



**mithra**  
Women's Health

# Annual Report 2017

**Specialists in Women's Health**  
Transforming Options for Women  
Through Innovation



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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 new and improved products that meet women's needs for better safety and convenience.

**Inspired by Women**



# Our Mission





# Mithra at a Glance

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

Estetrol (E4)

mithra<sup>cdmo</sup>

Complex  
Therapeutics

Mithra at a Glance

## E4: Mithra's native selective estrogen platform (NEST™)

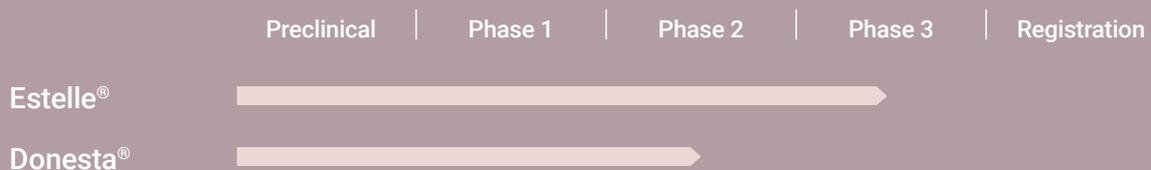
Mithra's goal is to develop, manufacture and commercialize new and improved products that meet women's needs for better safety and convenience, bringing novel options to a market characterized by a lack of innovation in recent years. In particular, there is a growing opportunity for estrogen-based products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

Mithra believes that E4 has the potential to transform the Women's Health market, providing potential benefits over current estrogens in several areas including oral contraception and hormone therapy (HT) during menopause. 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 E2 (Estradiol)<sup>2,3</sup>, a favorable risk of drug-drug interaction<sup>4</sup>, 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-being<sup>7</sup>.

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 (hormonal cancers), emergency contraception and osteoporosis, as well as in indications that go beyond the sector of Women's Health 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>1</sup> Klufft C et al., Contraception 2017; 95(2):140-7 ;

<sup>2</sup> Gerard C et al., Oncotarget 2015; 6(19):17621-36 ;

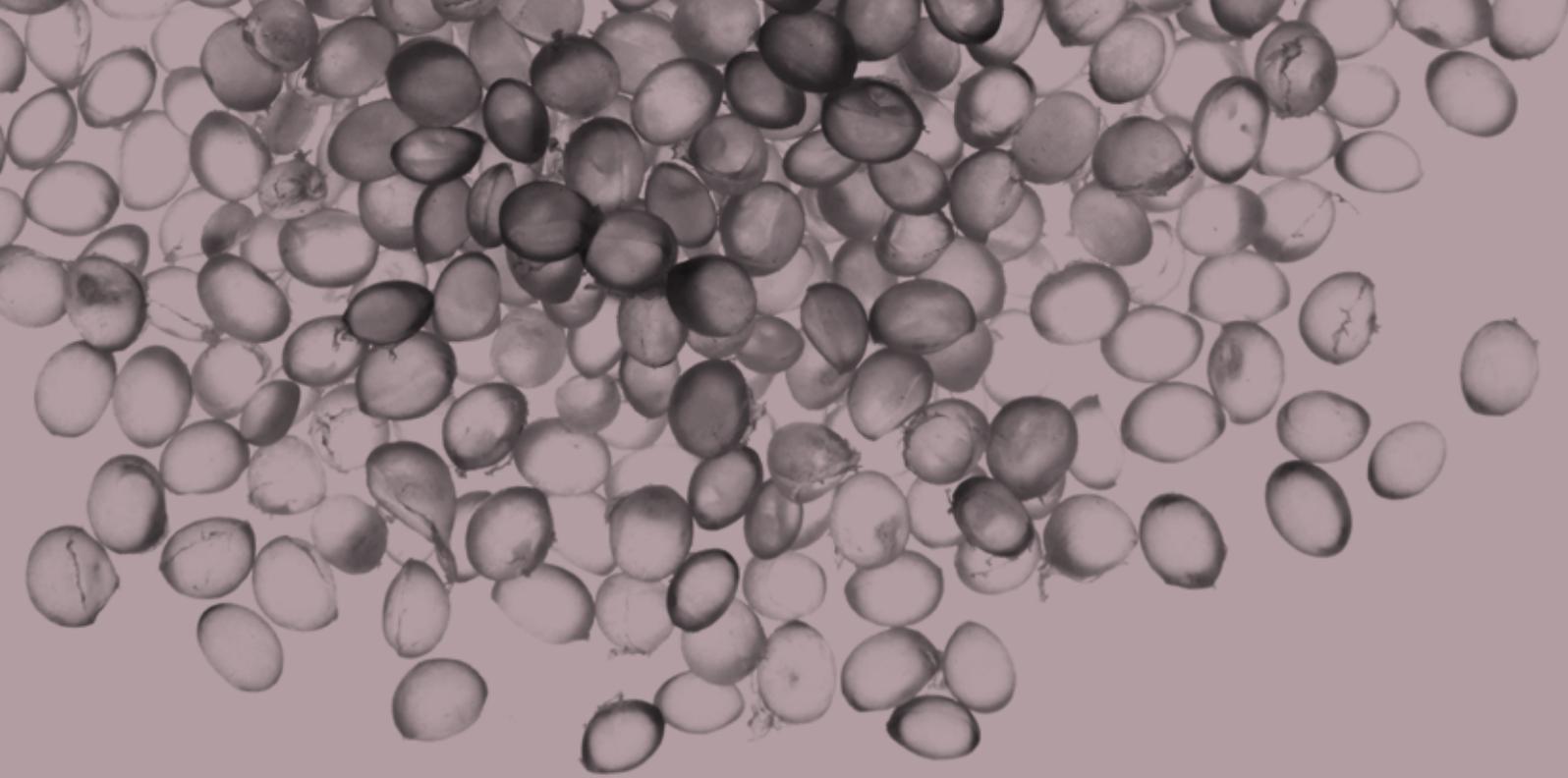
<sup>3</sup> Visser M et al., Horm Mol Biol Clin Invest. 2012;9:95-103 ;

<sup>4</sup> Visser M et al., Climacteric. 2008; 11 Suppl 1:64-8 ;

<sup>5</sup> M et al., Eur. J. Contracept. Reprod. Healthcare 2015; 20(6) :463-75

<sup>6</sup> Apter D. et al., Contraception. 2016;94(4):366-73 ;

<sup>7</sup> Apter D et al., Eur. J. Contracep. Reprod. Healthcare 2017 :22(4);



Mithra at a Glance

# Complex Therapeutics

Mithra 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 highly specialized drug delivery approaches for new indications using the hormone formulation expertise as well as the development and manufacturing capabilities at its dedicated CDMO research, development and specialist manufacturing center.

