons or legal entities and who need not be shareholders, shall be at least 3.

At least one half of the Board shall comprise non-executive Directors and at least 3 of them shall be independent Directors.

When dealing with a new appointment, the Chair of the Board shall ensure that, before considering the candidate, the Board has received sufficient information such as the candidate's curriculum vitae, the assessment of the candidate based on the candidate's initial interview, a list of the positions the candidate currently holds, and, if applicable, the necessary information for assessing the candidate's independence.

The Chair of the Board is in charge of the nomination procedure. The Board is responsible for proposing members for nomination to the General Shareholders Meeting, in each case based upon the recommendation of the Nomination & Remuneration Committee.

Should any of the offices of Director become vacant, whatever the reason may be, the remaining Directors shall have the right to temporarily fill such vacancy until the next General Shareholders Meeting, which shall make a final appointment.

Whenever a legal entity is appointed as a Director, it must appoint an individual as its permanent representative, chosen from among its shareholders, managers, Directors or employees, and who will carry out the office of Director in the name and for the account of such legal entity.

Any proposal for the appointment of a Director by the General Shareholders Meeting shall be accompanied by a recommendation from the Board, based on the advice of the Nomination & Remuneration Committee. This provision also applies to proposals for appointment originating from shareholders. The proposal shall specify the proposed term of the mandate, which shall not exceed 4 years. It shall be accompanied by relevant information on the candidate's professional qualifications together with a list of the positions the candidate already holds. The Board will indicate whether the candidate satisfies the independence criteria.

In principle, there is no quorum requirement for a Shareholders Meeting and decisions are generally passed with a simple majority of the votes of the Shares present and represented. Nevertheless, capital increases (unless decided by the Board of Directors within the framework of the authorised capital), decisions with respect to the Company's dissolution, mergers, de-mergers and certain other reorganisations of the Company, amendments to the articles of association (other than an amendment of the corporate purpose) and certain other matters referred to in the BCC not only require the presence or representation of at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, of the Company but also the approval of at least 75% of the votes cast. An amendment of the Company's corporate purpose or, subject to certain exceptions, the purchase and sale of own Shares, requires the approval of at least 80% of the votes cast at a Shareholders Meeting, which in principle can only validly pass such resolution if at least 50% of the share capital of the Company and at least 50% of the profit certificates, if any, are present or represented. In the event that the required quorum is not present or represented at the first meeting, a second meeting will be convened, such second meeting will be able to validly deliberate and resolve regardless of the number of Shares and profit certificates, if any, present or represented.

Significant agreements to which the issuer is a party and which take effect, alter or terminate upon a change of control of the issuer following a takeover bid, and the effects thereof, except where their nature is such that their disclosure would be seriously prejudicial to the issuer; this exception shall not apply where the issuer is specifically obliged to disclose such information on the basis of other legal requirements

As noted above, the Company has issued 1,089 warrants on 2 March 2015 for the benefit of the members of its Executive Management Team and consultants. Pursuant to the terms and conditions of this warrant plan, in the event of Liquidity event, which comprises a modification, as a result of a public bid or otherwise, of the (direct or indirect) control (as defined under Belgian law) exercised over the Company, the holders of warrants shall have the right to exercise them, irrespective of exercise periods/limitations provided by the plan. These warrants entitle their holders to subscribe for a total number of 1,796,850 securities carrying voting rights (all ordinary shares), each warrant entitling its holder to subscribe for 1,650 Shares of the Company at a subscription price of EUR 5,646.00 per

1,650 Shares (a part of which corresponding to the par value of the existing Shares on the day the warrants are exercised will be allocated to the share capital, the balance will be booked as an issue premium).

#### 1.6. Transactions within the authorized capital

There has been no transaction within the authorized capital in 2016.

#### 1.7. Acquisition of own Securities

Neither Mithra Pharmaceuticals SA nor any direct affiliate or any nominee acting in his own name but on behalf of the Company or of any direct affiliate, have acquired any of the Company's shares. Mithra Pharmaceuticals SA has not issued profit-sharing certificates or any other certificates.

# 1.8. Use of financial instruments by the Group as per art. 96 of the Belgian Companies' code

The Group did not use any financial derivative instruments.

# 1.9. Circumstances that could considerably affect the development of the Group

No special events have occurred that could considerably impact the development of the Group.

The Group has a business structure; built on: (i) a development portfolio which includes the development of Estetrol-based product candidates in the oral contraception and menopause indications and of complex therapeutical solutions; (ii) the CDMO development and manufacturing facility, which will manufacture an important part of its innovative products, including its Estetrol-based products (the growing importance of this business for Mithra has been confirmed by the interest shown by first rank international market actors in its innovative products portfolio and the achievements in this respect in terms of international business development), and (iii) a commercialized portfolio of branded generics and OTC products in several regions. Therefore, the risk factors related to each of these pillars are presented separately (as each has a different set of risks associated with it). As Mithra further evolved towards a biopharma company in 2016, most focus is on the development portfolio.

(i) No Estetrol-based product candidates have been approved nor commercialised and the lead product candidate is currently in Phase III. The successful development of the Group's Estetrol-based product candidates is highly uncertain. Estetrol-based product candidates must undergo preclinical and clinical testing supporting the clinical development thereof, the results of which, are uncertain and could substantially delay, which in turn could substantially increase costs, or prevent the Estetrol-based product candidates from reaching the market.

The Group's current lead Estetrol-based product candidates have not been approved nor commercialised. Estelle® for use in contraception is currently in Phase III studies, which will have to reconfirm its contraceptive efficacy, and in parallel with which a number of studies need to be conducted which are not expected to have a significant impact on any (potential) marketing authorisation approval, although these will play a role in determining the labelling and leaflet restrictions the product candidate would have upon approval (if any). Donesta<sup>®</sup> for use in hormone therapy in menopause is currently in Phase II (the pre-clinical and Phase I clinical trial support package is shared with Estelle<sup>®</sup>; the data would seem to suggest (but did not possess the statistical power to demonstrate) that Estetrol decreases hot flushes in a dose-dependent manner, but larger populations and longer treatment periods as recommended by regulatory guidance (12 weeks) will be necessary to optimally see a difference in the results between the different Estetrol doses tested). All Estetrolbased product candidates will be subject to extensive (pre-)clinical trials supporting the clinical development thereof to demonstrate safety and efficacy in humans (which will take several years) before they can apply for the necessary regulatory approval to enter the market and potentially obtain marketing authorisation with the relevant regulatory authorities. The Group does not know whether future clinical trials will begin on time, will need to be redesigned will be completed on schedule

(Phase III for Estelle® currently expected to give top line results between Q3 2018 and Q1 2019 and top line results for Phase II for Donesta® currently expected to be available end of late Q1 2018), if at all, and therefore cannot currently provide any timing estimates for the development and registration (if any) of Estelle® or Donesta® beyond the Phases of clinical development these product candidates are currently in.

At any stage of development, based on review of available pre-clinical and clinical data, the estimated costs of continued development, the triggering of certain contingent payments and low-single digit "royalty payments", (payable to the former shareholders of Uteron Pharma as part of the acquisition of Estetra by the Group), and up to EUR 12 million, for Donesta® (as described in the note on business combinations and asset deals), market considerations and other factors, the development of Estetrol-based product candidates may be discontinued.

Any further delays in completing clinical trials or negative results will delay the Group's ability to generate revenues from product sales of Estetrol-based product candidates, if any. This could have a material adverse effect on the Group's business, prospects, financial condition and results of operation.

(ii) The Group is, for its future development and pipeline, currently heavily focused on, and investing in, the development of its Estetrol-based product candidates. Its ability to realise substantial product revenues and, eventually, profitability in line with the investments envisaged will depend in large part on its ability to successfully develop, register and commercialise Estetrol-based product candidates.

The Group's pipeline currently comprises two product candidates which would, upon their marketing authorisation, be completely new original products. The Group will be dedicating the majority of its available cash resources to the development of these innovative Estetrol-based product candidates. If the Group would be unsuccessful in developing, commercialising and/or partnering these innovative original products, this would materially impact the revenue and profitability potential of the Group, as in that case, the nature of the Group's pipeline would be limited to the development (either directly or indirectly) of complex therapeutic solutions and the further development of its commercial business, both of which present market opportunities of a level which is significantly lower than the opportunity offered by the development of innovative original products. Both of these activities have a profile which is more limited in terms of funding need and growth potential compared to the development of innovative product candidates.

(iii) In order to successfully develop, register and commercialise its Estetrol-based product candidates, the Group will need to successfully manage the transition from a focus on the commercialisation and development of generic products to a company that is in addition, to a significant extent, involved in development and commercialisation of innovative original product candidates.

The Group has, to date, never fully developed, registered and commercialised an innovative product candidate. Such development, registration and commercialisation present significant new challenges.

In preparation, the Group has expanded and continues to expand its organisation and has attracted and continues to attract a number of experienced collaborators in this new field of development. However the Group may not be able to successfully integrate their experience and know-how, and to continue to further successfully expand its organisation and successfully conclude every development step. A failure to successfully do so could cause delays in the clinical development and/or the regulatory approval process, which could ultimately delay or even prevent the commercialisation of the Group's innovative product candidates. This could have a material adverse effect on the Group's business, prospects, financial condition and result of operation.

(iv) None of the complex therapeutics (including amongst others Zoreline<sup>®</sup> and Myring™) currently under development by the Group have received regulatory approvement. Complex therapeutic solutions must undergo bioequivalence or pharmacodynamics or any other studies, which could be subject to delays, which in turn could substantially increase costs, or prevent these generic products from reaching the market on time. All complex therapeutics will be subject to bioequivalence or pharmacodynamics or other studies (as deemed fit by the relevant regulatory agencies), to demonstrate that the generic product is bioequivalent to the previously approved drug, before they can receive the necessary regulatory approval to enter the market. In 2016, Myring™ was the first complex therapeutic solution produced by Mithra to demonstrate bioequivalence; for the other products (including Zoreline®), this is not yet the case. Any delays in completing studies, will delay the Group's ability to generate revenues from product sales of complex therapeutical solutions products if any. In case the Group would come late in the market, dependent on the market as of the point when three to five generics have been approved, it will suffer from significantly reduced market share, revenues and cashflows for the relevant generic product.

## (v) The Group's products may not obtain regulatory approval when expected, if at all, and even after obtaining approval, the drugs will be subject to ongoing regulation.

Upon completion of the relevant studies, the Group's products must obtain marketing approval from the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) or competent regulatory authorities in other jurisdictions before the products can be commercialised in a given market, and each such approval will need to be periodically renewed. Each regulatory agency may impose its own requirements and may refuse to grant or may require additional data before granting marketing approval even if marketing approval has been granted by other agencies. Changes in regulatory approval policies or enactment of additional regulatory approval requirements may delay or prevent the products from obtaining or renewing marketing approval. Also, post-approval manufacturing and marketing of the Group's products may show different safety and efficacy profiles to those demonstrated in the data on which approval to test or market said products was based. Such circumstances could lead to the withdrawal or suspension of approval. All of this could have a material adverse effect on the Group's business, prospects, financial condition and results of operation.

# (vi) The Group, being only commercially present in selected regions, will need to rely on partners for the commercialisation and distribution of its products in other regions

The Group's product candidates are being developed with the intention of a commercial launch throughout the world. The Company currently has only a commercial, marketing and sales organisation in place in the Benelux to launch its product candidates in these markets. As in 2016, the Group decided to put the affiliates in Germany and France on hold, it does not plan to build out a commercial organization in these territories.

Until now the Group has never marketed a product outside of the Benelux and has therefore limited experience in the fields of sales, marketing and distribution in other markets. The Group does currently not intend to deploy itself a sales and distribution organisation elsewhere in the world, but will rely for the commercial launch and distribution of its products on license and supply deals with partners. The partners identified at 31 December 2016 are GSP for Zoreline<sup>®</sup> and Fuji Pharma for Estelle<sup>®</sup> (for Japan and ASEAN). Post-period, a partnership was closed with Mayne Pharma for Myring<sup>™</sup> in the US and with Fuji Pharma for Donesta<sup>®</sup> (for Japan and ASEAN). Other partners have currently not yet been identified and there can be no assurance that the Group will ever identify such partners or find an agreement with such partners. Therefore its products might not be commercialised in all the markets the Group currently intends to commercialise its products. The Group's dependence on partners for the commercialisation of its products in certain regions results in a number of risks (including, but not limited to, less control over the partner's use of resources, timing, success, marketing of competing products by the partner, impact of future business combinations).

#### (vii) The pharmaceutical industry is highly competitive and subject to rapid technological changes. If the Group's current or future competitors develop equally or more effective and/or more economical technologies and products, the Group's competitive position and operations would be negatively impacted

The market for pharmaceutical products is highly competitive. The Group's competitors in the Women's Health market include many established pharmaceutical, biotechnology and chemical companies, such as Bayer, MSD, Pfizer and Actavis, many of which have substantially larger financial, research and development, marketing and personnel resources than the Group and could, therefore,

more quickly adapt to changes in the marketplace and regulatory environment. Competitors may currently be developing, or may in the future develop technologies and products that are more effective, safe or economically viable than any current or future technology or product of the Group. Competing products may gain faster or broader market acceptance than the Group's products (if and when marketed) and medical advances or rapid technological development by competitors may result in the Group's product candidates becoming non-competitive or obsolete before the Group is able to recover its research and development and commercialisation expenses. This could have a material adverse effect on the Group's business, prospects, financial condition and results of operation.

## (viii) The Group's patents and other intellectual property rights may not adequately protect its technology and products, which may impede the Group's ability to compete effectively.

The success of the Group depends in part on its ability to obtain, maintain and enforce its patents and other intellectual property rights for technologies and products in Europe, the United States and elsewhere. The Group directly holds 3 patent families on Estelle® and Donesta®, the first of which (covering both the indications of contraception and menopause) expires in 2022 (i.e., soon after the end of Phase III trials for Estelle® which is foreseen for H2 2018) and 5 patent families on different Estetrol synthesis routes. The Group will seek to protect the market opportunity for these product candidates after market authorisation approval (if any) by applying for market/data exclusivity (between maximum five to ten years depending on the territory) and/or patent extension (maximum five years) systems where possible, if at all. One of the main patents covering the synthesis of Estetrol will expire in 2032.

## (ix) The Group has a history of operating losses, is accumulating deficits and may never become profitable.

The Group has experienced operating losses since 2012. It experienced consolidated net losses of EUR 9.8 million in 2015 and EUR 35 million in 2016. These losses have resulted principally from costs incurred in research & development and from general and administrative costs associated with the operations. In the future, the Group intends to continue the clinical trial program for its candidate products, conduct pre-clinical trials in support of clinical development and regulatory compliance activities that, together with anticipated general and administrative expenses, and the construction and start-up of its CDMO, will result in the Group incurring further significant losses for the next several years and the Group's cash burn is expected to increase as a result of these activities in the next few years.