At present, Mithra's portfolio of Complex Therapeutics consists of the following products and product candidates:

## Myring™

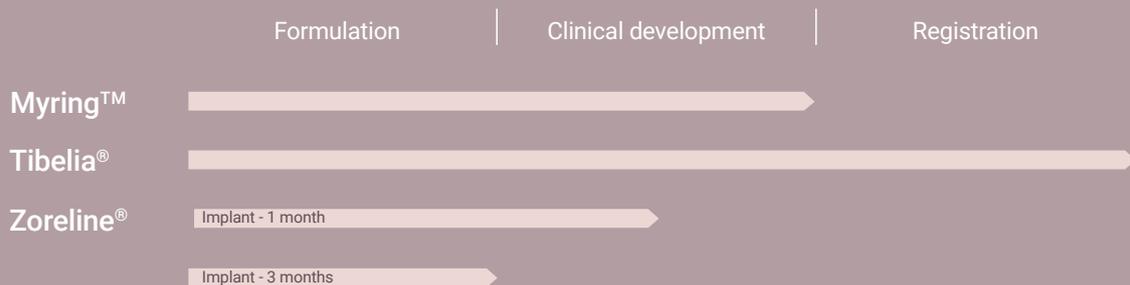
A contraceptive vaginal ring releasing a combination of hormones, made of Ethylene-vinyl-acetate copolymers (EVA).

## 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.



Mithra at a Glance

# Mithra CDMO

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

Mithra's CDMO, a 15 000 m<sup>2</sup> 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 allows Mithra to develop and produce its product portfolio in-house, including Complex Therapeutics based on polymer technology, such as Myring™ and Zoreline®. Another section of the CDMO, which will be finalized in H1 2019, will host the production of Estelle® and Donesta® tablets.

The CDMO enables Mithra to maintain a strong competitive position by reducing reliance on external providers, retaining intellectual property and expertise in-house.

The platform also provides its partners, such as GSP, with a high quality service covering most aspects of research, development and manufacturing of polymeric forms, implants, sterile injectables and tablets.



# Achievements in 2017

Achievements in 2017

## Innovation

In 2017, Mithra made significant progress across both its innovative E4 (Estetrol) and its Complex Therapeutics programs.

With regard to its E4 pipeline, the Phase III Estelle<sup>®</sup> oral contraceptive studies, E4Freedom, are progressing well, with recruitment completed in both the EU/Russia and US/Canada study. Top-line results for Mithra's novel contraceptive product candidate are on track and expected in Q3 2018 (EU/Russia) and Q1 2019 (US/Canada).

Post-period, Mithra also announced positive hemostasis results, pointing to the favorable safety profile of Estelle<sup>®</sup>, and of E4 in general.

Secondly, the Donesta<sup>®</sup> Phase IIb dose-finding study for menopausal symptoms, E4Relief, has been completed, and we expect to publish results in the second quarter of 2018.

Furthermore, Mithra also received orphan drug designation for E4 in neuroprotection, more particularly in neonatal encephalopathy, based on the promising preclinical results obtained. This underlines the potential of E4 in areas beyond Women's Health.

For its Complex Therapeutics, Mithra made great progress for its vaginal ring for contraception, Myring<sup>™</sup>: the production line at the CDMO for Myring<sup>™</sup> obtained GMP (Good Manufacturing Practice) approval in Europe, and the bioequivalence studies yielded excellent results, indicating that the product is equivalent to branded Nuvaring<sup>®</sup> (Merck). Myring<sup>™</sup> is on track for regulatory approval in Europe in H2 2018, with launch possible shortly thereafter. Post-period, Mayne Pharma, Mithra's partner for the US commercialization of Myring<sup>™</sup>, confirmed that the Abbreviated New Drug Application (ANDA) has been accepted for filing with the FDA. Consequently, the pathway to launch of the product candidate is on track and expected in H1 2019.

Also, for Tibelia<sup>®</sup>, Mithra's version of Livial<sup>®</sup> (Merck) for menopausal symptoms, the extended shelf-life of 36 months, as compared to 24 months for other currently available tibolone-based products, was confirmed. The product has now been launched in 6 countries, with additional launches planned in 2018.

Finally, the Mithra CDMO<sup>®</sup> is ramping up its R&D activities and product supply. Next to the preparations for the Myring<sup>™</sup> launch, Mithra also signed its first contracts for the injectables section with GSP (Generic Specialty Pharma). The second and final phase of construction, which is dedicated to tablet manufacturing for Estelle<sup>®</sup> and Donesta<sup>®</sup>, is well underway and on track to be completed in H1 2019, within the allocated budget (EUR 25.8 million).

REBITDA improved to  
**EUR -18.1 million**  
and a cash position of  
**EUR 36.2 million**

Revenues doubled to  
**EUR 46.3 million**  
of which license sales account for  
**EUR 29.4 million**

**EUR 48.2 million**  
investment in R&D  
driven by E4-based clinical pipeline

Achievements in 2017

## Corporate

In 2017, Christiane Malcorps replaced Philippe Suinen as a member of Mithra's nomination and remuneration committee. Philippe Suinen remains a member of Mithra's audit committee. Ms Malcorps has been a member of Mithra's Board of Directors (Mithra SA) and a member of the Board of Mithra's CDMO since 2016.

Mithra also strengthened its management team with the appointment of Christophe Maréchal as Chief Financial Officer, Michaël Dillen as Chief Legal Officer and Sofie Van Gijssels as Investor Relations Officer. Post-period, Geoffroy Dieu was appointed Chief Production Officer, to further strengthen the CDMO team.

In June 2017, Mithra successfully raised EUR 26.1 million in an oversubscribed private placement. The operation received the strong continued support of existing shareholders as well as the interest of both international and local specialist healthcare investors. The proceeds

of the transaction strengthened Mithra's cash position, positioning the company well to deliver on the further development of the E4 programs, the development of Myring™ up to commercialization, the scaling-up of the Mithra CDMO, and the acceleration of business development efforts.

Mithra was ranked 3rd in a regional survey organized by Randstad, the global leader in the human resources industry. The survey evaluates the attractiveness of companies established in the greater Liège area, and Mithra obtained top scores for "cutting edge technology" and "financial health". This regional ranking reflects Mithra's ability to continue to attract the best talent and skills needed to support its growth and development.

Mithra was also nominated for the sustainable partnership awards organized by SHIFT ([www.sustainablepartnerships.be](http://www.sustainablepartnerships.be)) for the development of its interactive web platform dedicated to Women's Health and to the improvement of the interaction between Health Care Professionals & patients ([www.gynandco.info](http://www.gynandco.info)).

# Business Development and Commercial Activity

## Business Development

2017 was a very important year in terms of business development activities. Summarizing, Mithra closed the following deals:

- In February 2017, Mithra granted an exclusive LSA to Mayne Pharma for the commercialization of Myring™ in the US. Mayne Pharma paid EUR 2.4 million upon signature, with further milestones of at least EUR 7.6 million from approval by the US FDA through to commercial launch of the product.
- Additional LSAs were signed for Myring™ with Gynial for Austria and with Adamed for the Czech Republic, followed post-period by an agreement with Alvogen for the Russian market. These contracts underline Mithra's know-how in polymer technology and its attractiveness to specialist players in Women's Health. As Mithra will produce Myring™ at its CDMO, and in view of the long-term sourcing commitment of Mithra's partners, the Company has expanded its production capacity for Myring™.
- In June, Mithra signed an exclusive LSA for the commercialization of Donesta® in Japan and a number of ASEAN countries with Fuji Pharma, the Japanese leader in Women's Health and Mithra's partner for Estelle® in these territories. The 20-year agreement is expected to generate low double-digit million development, regulatory and commercialization milestones. Mithra is also eligible for long-term supply revenues, as Donesta® will be produced at the Mithra CDMO.
- Towards the end of 2017, Mithra also signed an important contract with the Brazilian leader in Women's Health, Libbs, for an exclusive 20-year commercialization license for Estelle® in Brazil. Mithra received a EUR 20 million down payment, 50% of which is non-refundable, with 50% pending regulatory milestones. EUR 14 million has been received upon signature of the contract and the remaining EUR 6 million has been paid early 2018. The contract also contains a manufacturing agreement enabling Libbs to produce Estelle® for the Brazilian market at its production facility in Sao Paulo (Brazil). Over the duration of the contract, the agreement could generate several hundred million euros of revenues for Mithra.
- Mithra signed an exclusive agreement for Tibelia® in Canada with an undisclosed partner. The marketing authorization process with Health Canada is presently ongoing. Since Tibelia® would be the first tibolone-based Hormone Therapy product on the Canadian market, the product would be launched as a new treatment option. Currently, Tibelia® is on the market in the UK, Finland, Sweden, the Netherlands, Spain and Italy, with two additional launches planned in the course of 2018.
- In December, Mithra signed its first injectables contract for the Mithra CDMO with GSP, a leading player in generic healthcare products. The umbrella agreement comprises the development and production of four products.
- Also in December, Mithra successfully disposed of its French affiliate. Product marketing authorizations were transferred to Laboratoire CCD, a French-based Women's Health player, while at the same time a share purchase agreement for Mithra France was concluded with Theramex, whereby Theramex will take over the subsidiary, including its pharmaceutical license. Financial details of the agreements were not disclosed. The sale of the French subsidiary fits into Mithra's strategy to maximize the value of its non-core assets, and to fully focus on the development and partnering of its key E4-based programs.

## Commercial

Mithra continued to demonstrate its position as a leading player in the Benelux Women's Health market, with a market share (in number of cycles) of more than 40% in Belgium and approximately 30% in the Netherlands for contraception products.

In July, Mithra further strengthened its market position by signing a contract with Procare for the exclusive distribution of Papilocare® in Belgium and Luxembourg. Papilocare® is a therapy for the prevention and treatment of Human Papillomavirus (HPV) dependent lesions. Towards the end of 2017, Mithra also launched Laclimella®, a novel hormonal treatment for menopausal symptoms composed of 1 mg estradiol valerate and 2 mg dienogest.

As of 2018, both products form part of Mithra's growing portfolio of higher-margin, specialized products in Women's Health, to complement Mithra's existing marketed branded generics and to leverage the existing commercial infrastructure.



A portrait of Marc Coucke, Chairman of the Board, wearing glasses and a dark jacket, smiling. The image is semi-transparent and serves as a background for the text.

**Marc Coucke**  
Chairman of the Board

“

*2017 was another key year for Mithra, both in terms of clinical progress and business development. The contracts closed with leaders in the sector such as Libbs, Fuji and Mayne clearly show that Mithra is firmly on the radar as an innovative player in the growing field of Women's Health. More than ever, I am convinced that Mithra has the potential to improve options for women across the globe, while at the same time adding substantial shareholder value.*

A black and white portrait of François Fornieri, Chief Executive Officer of Mithra. He is a middle-aged man with curly hair and a beard, smiling at the camera. He is wearing a dark suit jacket over a light-colored shirt. The background is a plain, light color.

**François Fornieri**  
Chief Executive Officer

“

*During 2017 we again made substantial progress on our lead programs that we believe will deliver Mithra's long-term international growth as a transformational leader in Women's Health. We look forward to important read-outs for our two potential blockbusters, Estelle<sup>®</sup> and Donesta<sup>®</sup>, in 2018, and to the further acceleration of our business development efforts. 2018 certainly promises to be a pivotal year for Mithra!*

# Letter to Share- holders



*Dear Shareholders, colleagues and partners,*

*In 2017 and early 2018, we achieved a number of important R&D as well as business development milestones that accelerated Mithra's growth into a transformational Women's Health company.*

*Mithra made substantial progress across its three pillars: our highly promising E4 (Estetrol) portfolio, a new chemical entity product family that includes the lead clinical programs for Estelle® (contraception) and Donesta® (menopause); our Complex Therapeutics business, including Myring™; and our full spectrum research, development and complex manufacturing CDMO facility.*

*For Estelle®, a number of regulatory milestones were reached in 2017, including the finalization of recruitment in the Phase III EU/Russia and US/Canada studies, as well as in the PK substudy. Post-period, Estelle® also obtained very supportive Phase II results pointing to a favorable hemostatic profile, especially when compared to Estelle®'s benchmark, Yaz®. We are excited about these results, which further delineate the safety profile of Estelle® as a truly novel, 'fifth-generation' oral contraceptive with the potential to offer a superior risk/benefit profile vs currently commercialized oral contraceptives.*

*The Donesta® study, which addresses the significant unmet need for a safer, effective product for menopausal symptoms, also progressed well, and we are looking forward to presenting results in the second quarter of 2018.*

*Furthermore, in 2017, Mithra continued to strengthen its IP portfolio for E4, including with a patent in neuroprotection (neonatal encephalopathy), underlining the potential of E4 beyond the field of Women's Health.*

*With regard to the Complex Therapeutics, Myring™, our contraceptive vaginal ring candidate, gained further traction thanks to*

successful bioequivalence results, indicating that the product candidate is fully bioequivalent to originator product Nuvaring® (Merck). Also, the Myring™ production line at the CDMO obtained European GMP approval (Good Manufacturing Practice). This is an essential part of the regulatory process and a strong quality stamp for the CDMO team. Post-period, the Abbreviated New Drug Application (ANDA) for the vaginal ring has been accepted for filing by the FDA, which is another important regulatory milestone.

In 2017, we were also very pleased to announce a number of landmark deals with leaders in Women's Health, making it clear that Mithra is firmly on the radar with experts in the sector. More specifically, we closed an agreement with Fuji Pharma for Donesta® in Japan and ASEAN, following a deal for Estelle® with the same partner in these territories. Later in the year, we closed a contract with Libbs for Estelle® for the sizeable Brazilian market, triggering a EUR 20 million down payment, and we announced our agreement with Mayne Pharma for the exclusive license to Myring™ in the US.

Thanks to the revenue recognition of partnership deals and our stable Benelux commercial business, revenues doubled in 2017, to EUR 46.3 million.

Most of Mithra's projects are housed in our integrated R&D and production facility, the Mithra CDMO. This facility is now fully operational as a pharmaceutical ecosystem for our own projects, such as Myring™, and for partners interested in leveraging our expertise on a contract basis. For the latter, in 2017, we were happy to close an umbrella contract with GSP for the injectables section.

## 2018 outlook

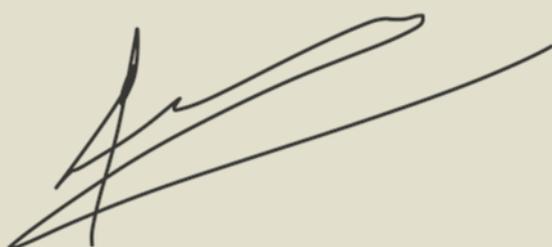
Building on the progress made in 2017, we are looking forward to substantial news flow in 2018 and early 2019. Most importantly, in 2018, we expect key read-outs of our potential blockbuster programs, Estelle® and Donesta®. Top-line Phase II dose-finding results for Donesta®, Mithra's novel menopause product candidate, are expected in Q2 2018. For our contraceptive candidate Estelle®, top-line results of the first pivotal Phase III study in the EU & Russia will be available in Q3 2018, with the US/Canada results to follow in Q1 2019.