There can be no assurance that the Group will ever earn significant revenues or achieve profitability resulting from its research and development activities.

The Group is also subject to the following risks, in addition to the risks mentioned above:

- The commercial success of the Company's products will depend on attaining significant market acceptance among physicians, patients, healthcare payers and the medical community.
- The Company's supply of innovative products and complex therapeutic solutions will be dependent on the successful and timely construction of its CDMO facility (which is being constructed on land owned by the Company and leased by it, with an option to purchase the facility and for which Phase 2 of the construction is scheduled to be finished in H1 2018), and the compliance with the regulatory requirements or finding alternative manufacturing resources.
- The Company may be exposed to product liability, no-fault liability or other claims and the risk exists that the Company may not be able to obtain adequate insurance or that the related damages exceed its current and future insurance cover.
- The Company is currently dependent on third parties for the pharmaceutical dossier and the supply of the products that it does not own but commercialises under its own trademarks;
- The Company might not be able to complete its own pharmaceutical dossiers for certain generic products in its portfolio, resulting in continued dependence on third party suppliers.
- The Company may require access to additional funding in the future, which could have a materially adverse effect on the Company's financial condition and results of operation and if the Company fails to obtain

such funding, the Company may need to delay, scale back or eliminate the development and commercialisation of some of its products.

- The Company may infringe on the patents or intellectual property rights of others and may face patent litigation, which may be costly and time consuming.
- The Company's patents and other intellectual property rights may not adequately protect its technology and products, which may impede the Company's ability to compete effectively.
- The Company's success depends on its key people, and it must continue to attract and retain key employees and consultants.
- The Company must effectively manage the growth of its operations and the integration of acquisitions recently made or made in the future may not occur successfully.
- The Company has obtained significant grants and subsidies (mostly in the form of "avances récupérables"). The terms of certain of these agreements may hamper the Company in its flexibility to choose a convenient location for its activities.

#### 1.10. Research and development

We are committed to fully exploiting the potential of Estetrol together with our technologic platform in complex therapeutical solutions to develop a diverse and broad portfolio of therapeutic treatments focused on women's health. We will continue to leverage all of the Group's advantages in view of identifying potential drug candidates across a range of women health products and other therapeutic areas and exploring and developing the potential of Estetrol where it has specific advantages. We will invest in further advancing the technological CDMO platform in terms of performance, applicability and scale.

We expect that research and development expenditures for the discovery, development and commercialisation of drug candidates will continue to increase as the Group progresses its clinical and pre-clinical programs into the next phase. In addition, we intend to initiate new discovery programs and we are committed to seek, maintain and expand our know-how and technologies and intellectual property position.

# 1.11. Conflicting interests of directors (Art. 523 of the Belgian Companies Code)

The Directors report that during the financial year two decisions have been taken that fall within the provisions of Art. 523 BCC. As required by Art. 523 BCC, the full minutes of the relevant meeting of the Board of Directors relating to such conflict of interests are reproduced hereunder.

During the financial year 2016, no transaction or other agreement between the Company (or its affiliates) and a Director other than the decisions reproduced hereunder was declared, which could be considered a conflict of interests within the meaning of Art. 523 BCC.

Furthermore, during the same financial year, there have been no transactions or other contractual relationships between the Group on the one hand, and a Director or executive manager, on the other hand, other than those that fall within the provisions of Art. 523 BCC or that have been disclosed under "related party transactions" set out below.

#### Meeting Board of Directors of 27 June 2016

#### Board of Directors' Meeting on 27 June 2016 at 1.30pm:

Mr H. J. Coelingh Bennink reported his own conflict of interest regarding the following point, on the agenda for the meeting of the Board, prior to any deliberations, as required by Art. 523 of the Companies Code:

Decisions to be taken with regard to consultancy contract to be signed between the Company and:

- Mr H. J. Coelingh Bennink
- Ms Carole Verhoeven

As required by the aforementioned article, the full minutes must be reproduced here for the relevant meeting of the Board of Directors that discussed the conflict of interests.

Minutes of the above board meeting:

"Prior to any discussions, Mr H. J. Coelingh Bennink stated that he was declaring a potential conflict of interest of a financial nature, as defined in Article 523 of the Companies Code, in the context of the proposal to discuss the agreements listed in the agenda.

His statement will be appended to these minutes and is reproduced below:

" Dear Directors.

Dear Auditor,

As a member of the Board of Directors of Mithra, I would like to declare, pursuant to Article 523 of the Belgian Company Code, that I am faced with a potential financial conflict of interest in respect of point 8. of the Agenda of today's Board meeting.

As I am CEO, President and shareholder of Pantarhei Bioscience (which would be the counterparty to the agreements being discussed in these points), as well as the "expert" concerned in one of the contracts, I am faced with a direct and indirect financial incentive that is opposed to that of the Company in the sense that any remuneration provided in these contracts would be paid by Mithra to Pantarhei. The impact consists of these fees of EUR 150 per hour for the first contract and EUR 250 per hour for the second contract.

Having declared the existence of this conflict, I shall abstain from participation in the deliberation on these contracts, pursuant to Art. 523 BCC. However, I am of the opinion that the agreements are justified and in the Company interest, as they provide the Company with expert services at a rate that is in line with market practice, from people who have worked on E4 for a long time, and which can therefore offer unique insights on the development path. Furthermore, the amount of time to be dedicated under both contracts is controlled by Mithra, and can therefore be managed actively.

Kind regards,

Prof. H. Coelingh Bennink"

Mr Coelingh Bennink also confirms that he has notified the company's auditors of this potential conflict of interests. He would withdraw during the discussion and vote on the decisions to be taken.

The other members of the Board of Directors noted the terms and conditions of the proposed agreements, which were presented by the CLO. These agreements provide a framework for the provision of services by Pantarhei Bioscience, who would assign two experts to perform the tasks entrusted to it. These two experts would be Mr H. J. Coelingh Bennink and Ms Carole Verhoeven, at hourly fees of EUR 250 and EUR 150 respectively.

Having considered the conflict of interests which had been declared, and following discussions, the Board decided to approve the substance of the proposed agreements, giving the CEO the authority to finalize negotiations on them, and to sign them on behalf of the Company.

The financial impact of this decision would be payment of the cost of the services of the two experts at the hourly rates stated above

The Board justified this decision by the fact that the terms and conditions proposed in these agreements are standard, especially given the skills of the experts who would perform the services, and that these are justified from the point of view of the company's interests. With regard to framework agreements, the volume of the services to be provided remained under the entire control of the Company."

#### Meeting Board of Directors of 22 november 2016

YIMA SPRL (through its standing representative Mr François Fornieri) and Mr François Fornieri, informed the Board in accordance with Art. 523 of the Companies Code of their conflict of interests in relation to the following items on the Board's agenda, prior to any deliberation:

- Discussion and possibly decisions to be taken regarding the sale of buildings held by the company in rue Saint-Georges and rue sur les Foulons in Liège to Mr François Fornieri or to a company held by him, and rental of the said buildings.
- Decision to be taken on the payment of 2015 and 2016 bonuses provided for in the management agreement agreed with YIMA SPRL

As required by the aforementioned article, the full minutes must be reproduced here for the relevant meeting of the Board of Directors that discussed the conflict of interests.

#### The minutes of the said Board meeting:

#### Point 1

Mr Fornieri having stated that he had withdrawn his offer, this point is withdrawn.

#### Point 2

Prior to any deliberation, YIMA SPRL and Mr François Fornieri declared that they had a conflict of interests of a financial nature as defined in Art. 523 of the Companies Code in relation to the proposal to discuss the agenda item, given that YIMA SPRL is the director-delegate of MITHRA, and that SPRL YIMA is the counterparty for this work, while Mr François Fornieri, also a director of MITHRA, is its manager and sole shareholder.

YIMA SPRL and Mr François Fornieri, confirm that they have notified the company auditors of the existence of this conflict of interests.

Mr François Fornieri, also representing YIMA SPRL, withdrew during the discussions and vote on these decisions.

The Chair of the Remuneration Committee provided a summary of the debates within the committee, and of its recommendations.

Having considered the conflicts of interest that had been declared, and after discussion, the Board decided on a bonus of EUR 75,000 to be paid in early 2017 to YIMA SPRL in relation to the 2015-2016 objectives defined in the management agreement, with the following objectives having been achieved:

- start of phase 3 of project Estelle® before the agreed date
- start of phase 2 of project Donesta® before the agreed date

A bonus will be linked to the 2017 financial year, of two times EUR 37,500, the first part payable on signature of the Business Development contracts for the sum of EUR 5 million, the second payable on signature of the Business Development contracts for the sum of 10 million euros (the first 5 million being included in the calculation).

The financial impact of this decision is the payment of an amount of EUR 75,000 to SPRL YIMA, and the potential payment of an identical amount to SPRL YIMA.

The Board justified this decision by the fact that it considers these bonuses to be aligned with the company's interests in terms of their amounts, their motivational character for SPRL YIMA and the stakes involved for the Company, and the alignment of these decisions with the management agreement between the Company and SPRL YIMA, as approved prior to the Company's floatation on the stock market."

# 1.12. Independence and expertise of at least one member of the audit committee

AHOK BVBA (standing representative: Mr Koen Hoffman) – Mr Hoffman obtained a Master of Applied Economic at the University of Ghent in 1990, followed by an MBA at Vlerick Business School in Ghent in 1991. He started his career in the Corporate Finance Bank at KBC Bank, in 1992. From October 2012 to July 2016, he was Chief Executive Officer of KBC Securities SA. He was a member of the Supervisory Board of KBC IFIMA SA (formerly KBC Internationale Financieringsmaatschappij N.V.) and of Patria Securities, as well as a member of the Board of Directors of Omnia Travel Belgium. Mr Hoffman is the Chief Executive Officer of Value Square and has been an independant director of Fagron SA since August 2016.

P.SUINEN SPRL-S (permanent representative: Mr Philippe Suinen) – Mr Suinen holds a degree in law from the University of Liège and a graduate diploma in European law from the University of Nancy. He entered public service in 1974 via the Government Recruitment Service and started his career at the Belgian Ministry of Foreign Affairs. From

1998 to 2014, he was CEO of A.W.E.X, General Administrator of WBI (Wallonia Brussels International) and APEFE (Association for the Promotion of Education and Training Abroad) and Senior Lecturer at the ULB (Free Brussels University). In 2014, he was elected President of the Chamber of Commerce and Industry of Wallonia (CCIW). During his career, he also served in several ministerial cabinets (Institutional Reforms, Education, Presidency of the Walloon Government and, as Chief of Cabinet, Foreign Trade and European Affairs, Vice-Presidency of the Belgian Federal Government, including transport, public enterprises, economy and telecommunications). He was also Vice-Chairman of the Board of SABENA and "Walloon of the Year" in 1999.

MEUSINVEST SA (standing representative: Mr Gaëtan Servais) - Mr Servais is a graduate in economics from the University of Liège. He began his career as a research assistant at the University of Liège. In 1995, Mr Servais joined the Federal Plan Budget as an expert and, following this, the Economic and Social Council of the Walloon Region. From 2001, he was private secretary to a number of Ministers in the Walloon Government. Since 2007, has been CEO of Meusinvest, a financial company whose business is structured into a number of subsidiaries in order to best meet the financing needs for small to medium enterprises (SME) located in the Province of Liège.

#### 1.13. Justification of the valuation rules

The current cash position of EUR 45.8 million will allow the Group to keep up with the financial obligations for at least the following 12 months. Consequently, the annual accounts have been prepared on the assumption that the Company is a going concern.

### 1.14. Appropriation of results

Mithra Pharmaceuticals SA, the parent Company, ended the financial year 2016 with a net loss of EUR 14.501.294,25.

The Board of Directors proposed to appropriate the loss of the year of EUR 14.501.294,25 to retained losses. This brings the total amount of retained losses to EUR 33.011.724

## 1.15. Important events subsequent to the accounting reference date

As of February 17, 2017 the Group announced that it has been granted EUR 1.9 million in non-dilutive funding<sup>1</sup> from the Walloon Region. The grant follows a decision by the Vice-President and Minister for Economy, Industry, Innovation and New Technologies of the Walloon Regional Government, Mr. Jean-Claude Marcourt.

The funding allows the Company to advance two ongoing research programs and covers up to 50% of the total value of both projects.

The first research program will look into the alternative production of Estetrol (E4) by biosynthesis. The second will cover the development of pharmaceutical grade Ethylene-Vinyl Acetate (EVA) for complex therapeutics solutions.

Mithra announced an exclusive long-term license and supply agreement that extends beyond 10 years with Mayne Pharma, a leading specialty pharmaceutical company, for the commercialization in the United States of Myring™, Mithra's combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA). Mayne Pharma is the second largest supplier of oral contraceptive products in the US market.

Under the terms of the agreement, Mithra will receive EUR 2.4m upon signature, as well as significant milestone payments on ANDA approval (market approval by the FDA) and on the commercial launch of the product. As a part of Mayne Pharma's long-term exclusive sourcing commitment, Mithra is considering the expansion of its production capacity for Myring™.

In March 2017, Fuji Pharma has signed a term sheet for its product candidate in menopause, Donesta<sup>®</sup>. Under the terms of the 20-year partnership agreement, Mithra will, depending on the progress of the development, receive single digit milestones. The term sheet comprises an exclusive supply obligation for the duration of the contract,

<sup>&</sup>lt;sup>1</sup> Non-dilutive funding is granted as recoverable advances ("avances récupérables") to support specific research and development programs. The funding is reimbursable over the economic life of the projects, as outlined in the Terms and Conditions. Thirty percent is refundable based on a fixed reimbursement schedule, while the balance is refunded under the form of royalties over the same period.

which would provide Mithra's CDMO with a steady flow of production work for its Estetrol-based products, and hence represent a source of revenue for Mithra over the entire term.

## 1.16. Grant of discharge to the directors and the statutory auditor

You are requested, for Mithra Pharmaceuticals SA, in accordance with the law and the Articles of Association, to grant discharge to the Directors and the Statutory Auditor for the duties carried out by them during the financial year ending 31 December 2016.

This report will be deposited according to the legal requirements and can be consulted at the Company's address.

Liege, 11 April 2017

For the Board of Directors,

Alychlo NV, represented by

Marc Coucke, Chairman

Yima SPRL, represented by

François Fornieri, Managing Director

## 2. Responsibility statement

We hereby certify that, to the best of our knowledge, the consolidated financial statements as of 31 December 2016, prepared in accordance with the International Financial Reporting Standards, as adopted by the European Union, and the legal requirements applicable in Belgium, give a true and fair view of the assets, liabilities, financial position and loss of the Group and the undertakings included in the consolidation taken as a whole, and that the management report includes a fair review of the development and the performance of the business and the position of the Group and the undertakings included in the consolidation taken as a whole, together with a description of the principal risks and uncertainties that they face.

On behalf of the Board of Directors

ALYCHLO NV, represented by

Marc Coucke, Chairman

Yima SPRL, represented by

François Fornieri, Managing Director

Yima SPRL, represented by

François Fornieri, CFO

## 3. Auditor report

MITHRA PHARMACEUTICALS S.A.