For Myring™, European approval can already be expected in Q2/Q3 2018, with launch in the following quarters. As post-period, the Abbreviated New Drug Application (ANDA) for the vaginal ring has been accepted for filing by the FDA, we can confirm the timeline towards potential launch in the US by our partner Mayne Pharma in H1 2019<sup>9</sup>. With USD 830 million in sales, the US market represents over 75% of the annual global sales of Nuvaring®, making this a key territory for the product<sup>10,11</sup>. Nuvaring® will go off patent in April 2018, and no generic version has been approved in the US to date.

The activity at our innovative research, development and manufacturing facility in Liège (Mithra CDMO) will also continue to ramp up: the first contracts are in place for the injectables section, with GSP, and the FDA GMP visit for the Myring™ section is planned for Q2 2018. This would be another important milestone for the CDMO as we get ready for the production of Myring™ for the US market. Moreover, the tablet section of the CDMO is still on track to be finalized in H1 2019.

Importantly, in 2018, we also expect to further accelerate our business development efforts, especially for our E4 blockbuster candidates Estelle® and Donesta®. As discussions with potential partners are on track, we are confident that we will realize the full commercial potential of our programs, including in the key geographies of EU and US. Hence, following a doubling of the revenues in 2017 versus 2016, we could anticipate a further increase in revenues, helped by the stable, well-established commercial business in the Benelux.

We are very much looking forward to the outcome of these upcoming events in the year ahead, which are sure to make 2018 a truly pivotal year for Mithra.



Marc Coucke



François Fornieri

<sup>9</sup> Myring™ will be marketed under a different trademark name in the US.

<sup>10</sup> According to IQVIA, as provided by Mayne Pharma, for the 12 months ending 31 January 2018

<sup>11</sup> IMS Health Q3 2018



# Strategy & Outlook

# 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 2018 the Company will continue to focus on its lead assets, Estelle® (Phase III in contraception) and Donesta® (Phase II in menopause), and in 2018, important clinical read-outs are expected for both product candidates.

Mithra will look to pursue strategic partnerships for the E4 assets: for Estelle®, Mithra is working to select a suitable partner for the key territories of US & EU, as well as for other territories, following the agreements closed with Fuji for Japan and ASEAN and Libbs in Brazil. Furthermore, Mithra expects to be well-positioned for partnering discussions for Donesta® following the Phase II results. Pending the results and in order to maximize the global potential of Donesta®, the Board of Directors considers several options for the further development of this asset.

Strategically, Mithra also intends to continue the expansion of its E4 platform in different indications, including in neuroprotection, where an ODD (Orphan Drug Designation) has been obtained in neonatal encephalopathy. Additional indications such as emergency contraception, wound healing and dysmenorrhea are also investigated.

While the later-stage E4-based programs currently hold the greatest value, the Board believes that these early-stage indications for E4 may also provide significant value and interesting partnering opportunities in the future, demonstrating the broad clinical potential of the E4 platform.

Commercially, Mithra aims to retain its leadership position in the Benelux contraceptive market throughout 2018, helped by the addition of higher-added value products such as Papilocare® for HPV and Laclimella® for menopause.

# Outlook

## Reaching clinical milestones and accelerating business development

Building on the progress in 2017, Mithra is looking forward to substantial news flow in 2018. In Q2, Mithra will publish its top-line Phase II dose-finding results for Donesta®, Mithra's novel menopause product candidate. Furthermore, results of the first pivotal Estelle® study in the EU & Russia will be available in Q3 2018, with the US/Canada Phase III results to follow in Q1 2019. At the same time, Mithra continues to work on additional indications in 2018, including progressing the preclinical work in neuroprotection.

For Myring™, European approval can be expected in Q2/Q3 2018, with a launch possible in following months. As post-period, the FDA accepted the filing submission of Myring™, Mithra's partner Mayne Pharma is getting ready for a US launch in H1 2019.

Mithra is confident to accelerate business development activity for its lead E4 assets as well as its Complex Therapeutics, selecting the best partner for maximizing the potential of the products and product candidates. If realized, the partnerships could lead to increased revenues in 2018, following a doubling of revenues in 2017.

The company is confident that these developments, along with the accelerating activity at its innovative research, development and manufacturing facility in Liège, will further solidify Mithra's position as a leading international player in Women's Health.

# R&D Projects

# Estetrol



*We are bringing potentially better therapeutic options to women.*

**Maud Jost**  
Estetrol Project Leader

## The potential benefits of E4:

- Favorable VTE risk profile<sup>12</sup>
- Favorable drug-drug interaction profile<sup>15</sup>
- Minimal increase of triglycerides<sup>16</sup>
- Lower breast pain and lower carcinogenic potential in the presence of E2<sup>13,14</sup>
- Good user acceptability, body weight control, excellent cycle control, improved spotting and general well-being<sup>17,18</sup>

## E4 – The first NEST™: Natural Estrogen with Selective action in Tissues

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

Thanks to its favorable 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 28 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), neuroprotection (e.g. hypoxic ischemic encephalopathy), dermatology (e.g. wound healing) and musculoskeletal pain.

<sup>12</sup> Kluff C et al., Contraception 2017; 95(2) :140-7 ;

<sup>13</sup> Gerard C et al., Oncotarget 2015; 6(19):17621-36 ;

<sup>14</sup> Visser M et al., Horm Mol Biol Clin Invest 2012; 9:95-103 ;

<sup>15</sup> Visser M et al., Climacteric 2008; 11 Suppl 1:64-8 ;

<sup>16</sup> Mawet M et al., Eur. J. Contracept. Reprod. Healthcare 2015; 20(6) :463-75

<sup>17</sup> Apter D. et al., Contraception 2016; 94(4):366-73 ;

<sup>18</sup> Apter D. et al., Eur. J. Contracept. Reprod. Healthcare 2017:22(4).



## Advisory Boards

In 2017, Mithra has continued its collaboration with its scientific committees, composed of European and North American experts in gynecology, to support the ongoing and next development steps of its products candidates based on E4, Estelle® and Donesta®.

The committees are also advising Mithra on the clinical relevance and the added value of E4 in the contraception and menopause fields, and they are working with Mithra to confront development plans with market to ensure the best match with patient needs. Additional advisory meetings are scheduled in 2018 to address the most recent progress and to obtain strategic, regulatory and development guidance to further delineate the product candidates.

## Further strengthening E4's IP

In 2017, Mithra further strengthened its IP portfolio with the addition of several patents and patent applications.

In January 2017, the US Patent and Trademark Office (USPTO) issued a Notice of Allowance for a patent covering 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. In December 2017, the same patent was granted in Eurasia.

Mithra also strengthened its patent position in Australia, with a patent granted to protect E4's synthesis process until 2032 and a certificate of grant covering E4's use alone as emergency contraceptive.

In June 2017, Mithra acquired the rights on an E4 patent for use in the treatment of HIE, for which an ODD (Orphan Drug Designation) was obtained from the European agency for development for neonatal encephalopathy. The patent is granted in several geographies, including Europe and the US.