Statutory auditor's report to the general meeting of the company for the year ended December 31st, 2016

# 3.1. Statutory auditor's report to the general meeting of the company Mithra Pharmaceuticals S.A. for the year ended December 31st, 2016

As required by law, we report to you on the performance of our mandate of statutory auditor. This report includes our opinion on the consolidated financial statements, as well as the required additional statement. The consolidated financial statements comprise the consolidated statement of financial position as at December 31st, 2016, the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended and the explanatory notes.

#### Report on the consolidated financial statements – unqualified opinion

We have audited the consolidated financial statements of the company MITHRA PHARMACEUTICALS S.A. for the year ended December 31st, 2016, prepared in accordance with the International Financial Reporting Standards as adopted by the European Union, which show a consolidated statement of financial position total of 172.696 (000) EUR and a consolidated income statement showing a consolidated loss for the year of 35.087 (000) EUR.

#### Responsibility of the board of Directors for the preparation of the consolidated financial statements

The board of Directors is responsible for the preparation of consolidated financial statements that give a true and fair view in accordance with the International Financial Reporting Standards as adopted by the European Union, and for such internal control as the board of Directors determines is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

#### Responsibility of the statutory auditor

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing (ISA's) as adopted in Belgium. Those standards require that we comply with the ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the statutory auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the statutory auditor considers the company's internal control relevant to the preparation of consolidated financial statements that give a true and fair view, in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the board of Directors, as well as evaluating the overall presentation of the consolidated financial statements.

We have obtained from the board of Directors and company officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Unqualified opinion

In our opinion, the consolidated financial statements of the company MITHRA PHARMACEUTICALS S.A. give a true and fair view of the group's equity and financial position as at December 31st, 2016, and of its results and its cash flows for the year then ended, in accordance with the International Financial Reporting Standards as adopted by the European Union.

#### Report on other legal and regulatory requirements

The board of Directors is responsible for the preparation and the content of the Directors' report on the consolidated financial statements.

In the context of our mandate and in accordance with the Belgian standard which is complementary to the International Standards on Auditing (ISAs) as applicable in Belgium, our responsibility is to verify, in all material respects, compliance with certain legal and regulatory requirements. On this basis, we make the following additional statement, which do not modify the scope of our opinion on the consolidated financial statements:

The Directors' report the consolidated financial statements includes the information required by law, is consistent with the consolidated financial statements and is free from material inconsistencies with the information that we became aware of during the performance of our mandate.

Battice, April 12th, 2017

BDO Réviseurs d'Entreprises Soc. Civ. SCRL

Statutory auditor

Represented by Felix FANK

## 4. Consolidated Income Statement

Thousands of Euro (€)		Year ende	ed 31 December
CONSOLIDATED INCOME STATEMENT	Notes	2016	2015
Revenues	9.6, 9.19	22.468	20.435
Cost of sales	9.20-21	(9.029)	(10.195)
Gross profit		13.439	10.240
Research and development expenses	9.20-21	(34.299)	(9.491)
General and administrative expenses	9.20-21	(8.226)	(10.329)
Selling expenses	9.20-21	(7.567)	(5.009)
Other operating income	9.19	677	321
Total operating expenses		(49.414)	(24.507)
Operating profit / (loss)		(35.976)	(14.267)
Financial income	9.23	165	3.841
Financial expense	9.23	(4.793)	(1.431)
Financial result		(4.627)	2.410
Share of (loss)/profit of associates and joint ventures accounted for using the equity method	9.10	(32)	(2.758)
Loss before taxes		(40.635)	(14.615)
Income taxes	9.24	5.548	4.794
Net loss for the period		(35.087)	(9.821)
Attributable to			
Owners of the parent		(35.087)	(9.821)
Non-controlling interest			
Profit / (Loss) per share			
Basic earnings per share (euro)	9.25	(1,13)	(0,32)
Diluted earnings per share (euro)	9.25	(1,13)	(0,32)

# 5. Statement of comprehensive income

Thousands of Euro (€)	Year ende	ed 31 December
CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME	2016	2015
Net result for the period	(35.087)	(9.821)
Other comprehensive income	(20)	(24)
Currency translation differences	(20)	(24)
Total comprehensive income for the period	(35.107)	(9.845)
Attributable to		
Owners of the parent	(35.107)	(9.845)
Non-controlling interest		
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	(35.107)	(9.845)

## 6. Consolidated Balance Sheet

Thousands of Euro (€)		Year ende	d 31 December
ASSETS	Notes	2016	2015
Property, plant and equipment	9.8	16.961	3.573
Goodwill	9.9	5.233	8.016
Other Intangible assets	9.7	79.130	78.234
Investments in associates	9.10	165	198
Deferred income tax assets	9.24	12.193	5.345
Other non-current assets		1.139	1.133
Non-current assets		114.820	96.498
Inventories	9.11	4.170	2.797
Trade & other receivables	9.12	7.955	9.498
Other Short Term investments	9.13	43.600	89.000
Cash & cash equivalents	9.14	2.150	7.794
Current assets		57.876	109.089
TOTAL ASSETS		172.696	205.587

Thousands of Euro (€)		Year end	ded 31 December
EQUITY AND LIABILITIES	Notes	2016	2015
Equity			
Share capital	7, 9.15	22.613	22.613
Share premium	7, 9.15	122.830	122.830
Retained earnings	7	(52.384)	(18.024)
Translation differences	7	(44)	(24)
Equity attributable to equity holders		93.015	127.394
Subordinated loans	9.16	6.431	1.602
Bank borrowings	9.16	1.061	1.428
Refundable government advances	9.16	8.255	8.513
Other loans	9.16	32.495	26.153
Provisions		266	266
Deferred tax liabilities	9.24	3.469	5.692
Non-current liabilities		51.977	43.653
Current portion of financial loan	9.16	945	404
Short term financial debts	9.16	6.010	17.450
Trade payables and other current liabilities	9.17	15.682	15.980
Corporate tax payable		73	43
Accrued charges & Deferred income		4.995	663
Current liabilities		27.705	34.540
			-
TOTAL EQUITY AND LIABILITIES		172.696	205.587

# 7. Consolidated statements of changes in Equity

Thousands of Euro (€)	Share Capital	Share Premium	Retained Earnings	СТА	Share based payments	Total Equity
Balance as at 1 January 2015	3.107	10.572	(8.154)	-	-	5.524
Result of the period	-	-	(9.821)	-		(9.821)
Currency translation differences	-	-	=	(24)		(24)
Merger with Ardentia of 22 May 2015	10.571	-	4.883	-		15.454
Incorporation in capital	15.384	(9.830)	(5.554)	-		-
Capital redution	(15.384)	-	=	-		(15.384)
Capital increase of 22 May 2015	4.273	50.331	-	-		54.604
Capital increase of 1 July 2015	4.840	74.487	=	-		79.327
Transaction costs for equity issue	(177)	(2.730)	=	-		(2.908)
Warrants	-	-	-	-	621	621
Balance as at 31 December 2015	22.613	122.830	(18.646)	(24)	621	127.394
Result of the period			(35.087)			(35.087)
Currency translation differences				(20)		(20)
Warrants					728	728
Balance as at 31 December 2016	22.613	122.830	(53.733)	(44)	1.349	93.015

## 8. Consolidated Cash Flow statement

	Year end	ed 31 December
Thousands of Euro (€)	2016	2015
Cash Flow from operating activities		
Operating result	(35.976)	(14.267)
depreciation, amortisation and impairment results	1.050	664
Taxes paid	(1.096)	(256)
Changes in fair value	(1.264)	(205)
Share based payments	728	621
Subtotal	(36.557)	(13.443)
Changes in working capital		
Increase/ (decrease) in Trade payables and other current liabilities	11.689	1.186
(Increase) / decrease in Trade receivables and other receivables	1.543	(5.039)
(Increase) / decrease in Inventories	(1.374)	(1.034)
(Increase)/decrease in other	23	266
Net cash provided by/ (used in) operating activities	(24.676)	(18.064)
Cash Flow from investing activities		
Business combinations	(8.500)	(18.916)
Purchase on tangible assets	(13.795)	(2.186)
Proceeds from sale of tangible assets	36	911
Purchase on intangible assets	(2.309)	(9.275)
Prepayments	-	787
Cash advances to associates	-	(2.978)
Investment in associates	-	(1.894)
Investment in other assets	(6)	(9)
Net cash provided by/ (used in) investing activities	(24.574)	(33.560)
Cash Flow from financing activities		
Payments on financial loan	(17.148)	(3.490)
Proceeds from financial loan & government advances	15.628	19.812
Net financial result	(274)	(607)
Dividends paid to owners	-	-
Proceeds from issuance of shares (net of issue costs)	-	131.023
Net cash provided by/ (used in) financing activities	(1.794)	146.738
Net increase/(decrease) in cash and cash equivalents	(51.043)	95.114
Cash & cash equivalents at beginning of the year	96.794	1.678
Cash & cash equivalents at end of the year	45.750	96.794

## 9. Notes to the consolidated financial statements

#### 9.1. General Information

Mithra Pharmaceuticals SA (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<sup>®</sup>, and a next generation hormone therapy, Donesta<sup>®</sup>- are built on Mithra's unique native estrogen platform (E4). Mithra also develops and markets complex therapeutic solutions and offers partners a complete spectrum of research, development and specialist manufacturing at its Mithra CDMO.

### 9.2. Summary of Significant Accounting Policies

The consolidated financial statements were prepared in accordance with IFRS as adopted by the European Union ("EU"). The consolidated financial statements are presented in thousands of euro (unless stated otherwise). The consolidated financial statements for the financial year ended 31 December 2016 have been approved for issue by the Board of Directors on 11 April 2017. The financial statements have been prepared on the basis of the historical cost price method. Any exceptions to the historical cost price method are disclosed in the accounting policies described hereafter.

#### 9.2.1. Basis of preparation

The consolidated financial statements were prepared in accordance with IFRS as adopted by the European Union ("EU"). The financial statements have been prepared on the basis of the historical cost price method. Any exceptions to the historical cost price method are disclosed in the accounting policies described hereafter.

The financial statements have been prepared on a going concern basis and in accordance with the main accounting principles set out in this section. The Group is expecting losses in the coming years, which is inherent to the current stage of the Group's business life cycle as a biopharmaceutical company. In this respect, the following underlying assumptions have been used:

- the continued positive evolution of the development of products and timely market approvals in countries where the products will be filed;
- the availability of additional financial resources to deal with the remaining development expenses and to fund the cash requirements in the first years of commercialization of the different products.

#### New Standards, Interpretations and Amendments adopted for the accounting period starting on 1 January 2016.

 None of the new Standards, Interpretations or Amendments that are mandatory for the first time for 31 December 2016 year-end affect the Group's accounting policies or any of the disclosures.

#### Summary of Standards and Interpretations issued but not yet effective.

At the date of authorization of these financial statements, the following Standards and Interpretations which have not been applied in these financial statements, were in issue but not yet effective for the year presented:

- IFRS 9 in respect of Financial Instruments which will be effective for the accounting periods beginning on or after 1 January 2018.
- IFRS 15 in respect of Revenue from Contracts with Customers which will be effective for accounting periods beginning on or after 1 January 2018.
- IFRS 16 in respect of Leases which is not yet endorsed by the EU as of 31 December 2016.
- IAS 12 in respect of Income taxes Amendments regarding the recognition of deferred tax assets for unrealized losses which is not yet endorsed by the EU as of 31 December 2016.

The nature and the effect of these changes were taken into consideration, but the above amendments did not affect the consolidated financial statements. The Group has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

#### 9.2.2. Basis of consolidation

#### a) Subsidiaries

The consolidated financial statements include all the subsidiaries over which the Group has control.

Control is achieved when the investor

- has power over the investee;
- is exposed or has rights to variable returns from its involvement with the investee; and
- has the ability to use its power to affect its returns.

If facts and circumstances indicate that there are changes to one or more of the three elements of control listed above, the investor shall reassess whether it controls theinvestee.

Subsidiaries are fully consolidated from the date on which control is transferred to the group. They are deconsolidated from the date that control ceases.

The acquisition method of accounting is used to account for business combinations by the group (refer to note 9.2.3)

Intercompany transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated unless the transaction provides evidence of an impairment of the transferred asset. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the group.

Any non-controlling interests in the results and equity of subsidiaries are shown separately in the consolidated statement of profit or loss, statement of comprehensive income, statement of changes in equity and balance sheet respectively.

#### b) Associates and joint ventures

An associate is an entity over which the Group has significant influence. Significant influence is the power to participate in the financial and operating policy decisions of the investee but is not control or joint control over those policies.

A joint venture is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the net asset of the joint arrangement. Joint control is the contractually agreed sharing of control of an arrangement, which exists only when decisions about the relevant activities require unanimous consent of the parties sharing control.

The results and assets and liabilities of associates or joint ventures are incorporated in these consolidated financial statements using the equity method of accounting. Under the equity method, an investment in an associate or joint venture is initially recognised at cost and adjusted for the Group's share of the profit or loss and other comprehensive income of the associate or joint venture. When the Group's share of losses of an associate or joint venture exceeds its interest in that associate or joint venture, the Group discontinues recognising its share of further losses.

An investment in an associate or joint venture is accounted for using the equity method from the date on which the investee becomes an associate or a joint venture. On acquisition of the investment, any excess of the cost of the investment over the Group's share of the net fair value of the identifiable assets and liabilities of the investee is recognized as goodwill, which is included within the carrying amount of the investment. The requirements of IAS 39 are applied to determine whether it is necessary to recognise any impairment loss with respect to the Group's investment in an associate or a joint venture. When necessary, the entire carrying amount of the investment (including goodwill) is tested for impairment in accordance with IAS 36 (Impairment of Assets), by comparing its recoverable amount with its carrying amount. Any impairment loss recognised forms part of the carrying amount of the investment. Any reversal of that impairment loss is recognised in accordance with IAS 36 to the extent that the recoverable amount of the investment subsequently increases.

#### 9.2.3. Business combinations

The Group applies the acquisition accounting method to account for business combinations. Identifiable assets acquired, and liabilities and contingent liabilities assumed, are, with limited exceptions, measured initially at their fair

values at the acquisition date. The consideration transferred for the acquisition of a subsidiary is the fair value of the assets transferred, the liabilities incurred to the former owners of the acquiree and the equity interest issued by the Group. This includes the fair value of any contingent consideration. Where the consideration transferred, together with the non-controlling interest, exceeds the fair value of the net assets, liabilities and contingent liabilities acquired, the excess is recorded as goodwill. The costs of acquisition are charged to the income statement in the period in which they are incurred.

Where not all of the equity of a subsidiary is acquired, the non-controlling interest is recognised either at fair value or at the non-controlling interest's share of the net assets of the subsidiary, on a case-by-case basis. Changes in the Group's ownership percentage of subsidiaries are accounted for within equity.