Post-period, the company also applied for a patent application based on the data generated in the Estelle® hemostasis Phase II substudy. This study indicated the favorable hemostatic profile of Estelle® when compared to a 4<sup>th</sup> generation COC, Yaz, while yielding effects that are at least comparable to those of a 2<sup>nd</sup> generation COC (Melleva), which is known as the 'safest' contraceptive pill for a number of important hemostatic parameters.



*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 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**

Co-founder of Mithra and President of the Scientific Advisory Board

# R&D Projects

# Estelle®

Estelle® is a combined oral contraceptive (COC) product candidate composed of 15 mg Estetrol (E4) and 3 mg Drospirenone (DRSP). The Estelle® program has completed recruitment for its two pivotal Phase III clinical trials in Europe and Russia as well as in the US and Canada. Study details can be found in the *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 efficacy, cycle control, and the general safety and acceptability of the 15mg E4 / 3mg DRSP combined oral contraceptive pill in healthy women aged 18-50 years old.

The study is taking place in 69 centers across Europe and Russia, and involves the participation of the study subjects over a period of 12 months (13 cycles, 1 cycle = 28 days). In total, over 12,000 female cycles of Estelle® have been completed.

### Primary outcome

- Contraceptive efficacy within the 18-35 year old population based on the Pearl Index<sup>19</sup> (PI)
- The European authorities request an overall PI with a two-sided 95% confidence interval (CI) such that the difference between the upper limit of the confidence interval and the point estimate does not exceed 1

### 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 enrolls 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, including 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. Post-period, the minimal requirement of 10,000 female cycles in the US was obtained. Together with the European study, Mithra has now also fulfilled regulatory requirements for a minimum total of 20,000 cycles, of which 50% are from North America.

### Primary outcome

- Contraceptive efficacy within the 18-35 year old population based on the Pearl Index<sup>20</sup> (PI)
- Unlike the European authorities, the FDA does not impose a cut-off for the PI's confidence interval. Rather, the American authorities consider the global risk/benefit ratio of a novel contraceptive product candidate. The FDA requires requires 20,000 evaluable female cycles, with at least 10,000 cycles from the US/Canadian study

### 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



## Estelle® Key program developments in 2017

- Over the course of 2017, the Phase III studies in the US & Canada as well as in Europe & Russia for Estelle® have been advancing well, with the finalization of recruitment in both the EU/Russia and the US/Canada. The Phase III Estelle® studies are on track to report top-line results between Q3 2018 (EU/Russia) and Q1 2019 (US/Canada).
- As per regulatory requirements, Mithra also conducted a Phase I study evaluating the effect of single, multiple and suprathreshold oral doses of E4/DRSP combinations (up to 5 times the therapeutic dose) on safety, tolerability and pharmacokinetic (PK) parameters, showing a good tolerability of all combinations, thus completing the PK data package. This study also included a QT assessment indicating a satisfactory safety profile for the QT interval.
- In May, Mithra initiated a PK ethnobridging study in order to determine the PK profile of Estelle® in Japanese and Caucasian subjects. The full results of the study, which forms part of the Estelle® studies with partner Fuji Pharma for the Japanese and ASEAN markets, were received late Q1 2018, and indicate a similar PK profile for Japanese and Caucasian subjects. For Fuji, this is a first important step towards bringing Estelle® to the Japanese and ASEAN market.
- In August, Mithra finalized recruitment for the Estelle® population PK substudy, which aims to determine the impact of demographic parameters (such as BMI, race and smoking) on the absorption, distribution and excretion of Estelle®. This study, which is part of the Estelle® Phase III program in the US/Canada, will also report top line results in Q1 2019, and can further delineate the unique profile of Estelle® in contraception.
- Following the agreement for Estelle® with Fuji Pharma for Japan and ASEAN closed in 2016, Mithra signed an important contract with the Brazilian leader in Women's Health, Libbs, for an exclusive 20-year commercialization license for Estelle® in Brazil. Mithra received a EUR 20 million down payment (50% of which is non-refundable), with EUR 14 million received upon signature of the contract and the remaining EUR 6 million paid in early 2018. The contract also contains a manufacturing agreement enabling Libbs to produce Estelle® for the Brazilian market at its production facility in Sao Paulo (Brazil), providing the Mithra CDMO with an important back-up supply. Over the duration of the contract, the agreement could generate several hundred million euros of revenues for Mithra.

## Estelle® Post-period results and prospects for 2018

- Post-period, Mithra published very promising top-line results for its hemostasis Phase II study. This substudy, which runs in parallel with the ongoing Phase III studies for Estelle®, analyzes a series of hemostatic, endocrine and metabolic parameters. Data are analyzed for 100 women divided over three treatment groups: 15 mg E4/3 mg DRSP (Estelle®), 30 mcg EE/150 µg LNG (Melleva®) and 20 µg EE/3 mg DRSP (Yaz®). The data indicate that for a number of key hemostatic parameters (including markers of VTE risk such as APC resistance and SHBG), Estelle® scores are comparable to Melleva®, a 2nd generation pill considered as the 'safest' on the market, and much better than 4th generation Yaz®. Given the importance of these parameters to help determine the venous thromboembolism (VTE) risk profile of a (combined) oral contraceptive, the results are closely studied by the regulatory bodies and keenly awaited by clinicians and (potential) commercialization partners for Estelle®. Results were presented at ISGE (Florence) on March 8, 2018.
- In March 2018, Mithra announced the completion of the minimum 10,000 cycles of Estelle® required in the US/Canada study and of more than 12,000 cycles of Estelle® in the European/Russian study. It has now also fulfilled regulatory requirements for a minimum total of 20,000 cycles, of which 50% have to be from North America. Moreover, regulatory guidance regarding the required number of subjects completing a full year of treatment (13 cycles) has already been reached in each trial.
- In April, Mithra also announced the execution of a binding head of terms with Searchlight Pharma for the exclusive commercialization of Estelle® in Canada. Mithra is eligible to receive up to EUR 15 million in upfront payments and sales-related revenues. In addition, Mithra will manufacture Estelle® for Searchlight at its CDMO facility and will also receive guaranteed annual recurring revenues based on minimum annual quantities (MAQ). Based on market assumptions and Mithra's forecasts, the agreement could achieve revenues of at least EUR 50 million for Mithra.

## Expected clinical news flow

### H1 2018

Full CSR results of hemostasis study

### H2 2018

Complementary data on ovarian function inhibition

### H2 2018

Results drug-drug interaction PK study

### Q3 2018 - Q1 2019

Top line results of Phase III studies

## Prestigious peer-reviewed Estelle® publication on well-being and body weight

Mithra published its Phase IIb Estelle® data on well-being and body weight in the leading peer-reviewed journal *Contraception*<sup>21</sup>. The article reports on Estelle®'s high acceptability, user satisfaction and general well-being, in addition to favorable body weight control. These elements are key for user compliance and continuation, and hence of great importance for the eventual commercial success of Estelle®.



## Estelle® positioned as a 'fifth generation' oral contraceptive

The contraceptive market is worth about USD 22 billion, with a CAGR of about 6%<sup>22</sup>. The worldwide Combined Oral Contraceptive (COC) market represents approximately USD 6.5 billion. While high-volume lower-priced generics take up a large chunk of the market, brands still account for 59% of the revenue<sup>23</sup>. Today, the best-selling pill remains the (non-reimbursed) Yaz family, with EUR 1.3 billion in sales<sup>24</sup>, despite the well-documented elevated VTE risk for this fourth-generation COC<sup>25</sup>.

For Estelle®, Yaz (EE/DRSP), is the benchmark, as Mithra's product candidate also contains the progestin DRSP, to allow for an improved quality of life and sense of well-being by women. However, given its hemostatic profile, Estelle® is a potentially safer contraceptive pill than Yaz. As following graph shows, Estelle® aims to be a truly novel contraceptive option, offering a unique benefit/risk profile versus currently commercialized COCs. Therefore, Mithra is convinced that, if approved, Estelle® has blockbuster potential.

	Better user acceptability	Favorable safety profile
1st & 2nd generation pill	-	+
3rd & 4th generation pill (e.g. Yaz family: EE + DRSP)	+	-
<b>Estelle®: potential 5th generation pill (E4 + DRSP)</b>	+	+

<sup>21</sup> <http://www.tandfonline.com/doi/full/10.1080/13625187.2017.1336532>

<sup>22</sup> Transparency Market Research 2017

<sup>23</sup> Kempen initiating coverage report, September 2016

<sup>24</sup> IMS Health Q3 2017

<sup>25</sup> Kluff C et al., *Contraception*. 2016

# R&D Projects

# Donesta®

Donesta® is a next generation orally-administered E4-based hormone therapy product candidate for the relief of vasomotor menopausal symptoms (VMS). In May 2016, Donesta® entered into a 12-week European Phase IIb dose-ranging study, *E4 Relief* (MIT-Do0001-C201).



## Primary outcome

- To define the minimum effective dose by evaluating changes in frequency and severity of moderate to severe VMS (hot flushes). In total four E4 doses (2.5 – 5 – 10 – 15 mg) are tested in this blinded study, plus placebo

## Secondary outcomes

- To evaluate the effects of different doses on vulvovaginal atrophy (VVA), 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/ quality of life
- To evaluate safety, including change in endometrial thickness

## Key program developments in 2017 and post-period events

- The study, which started recruiting in May 2016, progressed very well over the course of 2017.
- In June, Mithra signed an exclusive LSA for the commercialization of Donesta® in Japan and a number of ASEAN countries with Fuji Pharma, the Japanese leader in Women's Health and Mithra's partner for Estelle® in these territories. The 20-year agreement is expected to generate low double-digit million development, regulatory and commercialization milestones. Mithra is also eligible for long-term supply revenues, as Donesta® will be produced at the Mithra CDMO.
- Post-period, in January 2018, Mithra announced that over 200 patients in Czech Republic, Poland, Belgium, the Netherlands and the UK have completed at least 12 weeks of treatment.

## Prospects for 2018 – Donesta's potential as a novel, safer treatment for the unmet need in menopause

- Top-line results of the Donesta® study are expected in Q2 2018.
- The global menopause market currently stands at USD 8.6 billion and is expected to grow to approximately USD 16 billion by 2025, driven by growing awareness for Women's Health issues, the unmet medical need in menopause and the aging population, in addition to market expansion with the availability of new treatment options that provide a safer alternative to currently available therapies<sup>26</sup>. Studies show that approximately 78% of women experience menopausal symptoms, but less than 10% is currently treated.
- Currently, Premarin® (Pfizer), a 50-year old hormone therapy product composed of conjugated estrogens of pregnant mares, is still the best-selling menopause product, with over a billion in sales<sup>27</sup>. Alternative non- hormonal treatments, such as the use of anti-depressants, have proven largely unsuccessful.
- In 2001, the Women's Health initiative (WHI) has linked current HT treatments to an increased risk of breast cancer, coronary artery disease, stroke, and VTE.<sup>28</sup> Recent (re)analyses present a more subtle picture, indicating that there is a 'window of

opportunity' when treating menopausal symptoms at the beginning of menopause. More particularly, the results show that in that case, HT does not increase mortality due to cancer or cardiovascular (CV) events<sup>29</sup>. Also note that the WHI study has several limitations warranting caution, including the assessment of 1 dose, formulation, and route of administration in each trial<sup>30</sup>. Thus, results are not necessarily generalizable to other hormone preparations. Hence, safety concerns surrounding commercially available HT remain<sup>31</sup>, and there is an important unmet need for novel HT approaches that offer an improved risk/benefit ratio while addressing women's needs in terms of quality of life.

- As a response to this, a couple of HT and non-HT approaches to menopause are under development. Most notably, TherapeuticsMD (TXMD:NASDAQ GS) aims for approval of a new formulation of existing HT products, with an FDA-approved bioidentical combination of estradiol and progesterone. With regard to the non-HT approaches, most focus is on the NK(1),3 antagonists. Astellas (TSE:4503) has an NK3 antagonist in Phase IIb, and KaNDY Therapeutics has a NK1,3 receptor antagonist Phase IIb ready. However, while these product candidates may prove to be efficacious to suppress hot flashes, because of their mode of action, they do not attempt to address the host of symptoms associated with estrogen deficiency during menopause, including night sweats, sleep disorders, VVA (vulvo-vaginal atrophy), atherosclerosis, osteoporosis and bone density levels, and cardiovascular disease. Helping with the relief of these symptoms is essential to maintain a high level of quality of life for menopausal women.
- Donesta® (E4), given its unique mode of action as a natural estrogen, could address the unmet market need, offering a safer alternative to current VMS treatments, while offering the advantages of estrogens and HT therapy on symptoms associated with menopause. If approved, Donesta® could hence capture a substantial part of the growing menopause market.
- In view of the important market opportunity, Mithra is well-positioned for partnering discussions pending successful Phase II results of Donesta®. Pending the results and in order to maximize the global potential of Donesta®, the Board of Directors considers several options for the further Phase III development of Donesta®.
- Mithra plans further Donesta® KOL (Key Opinion Leaders) Board meetings in 2018 to fully assess the Donesta® Phase IIb results with leading experts in the field.

<sup>26</sup> Transparency Market Research 2017

<sup>27</sup> IMS Health Q3 2017

<sup>28</sup> Manson JE, Aragaki AK, Rossouw JE, et al. Menopausal Hormone Therapy and Long-term All-Cause and Cause-Specific Mortality:

The Women's Health Initiative Randomized Trials. JAMA 2017; 318(10): 927-38

<sup>29</sup> Baber RJ, Panay N, Fenton ATIWG. 2016 IMS Recommendations on women's midlife health and menopause hormone therapy. Climacteric 2016; 19(2): 109-50.

<sup>30</sup> The WHI studies were conducted with Premarin®.

<sup>31</sup> Baber RJ, Panay N, Fenton ATIWG. 2016 IMS Recommendations on women's midlife health and menopause hormone therapy. Climacteric 2016; 19(2): 109-50.

# R&D Projects

# Myring™

Myring™ is a flexible contraceptive vaginal ring product candidate 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®.

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™ has been shown to be bioequivalent to the Nuvaring® vaginal ring (Merck), which remains under patent protection until April 2018.