Where settlement of any part of cash consideration is deferred, the amounts payable in the future are discounted to their present value as at the date of exchange. The discount rate used is the entity's incremental borrowing rate, being the rate at which a similar borrowing could be obtained from an independent financier under comparable terms and conditions.

Contingent consideration is classified either as equity or a financial liability. Amounts classified as a financial liability are subsequently remeasured to fair value with changes in fair value recognised in profit or loss.

If the business combination is achieved in stages, the acquisition date carrying value of the acquirer's previously held equity interest in the acquire is remeasured to fair value at the acquisition date. Any gains or losses arising from such remeasurement are recognised in profit or loss.

#### 9.2.4. Segment information

An operational segment is a component of an entity:

- which exercises operating activities with which profits are being gained and with which costs can be made (including profits and costs from transactions with other components of the entity);
- of which the operational results are being judged regularly by the highest function of the entity who can take important operational decisions in order to make decisions regarding the granting of resources and to evaluate the financial results of the segment and;
- for which separate financial information is available. That is engaged either in providing specific products or services (business segment), or in providing products or services within a particular economic environment (geographical segment), which is subject to risks and rewards that are different from those of other segments.

#### 9.2.5. Foreign currency translation

The Group's consolidated financial statements are presented in Euros, which is also the parent company's functional currency.

Foreign currency transactions are translated into the functional currency of each entity using the exchange rates prevailing at the dates of the transactions. At the end of each reporting period the entity shall (a) translate the foreign currency monetary items at closing rate, (b) translate non-monetary items measured at historical cost in a foreign currency, using the exchange rate of the transaction date, (c) translate non-monetary items measured at fair value in a foreign currency using the exchange rates at the date the fair value was determined. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement within 'financial income or cost'.

On consolidation, assets and liabilities including related goodwill of components of the Group, are translated into Euros at rates of exchange ruling at the balance sheet date. Exchange adjustments arising when translating the financial statements of foreign subsidiaries, and those arising on loans to or from a foreign operation for which settlement is neither planned nor likely to occur and which therefore form part of the net investment in the foreign operation, are recognized initially in other comprehensive income and reclassified from equity to profit or loss on disposal or partial disposal of the net investment.

#### 9.2.6. Intangible Assets

#### a) Research & development costs

Expenditure on research activities is recognized as an expense in the period in which it is incurred.

An internally-generated intangible asset arising from development is recognized to the extent that all conditions for capitalization have been satisfied as specified in IAS 38:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

This recognition is conventional when a regulatory filing has been made in a major market and the approval from the regulators is considered as highly probable.

The amount initially recognised for internally-generated intangible assets is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria listed above. Where no internally-generated intangible asset can be recognised, development expenditure is recognised in profit or loss in the period in which it is incurred.

Subsequent to initial recognition, internally-generated intangible assets are reported at cost less accumulated amortisation and accumulated impairment losses, on the same basis as intangible assets that are acquired separately.

#### b) Acquired intangible assets

Separately acquired intangible assets are shown at historical cost. Contingent payments based on future performance are an attribute of a fair value measurement throughout the life of the asset. The contingent payments will be disclosed as a contingent liability. When the contingent liability becomes a liability the re-measurement at the end of each reporting period shall be accounted for as an adjustment to the cost of intangible assets to the extent that it relates to future benefits and reporting periods. Intellectual property rights, patents, licenses, know-how and software with a finite useful life are carried at cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost of these intangibles over their estimated useful lives of 7 to 10 years and starts at the moment the assets are available for use.

In the event an asset has an indefinite life, this fact is disclosed along with the reasons for being deemed to have an indefinite life.

Intangible assets acquired in a business combination, including in-process research and development, are initially measured as explained in paragraph 9.2.3

#### 9.2.7. Property, plant and equipment

Property, plant and equipment is carried at historical cost, less subsequent depreciation. Historical costs are capitalized and include expenditure that is directly attributable to the acquisition of the assets, expenditure for bringing the asset to the location and condition necessary for it to be capable of operating in the intended manner, including the in-house development costs.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of the replaced part is derecognised. All other repairs and maintenance expenses are charged to the income statement during the financial period in which they are incurred.

Land is not depreciated. Depreciation on other assets is calculated using the straight-line method to allocate their cost to their residual values over their estimated useful lives, as follows:

Buildings: 30 years

Machinery: 10-15 years

Vehicles: 3-5 years

Furniture and equipment: 5-8 years

ICT and other equipment: 3-5 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on disposals are determined by comparing the proceeds with the carrying amount and are recognized within 'Other operating income or expenses' in the income statement.

#### 9.2.8. Impairment of tangible, intangible assets and of goodwill

Assets with an indefinite useful life are tested for impairment annually and at each interim reporting date, and whenever there is an indication that the asset might be impaired. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The recoverable amount is the higher of fair value less costs to sell and value in use. To determine value in use, the forecasted future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

If the recoverable amount of an asset or cash generating unit is estimated to be less than the carrying amount, the carrying amount of the asset is reduced to its recoverable amount. A cash generating unit is the smallest identifiable Group of assets that generates cash inflows that are largely independent of the cash flows from other assets or Group of assets. An impairment loss is immediately recognised as an expense. Intangible and tangible assets other than goodwill that suffered an impairment are reviewed for possible reversal of the impairment at each reporting date. Where an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset in prior years. A reversal of an impairment loss is recognised as income. An impairment loss recognised for goodwill shall not be reversed in a subsequent period.

#### 9.2.9. Inventories

The inventories mainly consist of trade goods. Trade goods are valued at the lower of cost and net realisable value. Cost is determined using the first-in, first out (FIF0) method. Net realisable value represents the estimated selling price less all estimated costs of completion and costs to be incurred in marketing, selling and distribution.

#### 9.2.10. Trade receivables

Trade receivables are amounts due from customers for merchandise sold or services performed in the ordinary course of business and are measured at amortized cost using the effective interest rate method. The effective interest rate is the rate that exactly discounts estimated future net cash settlements or receipts through the expected life of the financial asset to its net carrying amount. Since trade receivables are expected to be received or paid in the short term after the date of their recognition and within an accounting period, it is assumed that the impact of discounting such short term trade receivable would be immaterial hence they are kept at invoice amounts (cost). This does not however exempt short term trade receivables from impairment assessment and tests. In conclusion, in practice amortized cost amount of trade receivables equals their invoice amounts.

#### 9.2.11. Other Short-term investments

Term deposits with an initial term of more than three months are held to maturity and measured at amortized cost.

#### 9.2.12. Cash and cash equivalents

Cash and cash equivalents are carried in the balance sheet at nominal value. For the purposes of the cash flow statements, cash and cash equivalents comprise cash on hand and deposits held on call with banks. In the balance sheet, bank overdrafts, if any, are included in borrowings in current liabilities.

#### 9.2.13. Share capital

Ordinary shares are classified as equity.

Incremental costs directly attributable to the issue of new ordinary shares or options are shown in equity as a deduction, net of tax, from the proceeds.

#### 9.2.14. Trade payables

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade payables are recognized initially at fair value and subsequently measured at amortised cost using the effective interest method.

#### 9.2.15. Borrowings

Borrowings are recognised initially at fair value, net of transaction costs incurred. Borrowings are subsequently carried at amortised cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognised in the income statement over the term of the borrowings using the effective interest method.

Fees paid on the establishment of loan facilities are recognised as transaction costs of the loan to the extent that is probable that some or all of the facility will be drawn down. In this case, the fee is deferred until the draw-down occurs. To the extent there is no evidence that it is probable that some or all of the facility will be drawn down, the fee is capitalised as a pre-payment for liquidity services and amortised over the period of the facility to which it relates.

#### 9.2.16. Current and deferred income tax

The tax expense for the period comprises current and deferred tax. Tax is recognised in the income statement, except to the extent that it relates to items recognised in other comprehensive income or directly in equity. In this case, the tax is also recognised in other comprehensive income or directly in equity, respectively.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Company and its subsidiaries operate and generate taxable income.

Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred income tax is recognised, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, deferred tax liabilities are not recognised if they arise from the initial recognition of goodwill. Deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realised or the deferred income tax liability is settled.

Deferred tax assets are recognised only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilised.

#### 9.2.17. Equity instruments

Equity instruments issued by the Company are recorded in the amount of the proceeds received, net of direct issue costs.

#### 9.2.18. Leases

Leases are considered as finance leases whenever the terms of the lease transfers substantially all the risks and rewards of ownership of the asset to the lessee. All other leases are classified as operating leases.

Assets held under finance leases are at the start of the lease term recognised as assets of the Group at their fair value or, if lower, at the present value of the minimum lease payments, each determined at the inception of the lease. The corresponding liability to the lessor is included in the balance sheet as a finance lease obligation. The financial costs need to be accounted to each term of the lease period so as to achieve a constant rate of interest on the remaining balance of the liability. Finance charges are expensed.

Rentals payable under operating leases are charged to income on a straight-line basis over the term of the relevant lease. Benefits received and receivable as an incentive to enter into an operating lease are also spread on a straight-line basis over the lease term.

#### 9.2.19. Revenue recognition

Income from sales of products and licenses is recognised when all the following conditions have been met:

- The significant risks and rewards of the ownership of goods have been transferred to the buyer;
- The Group retains neither effective control nor involvement to the degree usually associated with ownership over the goods sold;
- The amount of revenue can be measured reliably;
- It is probable that the economic benefits associated with the transaction will flow to the entity;
- The costs incurred or to be incurred in respect of the transaction can be measured reliably.

License up-front (signature fees) and non-refundable fees for access to prior research results, databases or access to markets are recognised when earned, provided that the Group has no continuing performance obligations and all conditions and obligations are fulfilled (this means after the delivery of the required information and such delivery is considered distinct from other promised goods or services).

If the Group retains continuing performance obligations, and if the stage of completion of the obligations can be measured reliably, the fee will be recognised on a straight-line basis over the contractual performance period. When a specific act or performance obligation is much more significant than any other acts, the recognition of the revenue is postponed until the significant act has occurred. Market authorisation for some of the collaboration agreements is considered to be a significant act.

Revenue will not be recognised if the amount cannot be reasonably estimated or if the payment is not reasonably assured. Deferred revenue represents amounts received prior to revenue being earned.

On this subject of the performing obligations, the IFRS 15 to be implement by 1 January 2018 will require the Group to identify performance obligations on the basis of distinct promised goods or services. To clarify the concept of 'distinct', the IASB has added the clarification that the objective of the assessment of a promise to transfer goods or services to a customer is to determine whether the nature of the promise, within the context of the contract, is to transfer each of those goods or services individually or, instead, to transfer a combined item or items to which the promised goods or services are inputs.

Under the IFRS 15 amendment, when the Group will grant a licence to a customer that will be distinct from other promised goods or services, the entity will have to determine whether the licence is transferred at a point in time or over time on the basis of whether the contract requires the Group to undertake activities that significantly affect the intellectual property to which the customer has rights. To clarify when the Group's activities significantly affect the intellectual property, the IASB has amended the application guidance and stressed that the activities significantly affect the intellectual property if the activities are expected to significantly change the form or the functionality of the intellectual property; or the ability of the customer to obtain benefit from the intellectual property is substantially derived from, or dependent upon, those activities.

This could affect the revenue recognition as from 1 January 2018 although the Group trusts that it already applies such guidance.

#### 9.2.20. Government assistance

Government grants are recognised as revenue on a systematic basis over the periods in which the entity recognises the related costs as expenses for which the grants are intended to compensate.

Refundable advances are accounted for as interest free loans for which the benefit of the below-market rate of interest is treated as a government grant. The benefit of the below-market rate of interest is measured as the difference between the initial fair value of the loan and the proceeds received. Accordingly, when estimating the liability, the Company (i) determines its best-estimate of the period during which it will benefit from the advance and (ii) determines the amount of the liability as the difference between the nominal amount of the loan and its discounted and risk-adjusted value using a market rate for a liability with similar risk profile to the Company. The liability is subsequently measured at amortised cost using the effective interest method. When there is reasonable assurance that the Company will comply with the conditions attaching to the grant, and that the grant will be received, the benefit is accounted for in deduction of the related research and development expenses that it is intended to compensate.

Repayment of refundable advances may be forgiven in certain circumstances. The liability component of refundable advances is treated as a government grant and taken to income only when there is reasonable assurance that the entity will meet the terms for forgiveness of the advance.

#### 9.2.21. Share-based payment arrangements

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date. Details regarding the determination of the fair value of equity-settled share- based payment transactions are set out in note 9.26.

The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, based on the Group's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Group revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity- settled share-based payment reserve.

The Group currently does not have cash-settled share-based payment arrangements.

## 9.3. Financial Risk Management

#### 9.3.1. Financial risk factors

#### a) Market risk

The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance.

#### Cash flow and fair value interest rate risk

The Group's interest rate risk arises from long-term and short-term borrowings. Borrowings issued at variable rates expose the Group to cash flow interest rate risk which is partially offset by cash held at variable rates. Borrowings issued at fixed rates expose the Group to fair value interest rate risk. Group policy is to maintain the majority of its long term borrowings in fixed rate instruments. All borrowings are euro denominated.

Based on the simulations performed, the impact on post tax profit and equity of a 0.1% shift would not be significant.

#### Foreign exchange risks

The Group is currently not materially exposed to foreign exchange risks. Any future exchange rate risks that might materially expose the Group will be monitored closely. If appropriate, adequate mitigating actions will be taken.

#### Price risks

The Group is currently not materially exposed to price risks.

#### b) Credit risk

Credit risk relates to the risk that a counterparty will fail to fulfil their contractual obligations with the result that the Group would suffer a loss. The Group's policy focuses on only working with creditworthy counterparties and, where necessary, requiring adequate securities. Information about the creditworthiness of counterparties is provided by independent ratings agencies and, if this is not available, the Group uses information that is publicly available as well as its own internal records. Credit risk is managed by the financial department of the parent company by means of individual follow-up of credit per counterparty.

The debtors' age analysis is also evaluated on a regular basis for potential doubtful debts. An analysis of trade receivables is shown below.

Thousands of Euro ( $\in$ ) Past due but not impaired

Year	Carrying amount	Neither impaired nor past due	0-60 days	61-90 days	91-120 days	>120 days
2016	3.510	2.529	414	237	6	325
2015	5.952	4.908	726	72	-	246

The group allows an average debtor's payment period of 30 days after invoice date. It is the group's policy to assess debtors for recoverability on an individual basis and to make provision where it is considered necessary. In assessing recoverability the group takes into account any indicators of impairment up until the reporting date. It is management's opinion that at the above reporting dates no further provision for doubtful debts was required.

Note that part of the receivables overdue for more than 120 days have been collected after year-end. The overall collectability risk for the remaining can be considered as immaterial.

The credit risk on cash investments is limited given that the counterparties are banks with high credit scores attributed by international rating agencies. The financial institutions have credit ratings varying from A- to A.

#### c) Liquidity risk

Thanks to the successful IPO the group maintains sufficient cash and marketable securities. Management reviews cash flow forecasts on a regular basis to determine whether the group has sufficient cash reserves to meet future working capital requirements and to take advantage of business opportunities.

The liquidity risk mainly relates to the non-current debts. The non-current debts primarily relate to the fair values of the contingent and deferred payments of the historical acquisitions. We refer to section 9.5 on business combinations which describes the timing and conditions linked to these liabilities.

The maturity analysis of the bank borrowings and subordinated debts as well as the trade and other payables are shown below:

Thousands of Euro (€)	Less than 3 months	Between 3 months and 1 year	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total
At 31 December 2016	20.927	5.957	599	7.934	1.934	37.351
Subordinated Loan & Bank Borrowings	177	5.957	599	7.934	1.934	16.601
Finance lease liabilities	-	-	-	-	-	-
Trade and other payables	20.750					20.750
At 31 December 2015	33.709	123	244	2.235	545	36.856
Subordinated Loan & Bank Borrowings	17.023	123	244	2.235	545	20.170
Finance lease liabilities	-	-	-	-	-	-
Trade and other payables	16.686					16.686

For the purpose of this liquidity risk analysis, the Trade and other payables also include the corporate tax payables (EUR 73k in 2016)

The EUR 5.510k CDMO Straight Loan (also see details in note 9.16.1) is positioned as current on the balance sheet, but the liquidity risk is not relevant as repayments are conditioned to the granting of "subsidies" by Société Publique Wallonne (SPW).

#### d) Capital risk management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders and to obtain over time an optimal capital structure to reduce the cost of capital.

The Group makes the necessary adjustments in the light of changes in the economic circumstances, risks associated to the different assets and the projected cash needs of the current and projected research activities. The current cash situation and the anticipated cash burn / generation are the most important parameters in assessing the capital structure. The Company objective is to maintain the capital structure at a level to be able to finance its activities for at least twelve months. Cash income from new partnerships is taken into account and, if needed and possible, the Company can issue new shares or enter into financing agreements.

### 9.4. Critical Accounting Estimates and Judgements

The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed below.

#### a) Accounting Basis

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Group's accounting policies.

The financial statements have been prepared on a going concern basis and in accordance with the main accounting principles set out before.

## b) Determination of the fair values of identifiable assets, liabilities and contingent liabilities in a business combination

In connection with the acquisition of Estetra and Novalon, the Group had to determine the fair values of the identifiable assets acquired and liabilities and contingent liabilities assumed in the business combination. Significant judgement was required in estimating these fair values. We also refer to section 9.5 on business combinations.

#### c) Estimated impairment

The Group tests annually whether goodwill and indefinite useful life intangible assets have suffered any impairment, in accordance with the accounting policy stated in note 9.2.8.

#### d) Income taxes

Significant judgment is required in determining the consolidated provision for income taxes. The Group is subject to income taxes in numerous jurisdictions and there are many transactions and calculations for which the ultimate tax determination is uncertain during the ordinary course of business. Measurement of the deferred tax asset related to the tax loss carry-forward involves significant judgement, notably related to the probable future tax profit.

#### e) Measurement of provisions

Significant judgement is required in the estimation of present obligations that arise from past events including the legal claims and other items. These judgments are based on the Group's prior experiences with these issues and are the best estimate of the Group's liability for these items.

#### f) Useful life and residual value

An estimation of the residual values and useful lives of tangible assets and intangible assets is required to be made at least annually. Judgement is required in estimating the useful lives of fixed asset categories. The residual value is the estimated amount that would be currently obtained from the disposal of the asset, after deducting the estimated costs of disposal, if the asset were already of the age and in the condition expected at the end of its useful life. The residual life is determined based upon discussions with local engineers.

#### g) Fair value measurement

Valuation methods, usually discounted cash flow analysis, are used to determine the fair value of some of its assets and liabilities that are not traded in an active market. These valuation methods require judgement.

#### 9.5. Business combinations and asset deals

The original fair-values of the below described assets are part of the table on the Intangible Fixed Assets in note 9.7.

#### 9.5.1. Estetra

In January 2015 Mithra acquired 100% of the shares of Estetra SPRL. Estetra SPRL was acquired to support Mithra's future organic growth of its commercial product portfolio.

The total consideration for the Estetra SPRL shares includes a payment of EUR 1 to the Watson Actavis Group and initial payments of EUR 7.470k to the former Uteron Pharma Shareholders, including Mr. Fornieri who is entitled to 20,26% (directly and indirectly) of the total consideration. After the IPO in July 2015, part of the milestones became immediately due for an amount of EUR 2.500k.

An additional consideration to the former Uteron Pharma shareholders of EUR 25.000k and USD 25.000k will be due if certain milestones relating to the development and commercialization of the products and sales targets are met. Furthermore, royalties will be due on future sales. These royalties are included in the contingent consideration.

The total consideration can be summarized as follows:

Thousands of Euro (€)	Nominal amount	Fair value
Cash	970	970
Deferred consideration (payable in cash)	6.500	6.500
Contingent consideration arrangement	47.112*	20.756**
	54.582	28.226

 $<sup>\</sup>star$  includes USD 25,000k. Nominal amount to be increased with the nominal amount of future variable royalty payments

<sup>\*\*</sup> includes the fair value of the estimated royalty payments

Following table shows the fair values of assets acquired and liabilities assumed at the date of acquisition.

Thousands of Euro (€)	Estetra SPRL
Current assets	500
Cash and & cash equivalents	434
Trade and other receivables	66
Non-current assets	30.725
Property, plant and equipment	33
Intangible assets	30.686
Other non-current assets	6
Liabilities	(6.813)
Trade and other payables	(751)
Government loans	(6.062)
Total identifiable net assets	24.412
Goodwill	3.814
Total	28.226

The intangible assets represent the Entrepreneurial Right, which is the collection of assets that allows Estetra to further develop and commercialize the Estelle® products. This therefore includes the research done prior to acquisition, the (running) applications for patents, other developments that would result in a first advantage to commercialize the Estelle® products and other related knowledge and know-how. The amortization is calculated using the straight line method to allocate the cost of these intangibles over their estimated useful life of 10 years, starting at the moment the assets are available for use.

Estetra SPRL received non-dilutive financial support from the Walloon Region. The support has been granted in the form of refundable cash advances for a total amount of EUR 8.673k at acquisition date. The fair value of the refundable advances was EUR 6.062k at acquisition date.

Goodwill represents the unexpressed value of the workforce and expected synergies arising from the acquisition.

The fair value of the total consideration and of the net assets acquired was determined by using a probability weighting approach that considered the possible outcomes based on assumptions related to the timing and probability of the product launch date, discount rates matched to the timing of the first payments, and probability of success rates and discount adjustments on the related cash flows. The purchase price allocated to the intangible assets was based on management's forecasted cash inflows and outflows and using an excess earnings method to calculate the fair value of assets purchased with consideration to other factors.

A significant increase (decrease) in the probability of the product launch (date) would result in a higher (lower) fair value of the assets acquired and contingent consideration liability. A significant increase (decrease) in the discount rate would result in a lower (higher) fair value of the contingent consideration liability and the net assets acquired. A significant increase (decrease) in the probability of the success rate would result in a higher (lower) fair value of the contingent consideration liability and the net assets acquired.

No deferred tax effects were recorded in consideration of temporary differences arising from the difference between the fair values of assets acquired and liabilities assumed at the acquisition date and their tax bases because Estetra SPRL has unused tax losses and tax credits in excess of any deferred tax liability that would result, and the probability criterion for recognizing a net deferred tax asset is not met at the acquisition date.

#### 9.5.2. Donesta Bioscience BV

On 30 March 2015 Mithra has signed a share purchase agreement to acquire all the shares in Donesta Bioscience B.V., a company incorporated in the Netherlands. Donesta holds titles and intellectual property rights relating to

Estetrol (excluding the rights related to Estelle®). The purchase price consists of an initial payment of EUR 8.000k, and further conditional payments with a maximum of EUR 12.000k upon reaching certain milestones.

As the acquisition of Donesta qualified for an asset deal – because the definition of a business as defined in IFRS 3 is not met – the transaction was measured initially at cost. Subsequently the intangible assets will be measured at their cost less any accumulated amortisation and any accumulated impairment losses. The transaction price further contains several instalments which, since the date of acquisition, are considered as a contingent price based on future performance, hence this measurement is more an attribute of fair value measurement throughout the life of the asset than being representative of the cost model upon initial recognition of the asset. Hence, the contingent payments are disclosed as a contingent liability with any liability being re-measured at the end of each reporting period as an adjustment to the cost of intangible assets to the extent that it relates to future reporting periods.

#### 9.5.3. Novalon

In December 2015 Mithra has acquired the complete ownership of Novalon SA and the relating worldwide distribution rights through a number of transactions:

- Signature of an share purchase agreement whereby 50% of the Novalon shares were acquired for a total consideration of EUR 9.400k
- Purchase of the worldwide rights relating to Novalon's two leading product developments (Zoreline<sup>®</sup> and Myring<sup>™</sup>) for a total consideration of EUR 8.500k

The fair value of the total consideration can be summarized as follows:

Thousands of Euro (€)	Total
SPA 50% of Novalon shares	9.400
Worldwide rights Zoreline® and Myring™	8.500
Consideration	17.900

Note that the consideration for the worldwide rights remained unpaid at 31 December 2015 and were included in other current liabilities (refer also to section 9.17).

Prior to this acquisition the Group already owned a minority stake in Novalon, in line with the rules for step-up acquisitions the previous held interest was remeasured at fair value which resulted in a gain of EUR 3.717k.

Thousands of Euro (€)	Novalon SA
At 1 January 2014	-
Acquisition 25% share	2.000
Loss of the period (25%) - equity accounting	(35)
At 31 December 2014	1.965
Step-up from 25% to 50%	1.500
Capital increase	300
Loss of the period - equity accounting till Dec 2015	(2.709)
At 8 December 2015 - at acquisition	1.056
Gain as a result of step-up accounting under IFRS	3.717
Consideration paid for step-up to 100%	17.900
Total participation Novalon 31/12/2015	22.673

Following table shows the assets acquired and liabilities assumed at the date of acquisition.

Thousands of Euro (€)	Novalon SA
Current assets	684
Cash and & cash equivalents	242
Trade and other receivables	442
Non-current assets	37.205
Property, plant and equipment	71
Intangible assets	36.262
Other non-current assets	871
Liabilities	(19.419)
Trade and other payables	(1.523)
Current accounts	(3.698)
Deferred tax liabilities	(5.692)
Fair value contractual obligations	(7.763)
Government loans	(743)
Total identifiable net assets	18.470
Goodwill	4.204
Total	22.673

The intangible assets represent the Entrepreneurial Right, which is the collection of assets that allows Novalon to further develop and commercialise the Zoreline<sup>®</sup> and Myring<sup>™</sup> products. The amortisation is calculated using the straight line method to allocate the cost of these intangibles over their estimated useful life of 7 years, starting at the moment the assets are available for use.

Goodwill represents the unexpressed value of the workforce and expected synergies arising from the acquisition. Novalon SA received non-dilutive financial support from the Walloon Region. The support has been granted in the form of refundable cash advances for a total amount of EUR 1.643k at 31 December 2015. It is estimated that the refundable advances had a fair value of EUR 743k at acquisition date.

The fair value of contingent payments relating to certain contractual obligations with respect to the acquired Zoreline<sup>®</sup> and Myring<sup>™</sup> products was estimated at EUR 7.763k, of which EUR 500k was to be invoiced in 2016 (and to be paid within one year after the invoicing date), while the remainder will only be invoiced annually as from 2017 at the earliest (with same payment terms conditions).

The fair value of the net assets acquired was determined by using a probability weighting approach (considering both scientific and commercial success) that considered the possible outcomes based on assumptions related to the timing and probability of the product launch date, discount rates matched to the timing of the first payments, and probability of commercial and scientific success rates and discount adjustments on the related cash flows. The purchase price allocated to the intangible assets was based on management's forecasted cash inflows and outflows and using an excess earnings method to calculate the fair value of assets purchased with consideration to other factors.

A significant increase (decrease) in the probability of the product launch (date) would result in a higher (lower) fair value of the assets acquired and contingent consideration liability. A significant increase (decrease) in the discount rate would result in a lower (higher) fair value of the contingent consideration liability and the net assets acquired. A significant increase (decrease) in the probability of the success rate would result in a higher (lower) fair value of the contingent consideration liability and the net assets acquired.

Deferred taxes relate to temporary differences arising from the difference between the fair values of assets acquired and liabilities assumed at the acquisition date and their tax bases.

## 9.6. Segment Information

At this moment, operating results are only being reviewed at global level within Mithra and hence, no distinction is being made in the evaluation between segments nor is any other segment information provided regularly to the chief operating decision maker. However, some key figures can be displayed geographically.

#### Geographical information

The control of Four (C)		Year end	ed 31 December
Thousands of Euro (€)	Notes	2016	2015
Belgium		12.899	16.134
The Netherlands		1.505	1.370
Luxembourg		443	415
Sales other countries		7.622	2.515
Total		22.468	20.435

#### Non-current assets

Thousands of Furs (6)		Year ended 31 December	
Thousands of Euro (€)	2016	2015	
Belgium	106.300	87.979	
Brazil	465	465	
Luxembourg	20	20	
The Netherlands	7.998	7.998	
France	25	25	
Germany	12	12	
Total	114.820	96.498	

The main non-current assets are located in Belgium, except for the intellectual property rights (relating to Estetrol, excluding the rights related to Estelle®) acquired in the Netherlands, an operating license in Brazil and some minor assets in the Netherlands, Luxemburg and Germany.

## 9.7. Intangible Fixed Assets

Thousands of Euro (€)	Operating license	Intellectual property rights	Software licences	Total
Cost				
At 31 December 2014	463	4.351		4.814
Additions		9.864	193	10.057
Exchange difference	1			1
Acquisitions through business combination		66.494		66.494
At 31 December 2015	464	80.709	193	81.366
Additions	2	2.057	250	2.309
Exchange difference				
Disposals		(782)	(18)	(800)
At 31 December 2016	466	81.984	425	82.875
Accumulated amortisation				
At 31 December 2014	-	2.633	-	2.633
Amortisation expense		497	2	499
At 31 December 2015	-	3.130	2	3.132
Amortisation expense		535	78	613
At 31 December 2016	-	3.665	81	3.745
Net Book Value				
At 31 December 2014	463	1.718	-	2.181
Cost	464	80.709	193	81.366
Accumulated amortisation and impairment	-	3.130	2	3.132
At 31 December 2015	464	77.579	191	78.234
Cost	466	81.984	425	82.875
Accumulated amortisation and impairment	-	3.665	81	3.745
At 31 December 2016	466	78.320	345	79.130

The intangible assets consist mainly of a portfolio of acquired product exploitation rights, market access fees and an operating license for the Brazilian market. The rights were acquired from 1999 to now from different pharmaceutical companies. The intangibles also include intellectual property rights for a new formulation of Tibolone.