## Key program developments in 2017

- In January 2017 and November 2017, Mithra announced the results of two bioequivalence studies for Myring™. The excellent results (re)confirm that Myring™ is bioequivalent to the branded version NuvaRing® (Merck).
- In May 2017, Mithra received European Good Manufacturing Approval (GMP) for the production line of Myring™ at the Mithra CDMO, allowing Mithra to file for marketing approval with the European agencies in July 2017. Myring™ is on track to receive European marketing approval in Q2/Q3 2018, with launch possible in following quarters.
- In 2017, Mithra closed an exclusive long-term license and supply agreement with Mayne Pharma (ASX: MYX) for the commercialization of Myring™<sup>32</sup> in the US. Next to a EUR 2.4 million down payment received, Mithra is eligible for further milestones of at least EUR 7.6 million from approval by the US FDA through to commercial launch of the product.
- Additional LSAs were signed for Myring™ with Gynial for Austria and with Adamed for the Czech Republic, underlining Mithra's know-how in polymer technology and its attractiveness to specialist players in Women's Health.

## Post-period news and prospects for 2018

- Post-period, Mithra and Mayne Pharma announced that the Abbreviated New Drug Application (ANDA) for Myring™ has been accepted for filing by the US Food and Drug Administration (FDA). The acceptance by the FDA is an important regulatory step, as it reconfirms the pathway towards launch of the product candidate in H1 2019.
- Post-period, Mithra signed an LSA with Alvogen for Myring™ in the Russian market. The Nuvaring market in Russia represents about EUR 13 million<sup>33</sup>.
- Although different players may enter the market after patent expiry in all territories, the competitive landscape is expected to be more favorable in the US than in Europe. This is important given that at approximately USD 830 million, the US represents over 75% of the value of Nuvaring®<sup>34</sup>. In Europe, Merck has launched its own generic, Circlet®, in several countries at nearly the same price or a slightly lower price than NuvaRing®. However, volumes for Circlet® have been minimal so far<sup>35</sup>. Secondly, Chemo developed and recently launched<sup>36</sup> a "hybrid" vaginal ring, using a different polymer with a different qualitative & quantitative composition than NuvaRing®. In the US, Merck has not launched Circlet®, but two companies are currently known to file for marketing approval. However, no bioequivalent version has been approved in the US to date<sup>37</sup>. Given that Chemo's ring is not fully bioequivalent according to FDA regulations, the ring is not expected to be launched on the US market as a generic of Nuvaring®. Hence, following approval, Mithra's partner Mayne Pharma may be well positioned to attain a significant market share of the US vaginal ring market.
- Mithra will produce Myring™ at its CDMO, and as part of the long-term sourcing commitment of Mithra's commercialization partners, the Company already expanded its production capacity for Myring™. Hence, next to the milestone payments expected, following approval and launch, Mithra is anticipating important financial contributions from the production of the vaginal ring at the Mithra CDMO.

<sup>32</sup> Myring™ will be marketed under a different trademark name in the US

<sup>33</sup> Nuvaring® (Merck) sales IMS Analytics Q3 2017. Myring™ will be marketed under a different trademark name in the US

<sup>34</sup> Nuvaring US sales for the 12 months ending 31 January 2018 (IQVIA, as provided by Mayne Pharma)

<sup>35</sup> IQVIA Q3/2017: 0.2% of worldwide volume of the vaginal ring has been realized by Circlet®

<sup>36</sup> Commercialization via distribution partners, including Exeltis, Sandoz and Mylan.

<sup>37</sup> <https://www.maynepharma.com/media/2036/1h18-investor-presentation-vfinal.pdf>

# R&D Projects

# 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 2017

- In November 2017, Mithra confirmed the extended shelf-life of 36 months for Tibelia®, as compared to 24 months for other currently available tibolone-based products, including originator product Livial® (Merck). The extended shelf-life is a further validation of Mithra's expertise in developing Complex Therapeutics, and offers a competitive advantage to distributors and patients.
- Also in 2017, Mithra signed an exclusive agreement for Tibelia® in Canada with an undisclosed partner. The marketing authorization process with Health Canada is presently ongoing. Since Tibelia® would be the first tibolone-based Hormone Therapy product on the Canadian market, the product would be launched as a new treatment option.
- Currently, Tibelia® is on the market in the UK, Finland, Sweden, the Netherlands, Spain and Italy.

## Post-period news and prospects for 2018

- In March 2018, Mithra's distribution partner Southern Cross Pharma obtained marketing authorization for the Australian market, with a launch planned in H2 2018. The Australian tibolone market amounts to about EUR 11 million<sup>38</sup>, with one generic competitor next to originator product Livial®.
- At least one additional launch of Tibelia® is planned in 2018.
- In 2018, Mithra aims to further grow its revenues for Tibelia®. Current global market value for tibolone is approximately EUR 115 million<sup>39</sup>. Livial® remains the market leader with a global market share of 52% in value and 49% in volume. Given the strong file, including the extended shelf-life, Mithra estimates that Tibelia® could take up a sizeable part of the global market in volume over the first 10 years of commercialization. This also depends on additional distribution contracts for the product, and on the potential penetration in North America, where Tibelia® could be launched as a new product as there are no tibolone-based products on the market.

# R&D Projects

# Zoreline<sup>®</sup>

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

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

Zoreline<sup>®</sup> is Mithra's product candidate for branded Zoladex<sup>®</sup> (AstraZeneca).



## Post-period news and prospects for 2018

- Post-period, Mithra obtained positive top-line results for its 1-month PK/PD pilot study for Zoreline<sup>®</sup>. More particularly, the Zoreline<sup>®</sup> PK study demonstrates a safety profile of the 1-month (3.6mg) implant comparable to Zoladex<sup>®</sup>, with results in line with regulatory requirements. Furthermore, the data collected in 58 patients also provide important information on the similar PD activity (efficacy) of the 1-month treatment in Zoladex<sup>®</sup> and Zoreline<sup>®</sup>.
- Mithra continues to work on the reformulation of the 3-month implant, with PK results in an animal model expected in H2 2018, and is currently evaluating further development steps. Pending positive results for the 3-month product candidate, Mithra could move into a pivotal clinical PD study for both the 1- and 3-month formulation.
- Supported by the positive 1-month results, Mithra remains committed to finding a partner to co-develop and commercialize Zoreline<sup>®</sup>, in line with the Company's strategy to partner with leaders in Women's Health for its different product candidates.
- Zoreline<sup>®</sup> represents an important commercial opportunity: in 2017, total sales for originator product Zoladex<sup>®</sup> (AstraZeneca) amounted to USD 693 million globally<sup>40,41</sup>. Moreover, with the exception of a couple of Eastern European countries<sup>42</sup>, no generic version of Zoladex<sup>®</sup> has been approved to date.