The increase in intangible assets during 2015 is primarily explained by the acquisition of Estetra (EUR 30.686k) and Novalon (EUR 36.262k), we also refer to section 9.5 on business combinations.

During 2015, Mithra also acquired through the acquisition of Donesta BV the titles and intellectual property rights relating to Estetrol (excluding the rights related to Estelle®) for an amount of EUR 8.000k and three former Watson Actavis (now Allergan) projects (Colvir, Vaginate and Alyssa). The latter were acquired for 1 Euro each to be increased with the refundable government advances relating to Colvir for an amount of EUR 782k and a milestone payment of EUR 500k. The milestone payments for both Donesta (conditional payments with a maximum of EUR 12.000k) and the Colvir, Vaginate and Alyssa assets are considered as contingent payments based on future

performance and will be accounted for as an adjustment to the cost of the intangible if and when the contingent liability becomes a liability.

In 2016, a disposal of intangible asset related to Colvir asset (EUR 782k in the above table) was decided as the project has been stopped. The addition under intangible asset is mainly related to costs for the recognition of remaining part of the Novalon transaction for products which were not part of the business combination transaction done in 2015.

## 9.8. Property, plant and equipment

Thousands of Euro (€)	Land and buildings	Leasehold improvements	Fixtures and equipment	Motor Vehicles	Total
Cost				-	
At 31 December 2014	1.059	260	2.021	103	3.443
Additions	-	1.581	562	43	2.186
Disposals	(21)	-	(892)	(12)	(926)
Acquisitions through business combination	-	-	100	3	102
At 31 December 2015	1.039	1.841	1.791	135	4.805
Additions	11.021	2	2.752	21	13.795
Disposals	-	-	-35		-35
At 31 December 2016	12.059	1.843	4.507	156	8.565
Accumulated amortisation					
At 31 December 2014	242	91	640	63	1.036
Disposals	-	-	(3)	(12)	(15)
Amortisation expense	34	26	91	26	178
Acquisitions through business combination	-	-	31	2	33
At 31 December 2015	276	118	759	79	1.232
Disposals	-	-	-	(1)	(1)
Amortisation expense	34	28	312	(1)	373
At 31 December 2016	310	146	1.071	77	1.604
Net Book Value					
At 31 December 2014	818	169	1.381	39	2.407
Cost	1.039	1.841	1.791	135	4.805
Accumulated amortisation and impairment	276	118	759	79	1.232
At 31 December 2015	763	1.723	1.031	56	3.573
Cost	12.059	1.843	4.507	156	18.565
Accumulated amortisation and impairment	310	146	1.071	77	1.604
At 31 December 2016	11.750	1.697	3.436	79	6.961

During the period, the Group recorded EUR 13.795k of additions to the tangible fixed assets which were mainly related to prepayments for its new production facility for the manufacturing of pharmaceutical products (CDMO). For this plant and related equipment, the Group entered into various finance leases (see financial note 9.28).

#### 9.9. Goodwill

Goodwill results entirely from the acquisition of Estetra (EUR 3.814k) and Novalon (EUR 1.420k). The finalization of the price exercise on its acquisition of Novalon SA lead the Company to decrease the goodwill compared to December 2015 (refer to section 9.5.3 for details on the original amount)

Goodwill is tested for impairment at least annually. In the year of acquisition of Estetra and Novalon, management confirmed the validity of the expected cash flow approach used when acquiring the businesses, breaking down the risks and using all expectations about possible cash flows and discounting the expected value at a rate of 12.48% ignoring risks for which the estimates of future cash flows have already been adjusted.

Considering the fact that the recoverable value of Estelle<sup>®</sup> was initially estimated using a Phase 2 discount rate (at acquisition, see note 9.5.1) which is no longer required, that the WACC is reduced, and also taking into account that the Company was able to negotiate deals outside of the European and US markets which were the basis for the underlying business plan, no impairment loss resulted. The same applies for Donesta<sup>®</sup> and the Novalon products.

#### 9.10. Investments in associates

Thousands of Euro (€)	Novalon	Targetome	Total
At 1 January 2015	1.965	155	2.120
Step-up from 25% to 50%	1.500		1.500
Capital increase	300	94	394
Loss of the period - equity accounting *	(2.708)	(50)	(2.758)
Acquisition 100% - fully consolidated	(1.056)		(1.056)
At 31 December 2015	-	198	198
Loss of the period - equity accounting *		(33)	(33)
At 31 December 2016	-	165	165

<sup>\*</sup> Novalon is accounted for under the equity method till the moment of control

After a transaction in March 2015 leading Mithra to hold 50% of its associate Novalon SA, neither Mithra, nor any other shareholder, was able to determine on its own the strategic path of Novalon SA. Consequently none of the shareholders controlled Novalon on its own. The shareholders agreed to share control. Joint control exists because decisions about the relevant activities require unanimous consent of both parties. Novalon was therefore presented as a joint venture (and consequently accounted for using the equity method) until December 2015 when Mithra acquired the remaining shares (50%) and became the sole shareholder of Novalon. We also refer to section 9.5 on business combinations.

During 2015, the Group participated in a capital increase in Targetome increasing its participation from 24,7% to 25,13%.

In 2016, the Targetome value was reduced in consequence of a loss for the period as per the equity method.

### 9.11. Inventories

Thousands of Fire (C)		As at 31 December		
Thousands of Euro (€)	2016	2015		
Mithra Pharmaceuticals SA	3.660	2.428		
WeCare Pharmaceuticals BV	14	19		
Mithra Pharmaceuticals GmbH	496	349		
Inventory	4.170	2.797		

In 2016, it has been decided to write-off 85% of the net value of Midien products in the inventory of Mithra Pharmaceuticals GmbH, and the remaining value of Midien is EUR 35k.

Thousands of Fure (6)		As at 31 December
Thousands of Euro $(m{\epsilon})$	2016	2015
Raw materials & consumables	147	190
Finished goods	4.023	2.607
Inventory	4.170	2.797

## 9.12. Trade Receivables and other current assets

Thousands of Euro (6)		As at 31 December	
Thousands of Euro (€)	2016	2015	
Trade receivables	3.510	5.952	
Recoverable VAT	3.331	2.205	
Prepayments	414	584	
Other	701	758	
Total Trade receivables	7.955	9.498	

The major part of the recoverable VAT stated at December 2016 closing has been collected in Q1 2017.

#### 9.13. Other short term investments

Thousands of Furs (C)		As at 31 December		
Thousands of Euro (€)	2016	2015		
Term deposits > 3 months	43.600	89.000		
Other short-term deposits	43.600	89.000		

These are term deposits with banks with an initial term between 3 and 12 months.

## 9.14. Cash and cash equivalents

Thousands of Fura (C)		As at 31 December
Thousands of Euro (€)	2016	2015
Cash at bank and in hand	2.150	7.794
Total cash and cash equivalents	2.150	7.794

## 9.15. Share capital

These shares are fully paid and have no nominal value.

#### 9.15.1. General

At 31 December 2016 and 31 December 2015, the Company's share capital was represented by the following number of shares (units).

		As at 31 December
Number of shares	2016	2015
Share capital	31.129.756	31.129.756

These shares are fully paid and have no nominal value.

#### 9.15.2. Changes in capital

The change of the number of shares during each of the periods ending on 31 December 2016 and 31 December 2015 is as follows:

Thousands of Euro (€)	Number of Shares	Issued Capital	Share premium	Total
Balance at 1 January 2016	11.078	3.107	10.571	13.678
Transactions on 22 May 2015				
- Merger with Ardentia	7.050	10.571		10.571
- Incorporation in capital of share premium		9.829	(9.829)	-
- Incorporation in capital of retained earnings		5.555		5.555
- Reduction of capital	(6.805)	(15.384)		(15.384)
- Share split	18.671.627			-
- Capital increase by contribution in cash	5.836.233	4.273	50.331	54.604
Initial Public Offering on 1 July 2015				
- Capital increase	6.610.573	4.840	74.487	79.327
- Transaction costs for equity issue		(177)	(2.730)	(2.908)
Balance at 31 December 2015	31.129.756	22.613	122.830	145.443
Nihil				
Balance at 31 December 2016	31.129.756	22.613	122.830	145.443

The following capital transactions took place between 1 January 2015 and 31 December 2015:

By resolution of an extraordinary general shareholders' meeting held on 22 May 2015, share capital was
increased by a merger with Ardentia, against issuance of 7.050 new common shares without nominal
value at an issue value of EUR 0,19 per new share. An amount of EUR 10.571k was booked as capital
increase and an amount of EUR 4.883k was booked as an increase in retained earnings. The merger was

- followed by an incorporation of share premium for EUR 9.829k and of retained earnings for EUR 5.555k, then by a reduction in capital of EUR 15.384k, voiding 6.805 shares.
- By resolution of an extraordinary general shareholders' meeting held on 22 May 2015, share capital was increased by a contribution in cash, against issuance of 5,836,233 new common shares without nominal value at an issue value of EUR 0,19 per new share. An amount of EUR 4.273k was booked as capital increase and an amount of EUR 50.331k was booked as an increase in share premium.
- By resolution of an extraordinary general shareholders' meeting held on 22 May 2015 a share split was performed dividing 11.323 shares in to 18.682.950 shares with no changes in voting rights or participation in the result.
- By resolution of an extraordinary general shareholders' meeting held on 22 May 2015, a merger with Mithra RDP was performed without issuance of new shares.
- By resolution of an extraordinary general shareholders' meeting held on 22 May 2015, a merger with Mithra IBD was performed without issuance of new shares.
- By resolution of an extraordinary general shareholders' meeting held on 8 June 2015, in the framework of its Initial Public Offering on Euronext Brussels, a capital increase was authorized which was closed on 1 July 2015, resulting in the issue of 6.023.809 new shares at an issue price of EUR 12 per share, i.e. EUR 72.286k in the aggregate, of which EUR 4.401k was incorporated in the capital and EUR 67.876k was booked as issue premium. Furthermore, by that same resolution, an over-allotment warrant was issued which was exercised on 4 August 2015, resulting in the issue of 586.764 new shares at an issue price of EUR 12 per share, i.e. EUR 7.041k in the aggregate, of which EUR 430k was incorporated in the capital and EUR 6.612k was booked as issue premium.

There was no capital transactions between 1 January 2016 and 31 December 2016.

### 9.16. Borrowings

An overview of the borrowings is shown below.

Thousands of Fire (f)	As at 31 December		
Thousands of Euro (€)	2016	2015	
Bank borrowings	1.061	1.428	
Subordinated loan	6.431	1.602	
Other loans	2.975	-	
Refundable government advances	8.255	8.513	
Other financial liabilities	29.520	26.153	
Non Current	48.242	37.695	
Bank borrowings	5.671	17.106	
Subordinated loan	83	35	
Other loans	380	-	
Refundable government advances	321	214	
Other financial liabilities	500	500	
Current	6.955	17.855	
Total Borrowings	55.197	55.550	

Below we present the characteristics of first the bank borrowings and subordinated loans, secondly the refundable government advances and finally the other financial liabilities.

#### 9.16.1. Banks borrowings and subordinated loans

The detailed breakdown and the characteristics of the banks borrowings and loans is as follows:

Thousands of Euro (€)	Interest rate %	Fixed / Variable	Maturity	2016	2015
Unsecured subordinated loans				458	500
Non-current				375	465
Development Brazilian/Dutch subsidiary	4,95%	Fixed	2022	375	465
Current				83	35
Development Brazilian/Dutch subsidiary	4,95%	Fixed	2022	83	35
Secured subordinated loans				6.056	1.137
Non-current				6.056	1.137
CDMO Phase 1 Immobilier – prefin.	6,50%	Fixed	2018	5.576	1.137
CDMO Phase 2 Mobilier – prefin.	5,75%	Fixed	2018	480	-
Secured borrowings				10.087	18.533
Long term bank loan					
Non-current				1.061	1.428
Investment loans	2,00%	Fixed	2023	640	739
Working capital funding	5,24%	Fixed	2023	421	484
Straight Ioan CDMO Phase 1		Variable	2017		205
Current				161	155
Working capital funding	5,24%	Fixed	2023	62	58
Investment loans	2,00%	Fixed	2023	99	97
Short term bank loans					
Current				5.510	16.950
Financing Holiday Pay	1,62%	Fixed	2016	-	50
Other		Variable	2016	-	16.900
Straight Loans ING - CDMO		Variable	2017	5.510	-
Other loans					
Non-current				2.975	-
Innodem	2,57%	Fixed	2026	2.975	-
Current				380	-
Innodem	2,57%	Fixed	2026	380	-
Total non-current				10.467	3.030
Total current				6.134	17.140
Total				16.601	20.170

The EUR 5.510k CDMO Straight Loan is referred as a current borrowing because of the short term nature of the straight loans, but part of the repayments will be done until December 2018 or at the granting of "subsidies" by Société Publique Wallonne (SPW), whichever occurs first.

Securities given by the Company primarily consist of Receivable pledges (of EUR 7.200k), pledges on future receivables related to subsidies from the Walloon Region given as securities for the loans referred in the above table as Straight Loans ING — CDMO, receivable pledge mandates (of EUR 6.250k) and mortgage mandates (of EUR 1.450k) in respect of the office building owned by the Company.

#### 9.16.2. Refundable government advances

The Group has also been awarded grant support from the Walloon region. Payment of awarded amounts that have not yet been received is subject to the achievement of certain milestones. Grants are subject to certain obligations. In case such obligations are not complied with, the grants could be suspended, reviewed or reclaimed. The Group has the obligation to continue the development of the relevant project. In case such project is stopped, the Group can return rights to the results and the data generated in the project to the Société Publique Wallonne (SPW), in which case the repayment obligation also lapses. The Company's ongoing grant programs are refundable advances.

The refundable advances have a fixed repayment part and variable repayment scheme. The variable part is dependent on the success of the project (i.e. based on a percentage on turnover). It should be noted that, while the variable parts of these advances are only due upon commercialization, the fixed parts are due in any event. The fixed and variable part can never exceed the double of the initial received amount. The final variable part to be repaid will depend on the performance of the product candidate.

Below we have listed an overview of the Group's main ongoing grant programs for its key products:

	Year ended 31 December		
Thousands of Euro (€)	2016	2015	
Refundable government advances Estetra	7.072	6.512	
Other refundable government advances	1.504	2.214	
Total refundable government advances	8.576	8.726	

- Several refundable government advances have been granted to Estetra SA in connection with the development of Estelle and the synthesis of E4 of which EUR 10.229k has been cashed by the Group as at 31 December 2016. The fixed repayments will need to be made over a period till 2029. The value of these refundable government advances amounted to EUR 7.072k and EUR 6.512k respectively as at 31 December 2016 and 2015.
- During 2015 a regional government advance amounting to EUR 2.898k has been granted to the Group in connection with the development of the menopause indication of which EUR 725k has been effectively paid by 31 December 2015. The advance is to be repaid in accordance with fixed and variable reimbursements a described above. The fixed reimbursements will start in 2017 over a period of 10 years. The variable reimbursements are depending on the achievement of turnover targets and start as soon as the related products are marketable. Note that the difference between the fair value of EUR 95k as at 31 December 2016 and the amounts collected are deferred as the associated costs for the clinical studies were not yet incurred. This fair value is part of the EUR 1.504k stated in the above table.
- In addition to the above grant program for development of the menopause indication and amounting EUR 2.898k, the Group has been awarded refundable government advances for other projects such as Zoreline®, Tibelia®, CDMO, Drospirenone, Colvir for which the fair value was recognised as at 31 December 2016 and are part as well of the EUR 1.504k stated in the above table.

#### 9.16.3. Other financial liabilities

Other non-current financial liabilities primarily include the fair value of the contingent consideration for Estetra (EUR 22.418k) as well as the fair value of contingent payments relating to certain contractual obligations with respect to the acquired Zoreline<sup>®</sup> and Myring™ products (EUR 7.102k). We refer to note 9.5 for a description of the characteristics of these debts. The strong increase of fair value for the contingent consideration for the Estetra (EUR 22.418k in 2016 compared to EUR 18.889k in 2015) is the result of a change in the discount rate applied (12,48% instead of 13,88%), and is also explained because there was no longer a phase 2 probability used, together with the evidence of license sales.

### 9.17. Trade payables and other current liabilities

Thousands of Euro (€)	As at 31 December	
Thousanus of Euro (€)	2016	2015
Trade account payables	9.312	4.613
Invoices to receive	5.727	1.362
VAT payable	25	562
Salaries and social security payable	600	721
Deferred income & accrued charges	4.994	663
Other debts	18	8.722
Trade payables and other current liabilities	20.676	16.643

The decrease in other debts is explained by the fact that the worldwide rights for Zoreline® and Myring™ were unpaid at 31 December 2015, and have been paid in 2016.

The increase in deferred income is the deferred revenue recognition of the Fuji Pharma deal (EUR 4.500k) for which the Company received the payment in 2016. On the same deal, another payment of EUR 5.500k could be recognized as revenue (see note 9.19).

#### 9.18. Financial instruments

#### Classes and fair value of financial instruments

All financial instruments, except the contingent consideration for the Estetra business combinations, contingent assets and liabilities for contractual obligations at Novalon and refundable government advances which were initially fair valued have been carried at amortized cost. Given the current nature of the other financial assets and liabilities involved, and given the difficulty to determine the Company's fair value of specific borrowings, the Company considers that the carrying amounts of the relating financial instruments approximate their fair values.

#### Fair value hierarchy and measurements

IFRS 7 requires disclosure of financial instruments that are measured at fair value at the balance sheet date level of the following fair value measurement hierarchy:

- Level 1: fair value measurements are those derived from quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2: fair value measurements are those derived from inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices)
- Level 3: fair value measurements are those derived from valuation techniques that include inputs for the asset or liability that are not based on observable market data (unobservable inputs)

#### Financial Assets:

Trade & other receivables, Other short term deposits and Cash & cash equivalents items will typically be considered as Level 2, cfr notes 9.12, 9.13 and 9.14 for the fair values of these financial assets which do not differ from the book values.

#### Financial liabilities:

The following table presents the group's liabilities that are measured at fair value at 31 December 2016 and 2015:

Th		As at 31 December	
Thousands of Euro ( $\epsilon$ )	2016	2015	
Non Current liabilities	37.775	34.665	
Refundable government advances	8.255	8.513	Level 2
Other financial liabilities	29.520	26.153	Level 3
Current liabilities	821	713	
Refundable government advances	321	213	Level 2
Other financial liabilities	500	500	Level 3

Following table shows the roll forward of the level 2 and 3 financial liability instruments:

Thousands of Euro (€)	Refundable government advances	Other financial liabilities	Total
Balance at 1 January 2015	-	-	-
Busines combination and acquisition of assets	8.082,00	35.989,00	44.071,00
New government advances	780,00	-	780,00
Charged/(credited) to income statement	(136,00)	634,17	498,17
Settlements	-	(9.970,00)	(9.970,00)
Balance at 31 December 2015	8.726,00	26.653,17	35.379,17
Busines combination and acquisition of assets			-
New government advances	440,67		440,67
Charged/(credited) to income statement	(208,00)	3.367,00	3.159,00
Settlements			-
Other	(385,90)		(385,90)
Balance at 31 December 2016	8.572,77	30.020,17	38.592,94

The fair value of the refundable government advances and contingent payments has been determined using a probability weighting approach based on the discounted cash flows as described above.

A 1% increase in the discount rate used would lead to a decrease of the fair value of the contingent liabilities of EUR 1.001k while a 5% increase in the probability used would lead to an increase of EUR 4.067k.

# 9.19. Revenue and other operating income

The Group's revenue consists of products sales and license revenues as follows:

Thousands of Euro (€)	\	Year ended 31 December	
	2016	2015	
License revenues	5.740	1.833	
product sales	16.728	18.602	
Total revenues	22.468	20.435	

In 2016, the revenues from License sales has increased thanks to the recognition of part of the upfront payment (EUR 5.500k) made by Fuji Pharma. See also note for 9.17 for the upfront payment recognised under "Trade payables and other current liabilities". Hence, this is a deferred revenue recognition.

Other operating income includes:

	Ye	Year ended 31 December	
Thousands of Euro (€)	2016	2015	
Recharged expenses	71	311	
Other revenues	606	11	
Other operating income	677	321	

Item "Other revenues" is mainly referring to a regularization of exemption from the withholding tax on professional income.

# 9.20. Expenses by nature

A breakdown of the expenses by nature of the costs of goods sold, Research and development costs, G&A and selling costs is summarized below. A breakdown of the employee benefit expenses is given in note 9.21.

Th	Year end	Year ended 31 December	
Thousands of Euro (€)	2016	2015	
Costs by nature			
Trade goods, raw materials and consumables	7.656	9.161	
Employee benefit expenses	10.039	8.617	
External service providers	29.055	10.356	
Other expenses	8.099	2.728	
Corporate branding expenses	760	1.735	
Depreciation, amortization and impairment charges	985	677	
Changes in inventories of finished goods and work in progress	1.374	1.034	
Commissions	850	511	
Operating lease payments	302	205	
Total costs by nature	59.120	35.024	
Costs by type			
Cost of sales	9.029	10.195	
Research and development expenses	34.299	9.491	
General and administrative expenses	8.226	10.329	
Selling expenses	7.567	5.009	
Total costs by type	59.120	35.024	

Investments in Mithra's innovative product portfolio, start of the phase III studies for Estelle® and phase II for Donesta®, together with Myring™ and Zoreline® development, has driven the increase in R&D expenses by EUR 24.808k to EUR 34.299 in 2016.

# 9.21. Employee benefit expenses

The costs related to personnel and mandated contractors can be summarized as follows:

Thousands of Euro (€)	١	Year ended 31 December	
	2016	2015	
Wages, salaries, fees & bonuses	8.945	7.762	
Pension costs: defined contribution plan	137	89	
Pension costs: defined benefit plan	0	0	
Share based payments	728	622	
Other	229	144	
Total	10.039	8.617	

In 2016, the Group employed at year-end 80 FTE's (66 FTE's in 2015) which can be allocated to the following departments:

Number of employees		As at 31 December	
Number of employees	2016	2015	
R&D Staff	39	24	
G&A Staff	23	24	
Sales staff	18	18	
Total	80	66	

### 9.22. Retirement benefit schemes

The Group offers several post-employment, death, disability and healthcare benefit schemes. All employees have access to these schemes. The death, disability and healthcare benefits granted to employees of the Group are covered by external insurance companies, where premiums are paid annually and charged to the income statement as they become payable. The post-employment pension plans granted to employees of the Group are defined contribution plans. A defined contribution plan is a pension plan under which the Group pays a fixed contribution into a separate entity. The contribution obligations to the defined contribution plans are expensed by the Group in the income statement as they were incurred. Although defined contribution plans in Belgium are legally subjected to a minimum guaranteed return of 3.25% on employer contributions and 3.75% on employee contributions, the postemployment pension plans are accounted for as defined contribution plans, since the legally required return is basically guaranteed by the external insurance company. Any liability that may currently result is immaterial.

## 9.23. Financial income and expenses

The country of F (C)		Year ended 31 December	
Thousands of Euro (€)	2016	2015	
Interest income	122	115	
Other financial income	43	3.726	
Total financial income	165	3.841	

Other financial income in 2015 included the gain realized as a result the step-up acquisition of Novalon for a total amount of EUR 3.717k.

Theorem de of Four (C)		Year ended 31 December
Thousands of Euro (€)	2016	2015
Interest expenses	(175)	(430)
Other financial expenses	(4.618)	(1.001)
Total financial expense	(4.793)	(1.431)

Other financial expenses primarily include the impact of the changes in fair value of the contingent liability (see note 9.16.3) for the Estetra acquisition (EUR 3.537k in 2016 and EUR 633k in 2015). In 2016, there was a strong increase in the fair value accounting of Estetra earn-outs, so a liability on the balance sheet, which had to be recognized in the income statement as financial expenses, so a loss in earnings.

# 9.24. Income tax expense

The tax expenses consist of:

The control of Control (C)	Year ended 31 December	
Thousands of Euro (€)	2016	2015
Current tax income / (expense)	(126)	12
Deferred tax income/(expense) related to temporary differences and tax losses	6.674	4.782
Withholding tax income / (expense)	(1.000)	-
Total	5.548	4.794

The income taxes in 2015 and 2016 are still the result of temporary differences and taxes losses carried forward, and is thus a non cash item.

Withholding taxes of EUR 1.000k relates to the Fuji Pharma downpayments, see also notes 9.17 and 9.19 for this license sale contract.

### Reconciliation effective versus theoretical taxes

The tax result for the year can be reconciled to the result for the year as follows:

Thousands of Euro (€)		Year ended 31 December	
mousanus of Euro (t)	2016	2015	
Income / Loss (-) before tax	(40.635)	(14.615)	
Country's statutory tax rate	33,99%	33,99%	
Tax expenses / income (-) (theoretical)	(13.812)	(4.968)	
Tax expenses / income (-) in income statement (effective)	(5.548)	(4.794)	
Difference in tax expenses / income (-) to explain	8.264	174	
- Use of existing tax losses for which no deferred tax was recognized	-	(1.101)	
- Permanent differences for which no deferred tax is recognized	1.651	938	
- Tax losses for which no deferred tax income was recognized	251	268	
- Tax losses for which no deferred Tax was recognised at lower % due to PID	5.592	-	
- withholding taxes	1.000	-	
- Other	(281)	21	
- Differences in tax rate	50	48	
	8.263	174	

#### Deferred tax assets

A detailed overview of the deferred tax asset is shown below:

Thousands of Euro (€)	As a	As at 31 December	
	2016	2015	
Deferred tax asset to be recovered after more than 12 months	12.193	5.345	
Deferred tax asset to be recovered within 12 months		-	
Deferred tax assets	12.193	5.345	

The deferred tax asset mainly relates to fiscal losses carried forward at the level of Mithra, Estetra and Novalon and to a lesser extent timing differences as a result of differences in accounting principles at the level of these companies. Management is convinced that such companies will generate sufficient profits in the future in order to be able to recover the fiscal losses carried forward and justify the recognition of the deferred tax asset.

The movement in the deferred tax asset is as follows:

	Temporary D				
Thousands of Euro (€)	Expensed restructuring costs	Expensed R&D costs	Other	Fiscal Losses	Total
At 1 January 2015	1	352	210	-	563
Charged / (credited) to income statement	-	(28)	(231)	5.041	4.782
At 31 December 2015	1	324	(21)	5.041	5.345
Charged / (credited) to income statement	0	(1)	(779)	7.628	6.848
At 31 December 2016	1	323	(800)	12.669	12.193

#### **Deferred tax Liabilities**

The deferred tax liabilities (EUR 3.469k in 2016 and EUR 5.692k in 2015) result from the Novalon transaction and primarily relates to temporary differences arising from the difference between the fair values of assets acquired at the acquisition date and their tax bases.

# 9.25. Result per share

Basic loss per share is calculated by dividing the net result attributable to shareholders by the weighted average number of shares outstanding during the year.

Thousands of Euro (€)	Year end	Year ended 31 December		
Hibusalius di Eulo (t)	2016	2015		
Result for the purpose of basic loss per share, being net loss	(35.087)	(9.821)		
Weighted average number of shares for the purpose of basic loss per share	31.129.756	31.129.756		
Basic loss per share (in Euro)	(1,13)	(0,32)		
Diluted loss per share (in Euro)	(1,13)	(0,32)		

### 9.26. Share-based payments

By a decision of the extraordinary shareholders' meeting of 2 March 2015 the Company issued 1.089 warrants primarily to key management with an exercise price of EUR 5.646 per warrant. Warrants are conditional on the person completing 4 years of service (vesting period). These warrants are exercisable as of 2019. The fair value of the 1.089 warrants at grant date is estimated at EUR 2.789k. The fair value of each option is estimated using the Black & Scholes model based on the following assumptions:

Number of warrants granted	1.089
Exercise price per warrant (1.650 shares)	EUR 5.646
Expected dividend yield	-
Expected stock price volatility	45,30%
Risk-free interest rate	0,53%
Expected duration	8 years
Fair value	EUR 2.789

All warrants are still outstanding at 31 December 2016.

During the reporting period EUR 728k was charged to the statement of profit or loss.

## 9.27. Contingencies and arbitrations

### Organon/Merck patent dispute

Since 2008, Mithra is involved in a legal proceeding against Organon NV and Merck Sharp & Dohme BV regarding an alledged patent infringement. Currently, Organon and Merck claimed provisional damages of EUR 1,000,000 while they estimate the actual loss on profit at EUR 2,465,507. A judgment partially ruling in favor of Organon and Merck was rendered on 11 December 2015 and the Commercial Court appointed an expert to advise on the damages suffered by Organon and Merck because of the partial infringement. Mithra lodged an appeal for overturning the judgment. Therefore, the procedure is now pending before the Court of Appeal. No hearing date has been set yet. Note that a provision in relation to this claim has been recognized in these consolidated financial statements based on management's best assessment.

### Contrel dispute

A pending litigation exists between Mithra and Contrel Europe, arising out dispite based on a collaboration agreement between the two parties dated 31 January 2005 in respect of the product Femilis Slim that was under development by Contrel. In May 2009, Mithra initiated proceedings against Contrel Europe on the basis of the noncompliance by Contrel with this agreement, with a view to having the court order the forced execution of the agreement. In the framework of this agreement, Mithra has set out the importance of the product in question, which targeted a market of potentially tens of millions. However, Mithra's primary aim was to ensure that the contract was executed. Contrel Europe, in the course of the procedure, initiated a counterclaim, provisionally valued at EUR 1.00, in which it in turn alleged breaches of contract by Mithra (based, amongst other things, on the allegation that Mithra would have prioritized the development of Levosert (in the same sphere of application) over the development of Femilis Slim, which Mithra disputes). In January 2014, the litigation was sent to the judicial list, where it will remain until either of the parties would choose to reactivate it.

### Conditional payments

Reference is made to the business combinations and asset deals with respect to contingent payments regarding the acquisition of the shares of Estetra SPRL and Donesta Bioscience B.V. and contingent payments as a result of contractual obligations at the level of Novalon.

### 9.28. Commitments

#### Rent and Lease commitments

On 17 November 2014, the company has entered into finance leases for the construction and use of a production facility for the manufacturing of pharmaceutical products. The leases were supposed to commence at the earliest of the operational qualification of the construction or 31 October 2016. These leases were amended in 2016. The amendment consisted of a change for the entering into force of the leases until 30 April 2017, together with a grace period on the principal repayments until April 2019. The total investment for phase I was supposed to amount to EUR 49.400k. Mithra committed to participate up to 32,87% in the financing of the construction through transferring the proceeds of a subordinated loan and grants that will be pre-financed by straight loans. The remainder is financed through two lease agreements: a lease contract of land and building with a term of 15 years for a total amount of EUR 24.900k and an equipment lease for a total amount of EUR 8.000k with a term of 7 years. The leasing of EUR 24.900k was amended during the course of 2016 and is now for EUR 25.164k.

Additionally on 20 May 2016, the company entered into new finance leases for the phase II constructions of the production facilities for the manufacturing of pharmaceutical products for which the total investment was estimated at ca. EUR 25.835k. The leases will commence at the earliest of the operational qualification of the construction or 30 April 2019. Similar to the phase I financing, Mithra committed to participate up to 35,04% in the financing of the construction through transferring the proceeds of a subordinated loan and of grants that will be pre-financed by straight loans. The remainder is financed through two lease agreements: a lease contract of land and building with a term of 15 years for a total amount of EUR 9.097k and an equipment lease for a total amount of EUR 7.685k with a term of 7 years.

### Collaborative research and development arrangements

Mithra has signed an agreement with PRA Health Sciences as a Clinical Research Organisation (CRO) for the upcoming phase III clinical trials on its product candidate Estelle<sup>®</sup>, a combined oral contraceptive, composed of 15 mg of Estetrol (E4) and 3 mg of Droperinone (DRSP) for a total budget of EUR 60 million. The study will cover a two year period after the start.

For the further conduct and finalisation of the Phase II dose-finding study of its project Donesta® Mithra decided to transition from Chiltern to Syntaract as CRO (Clinical Research Organization).

# 9.29. Related party transactions

For fiscal year 2016, the related parties with which other transactions have occurred are as follows:

- YIMA SPRL (an entity controlled by François Fornieri, a director and member of the key management of the Company);
- Le Bocholtz SA (an entity controlled by François Fornieri, a director and member of the key management of the Company);
- Pantarhei Bioscience NV (an entity controlled by Mr Herjan Coelingh Bennink, former director for the Company);
- JAZZ A LIEGE ASBL, (an entity in which Mr Gaëtan Servais (permanent representative of Meusinvest SA, director of the Company) acted as director);
- C.I.D.E. SOCRAN ASBL, an entity in which Mr Marc Foidart (permanent representative of Investpartner SC SCRL (former director of the Company) and Mr Gaëtan Servais (permanent representative of Meusinvest SA, director of the Company) indirectly acted as directors);

• Vitamines Events SA (an entity controlled by François Fornieri, a director and member of the key management of the Company);

Transactions between the Company and its subsidiaries, which are related parties, are eliminated in the consolidated accounts and no information is provided hereon in this Section. However, the associate Targetome (and Novalon during 2014) have been included as related parties.

### 9.29.1. Assets acquired from related parties

In January 2015, Mithra acquired Estetra of which Mr Fornieri was a shareholders. The total consideration for the Estetra SPRL shares includes a payment of EUR 1 to the Watson Actavis (now Allergan) Group and initial payments of EUR 7,470k to the former Uteron Pharma Shareholders, including Mr. Fornieri who is entitled to 20.26% (directly and indirectly) of the total consideration. After the IPO in July 2015, part of the milestones became immediately due for an amount of EUR 2,500k.

There was no transaction during the course of 2016.

### 9.29.2. Key management compensation

Refer to the table below for the compensations paid to key management:

Thousands of Euro (€)	Dec 2016	Dec 2015
Basic Salary	2.508	2.120
Variable Remuneration	-	-
Group Insurance (pension, invalidity, life)	4	6
Other (car, cell phone, hospitalization)insurance	20	22
Share based compensations (*)	728	621
Total	3.260	2.769

<sup>\*</sup> We also refer to section 9.26 on share based payments

### 9.29.3. Sales/Purchase of other services and goods

Thousands of Euro	Type of services	2016	2015
Total services rendered to entities directors	s controlled by or with significant influence from key management /	0	1
Vesteco	Reinvoicing IT expense	0	1
Total services purchased from entities controlled by or with significant influence from key management / directors		156	211
Yima sprl	Rental services builiding Foulons	119	110
Vitamine Event	Event organisation	28	39
Bocholtz	Event organisation - rent meeting rooms	10	61

### 9.29.4. Aggregated trade receivable / payable balance due from / to related parties

Thousands of Euro (€)	2016	2015
Receivables from entities controlled by or with significant influence from key management / directors	10	0
Payables to entities controlled by or with significant influence from key management / directors	126	111
Payables to other related parties		

### 9.29.5. Loans to or from related parties and other debts from related parties

Thousands of Euro (€)	2016	2015
Loan from / to entities controlled by key management / directors	0	0

#### 9.29.6. Transactions with non-executive directors

The total amount of the remunerations and the benefits paid in 2016, to the non-executive Directors (in such capacity) was EUR 255.835 (gross, excluding VAT), split as follows:

Name	Nature	Remuneration as Director	as Member of a committee	As Chair of the Board
Marc Beyens	Non-exec	20.000		
CG Cube	Non-exec	20.000		
CEFMA Consult	Non-exec	5.000		
Meusinvest	Non-exec	20.000	1.780,82	
Investpartner	Non-exec	12.986,30	3.246,58	
Prof. Coelingh Bennink	Non-exec	17.917,81	4.479,45	
Alychlo	Non-exec - Chair	20.000	1.780,82	7.123,29
BDS Management	Non-exec	12.822	3.205	12.822
Jean Sequaris	Independent	10.410,96	5.205,48	
P. Suinen	Independent	20.000	10.000	
Jacques Platieau	Independent	20.000	1.780,82	
Ahok	Independent	7.068,49	1.767,12	
Eva Consulting	Non-exec	7.123,29		
Aubisque	Non-exec	7.123,29		
Christiane Malcorps	Non-exec	1.360		

### 9.30. Events after the balance sheet date

As of February 17, 2017 the Group announced that it has been granted EUR 1,9 million in non-dilutive funding<sup>2</sup> from the Walloon Region. The grant follows a decision by the Vice-President and Minister for Economy, Industry, Innovation and New Technologies of the Wallloon Region Government, Mr. Jean-Claude Marcourt.

The funding allows the Company to advance two ongoing research programs and covers up to 50% of the total value of both projects.

The first research program will look into the alternative production of Estetrol (E4) by biosynthesis. The second will cover the development of pharmaceutical grade Ethylene-Vinyl Acetate (EVA) for complex therapeutics solutions.

Mithra announced an exclusive long-term license and supply agreement that extends beyond 10 years with Mayne Pharma, a leading specialty pharmaceutical company, for the commercialization in the United States of Myring™, Mithra's combined hormonal contraceptive vaginal ring made of ethylene vinyl acetate copolymers (EVA). Mayne Pharma is the second largest supplier of oral contraceptive products in the US market.

Under the terms of the agreement, Mithra will receive EUR 2,4 million upon signature, as well as significant milestone payments on ANDA approval (market approval by the FDA) and on the commercial launch of the product. As a part of Mayne Pharma's long-term exclusive sourcing commitment, Mithra is considering the expansion of its production capacity for Myring $^{\text{M}}$ .

<sup>&</sup>lt;sup>2</sup> Non-dilutive funding is granted as recoverable advances ('avances récupérables') to support specific research and development programs. The funding is reimbursable over the economic life of the projects, as outlined in the Terms and Conditions. Thirty per cent is refundable based on a fixed reimbursement schedule, while the balance is refunded under the form of royalties over the same period.

In March 2017, Fuji Pharma has signed a term sheet for its product candidate in menopause, Donesta<sup>®</sup>. Under the terms of the 20-year partnership agreement, Mithra will, depending on the progress of the development, receive single digit milestones. The term sheet comprises an exclusive supply obligation for the duration of the contract, which would provide Mithra's CDMO with a steady flow of production work for its Estetrol-based products, and hence represent a source of revenue for Mithra over the entire term.

## 9.31. Mithra Pharmaceuticals companies consolidation scope

#### Subsidiaries

The Group's financial statements consolidate those of the following undertakings:

		2016	2015
The Company has the following subsidiaries		Ownership %	Ownership %
Mithra Recherche et Développement SA		100%	100%
Registered office	Rue Saint-Georges 5 4000 Liège		
Incorporation Date	13/06/2013		
Company registration n°	534.909.666		
Fund SA		100%	100%
Registered office	Rue Saint-Georges 5 4000 Liège		
Incorporation Date	1/07/2013		
Company registration n°			
Mithra Lëtzebuerg SA		100%	100%
Registered office	Boulevarddela Petrusse 124, 2330 Luxembourg		
Incorporation Date	27/12/2012		
Company registration n°	LU25909011		
Mithra Pharmaceuticals CDMO SA		100%	100%
Registered office	Rue Saint-Georges 5 4000 Liège		
Incorporation Date	13/06/2013		
Company registration n°	534.912.933		
Mithra Pharmaceuticals GmbH		100%	100%
Registered office	Promenade 3-9 Raumm 22 DE - 52076 Aachen Germany		
Incorporation Date	27/12/2013		
Company registration n°	DE 295257855		
Mithra Farmacêutica do Brasil Ltda		100%	100%
Registered office	Rua Ibituruna N° 764 Saúde, São Paulo Brésil		
Incorporation Date	28/02/2014		
Company registration n°	NIRE N°35.220.476.861		
WeCare Pharmaceuticals BV		100%	100%
Registered office	Lagedijk 1-3, NL -1541 KA Koog aan de Zaan		

The Company has the following subsidiaries		2016 Ownership %	2015 Ownership %
Incorporation Date	23/09/2013		
Company registration n°	NL08165405B01		
Novalon SA		100%	100%
Registered office	Rue Saint-Georges 5 4000 Liège		
Incorporation Date	17/11/2005		
Company registration n°	877.126.557		
Mithra Pharmaceuticals SAS		100%	100%
Registered office	Rue de l'Est 45 92100 Boulogne-Billancourt France		
Incorporation Date	13/03/2015		
Company registration n°	FR 48810337139		
Estetra SPRL		100%	100%
Registered office	Rue Saint Georges, 5 4000 Liège		
Incorporation Date	01/09/2009		
Company registration n°	818.257.356		
Donesta Bioscience BV		100%	100%
Registered office	Boslaan 11 3701 CH Zeist The Netherlands		
Incorporation Date	23/12/2011		
Company registration n°	Commercial Register No. 54167116		

## Associates

The following associates are accounted for using the equity method in the Group's financial statements:

The Company has the follow	wing associates	2016 Ownership %	2015 Ownership %
Targetome SA Registered office Incorporation Date Company registration n°	Traverse de l'hôpital 5, Liège 15/07/2010 827,564,705	25,13%	25,13%

# 9.32. Disclosure audit fees

In Euro (€)		
Auditor's fees	80.081	
Fees for exceptional services or special missions (audit related)	-	
Tax consultancy (audit related)	-	
Fees for exceptional services or special missions (external to audit)	-	
Tax consultancy (external to audit)	-	
Total	80.081	

## 9.33. Condensed statutory financial statements of Mithra SA

In accordance with Art. 105 of the Belgian Companies' Code, the condensed statutory standalone financial statements of Mithra Pharmaceuticals SA are presented. These condensed statements have been drawn up using the same accounting principles for preparing the complete set of statutory financial statements of Mithra Pharmaceuticals SA at and for the year ending 31 December 2016 in Belgian GAAP.

The management report, the statutory financial statements of Mithra Pharmaceuticals SA and the report of the statutory auditor will be filed with the appropriate authorities and are available at the Company's registered offices.

#### Thousands of Euro (€)

Assets as at	2016	2015
Fixed assets	39.798	39.363
Intangible fixed assets	4.114	5.082
Tangible fixed assets	1.834	1.769
Financial fixed assets	33.849	32.512
Current assets	106.659	117.467
Amounts receivable	53.385	19.007
Inventory	3.660	2.428
Current investments	-	
Cash at bank and in had	44.951	95.500
Deferred charges and accrued income	4.663	531
Total assets	146.457	156.830

#### Thousands of Euro (€)

Liabilities as at	2016	2015
Equity	116.040	130.541
Capital	22.790	22.790
Share premium account	125.561	125.561
Reserves	598	598
Accumulated profits (losses)	(33.012)	(18.510)
Grants	104	104
Provisions	266	266
Amounts payable after more than one year	4.411	1.680
Current liabilities	25.740	24.343
Short term debts	-	16.900
Short term portion of LT debts	624	242
Amounts payable within one year	20.584	7.140
Deferred charges and accrued income	4.532	61
Total assets	146.457	156.830

### Thousands of Euro (€)

Summary income statement	2016	2015
Operating income	21.578	18.295
Turnover	21.126	18.112
Other operating income	451	183
Operating charges	35.572	32.561
Cost of goods sold	8.214	9.078
Services and other goods	21.895	19.089
Remuneration, social security costs and pensios	3.801	3.138
Depreciations of and amounts written off formation expenses, intangible and tangible fixed assets	1.289	1.061
Other operating charges	373	195
Operating profit	(13.995)	(14.266)
Financial result	517	(405)
Financial income	747	242
Financial charges	230	647
Gain (loss) on ordinary activities before taxes	(13.478)	(14.672)
Extraordinary result	-	(2.850)
Extraordinary cost	-	2.850
Extraordinary income	-	
Profit (loss) for the year before taxes	(13.478)	(17.522)
Taxes	1.024	21
Profit (loss) for the period available for appropriation	(14.501)	(17.543)

### Thousands of Euro (€)

Capital statement	2016	2015
A. Capital		
1. Issued capital		
- At the end of the previous year	22.790	3.107
- Changes during het year	-	19.683
- At the end of this year	22.790	22.790
2. Capital representation		
2.1 Shares without par value		
- bearer and dematerialised	31.129.756	31.129.756
B. Own shares held by		
C. Commitmentes to issue shares		
D. Autorised capital not issued		