<sup>40</sup> IMS Health Q3 2017. CAGR (in volume; 2013-2017: 0%)

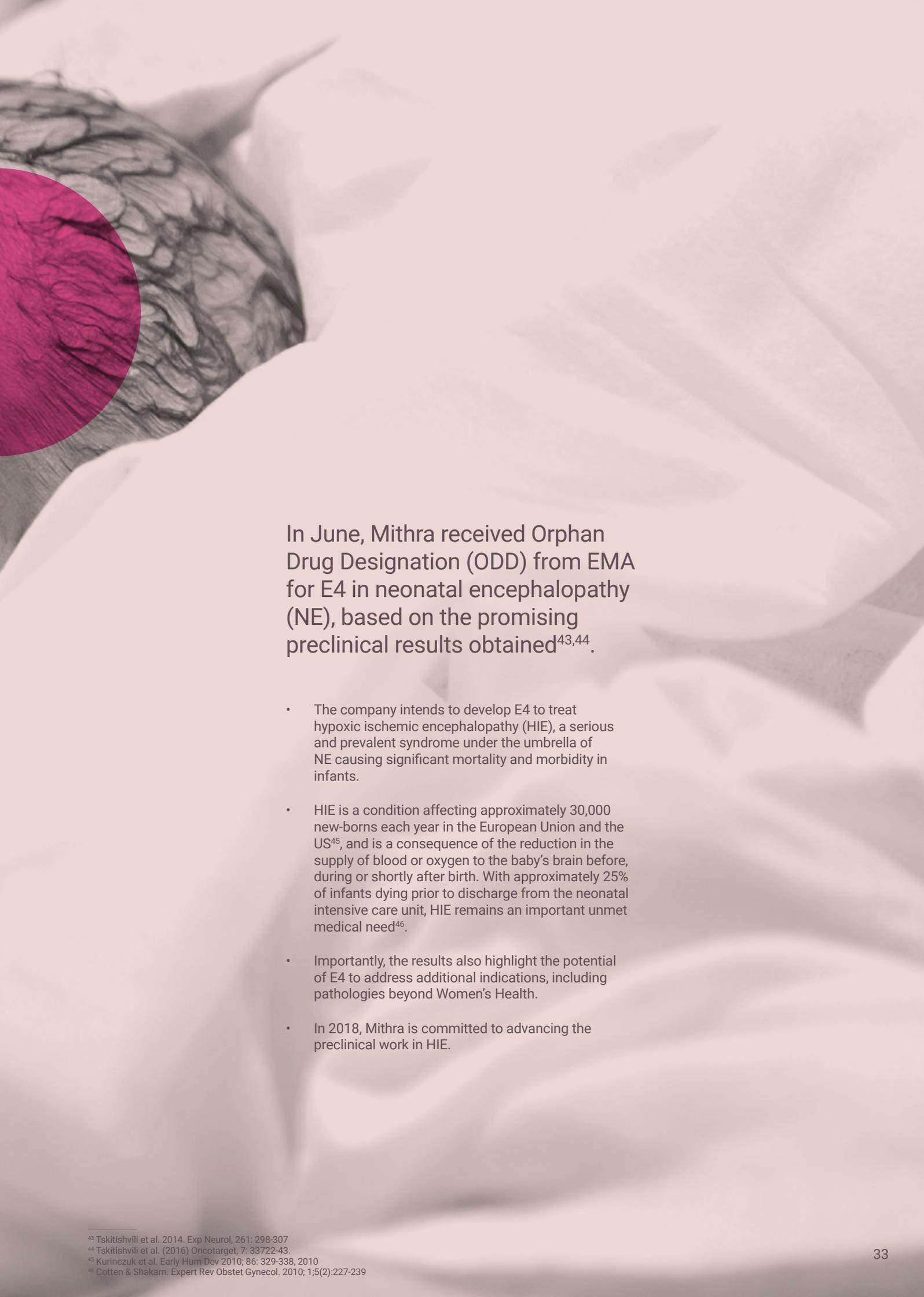
<sup>41</sup> Zoladex<sup>®</sup> is a brand owned by AstraZeneca. In 2017, AstraZeneca entered into an agreement with TerSera Therapeutics for the commercial rights to Zoladex<sup>®</sup> in the US & Canada.

<sup>42</sup> In 2016, Reseligo<sup>™</sup> was launched by Alvogen in selected Central & Eastern European countries.

R&D Projects

# Preclinical Development: Neuro- protection





In June, Mithra received Orphan Drug Designation (ODD) from EMA for E4 in neonatal encephalopathy (NE), based on the promising preclinical results obtained<sup>43,44</sup>.

- The company intends to develop E4 to treat hypoxic ischemic encephalopathy (HIE), a serious and prevalent syndrome under the umbrella of NE causing significant mortality and morbidity in infants.
- HIE is a condition affecting approximately 30,000 new-borns each year in the European Union and the US<sup>45</sup>, and is a consequence of the reduction in the supply of blood or oxygen to the baby's brain before, during or shortly after birth. With approximately 25% of infants dying prior to discharge from the neonatal intensive care unit, HIE remains an important unmet medical need<sup>46</sup>.
- Importantly, the results also highlight the potential of E4 to address additional indications, including pathologies beyond Women's Health.
- In 2018, Mithra is committed to advancing the preclinical work in HIE.

<sup>43</sup> Tskitishvili et al. 2014. Exp Neurol, 261: 298-307

<sup>44</sup> Tskitishvili et al. (2016) Oncotarget, 7: 33722-43.

<sup>45</sup> Kurinczuk et al. Early Hum Dev 2010; 86: 329-338, 2010

<sup>46</sup> Cotten & Shakam. Expert Rev Obstet Gynecol. 2010; 1;5(2):227-239

# Mithra CDMO

Fully integrated ecosystem for state-of-the-art research, development & manufacturing. Inaugurated in September 2016 as a facility specialized in polymeric forms, sterile injectables and hormonal tablets.



## The strategic rationale for operating an in-house CDMO<sup>47</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 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.

# Full range of services

## Drug Delivery Services

Pharmaceutical development



Clinical supply manufacturing



Stability studies



Contract manufacturing



Logistics and supply chain

## Supporting services

Quality assurance

Regulatory services

## Milestones in 2017

- In 2017, Mithra obtained GMP approval for the Myring™ section of the CDMO from the European Authorities. This is an important acknowledgement of the capabilities of the R&D and production team of the Mithra CDMO.
- Also, following a tech transfer, Mithra presented excellent bioequivalent results for Myring™ produced at the CDMO, which further supports the filing with the authorities in Europe but especially in the US.
- In December, Mithra signed its first injectables contract for the Mithra CDMO with GSP (Generic Specialty Pharma), a leading player in generic healthcare products. The umbrella agreement comprises the development and production of four products. Importantly, since the products are designed to receive GMP accreditation, they should allow for European and US GMP approval of the injectable section at the Mithra CDMO. This should open the door to additional injectables partnerships.

## Prospects for 2018

- In Q2 2018, Mithra expects an FDA visit as an important step towards GMP approval from the American authorities for the Myring™ production.
- Following marketing authorization in Europe, Mithra can also start the production for its European partners Gynial (Austria) and Adamed (Czech Republic).
- As pending marketing approval, Mayne Pharma aims to launch Myring™ on the US market in H1 2019, Mithra will also ramp up the production capacities of the Myring™ production line for the commercialization in the US.
- The second and final phase of construction will continue in 2018, and 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.
- Mithra's business development activity for the injectables section is also accelerating, with potential additional contracts to follow in 2018.
- Mithra also intends to start its Estelle® validation batches in Q3 2018, and continues to prepare for a GMP audit of its QC, tablet manufacturing and R&D facility.

# About Women's Health

Mithra launched *Gyn&Co* 2 years ago as 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 the field of 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.

*Gyn&Co*'s content is supported by more than 40 professionals in the field of Women's Health, which together contributed around 200 articles since the website's launch. In 2017, *Gyn&Co* received almost 1.3 million individual visits, mainly from readers in Belgium and France.

**1.3 million**  
individual visits  
in 2017



Figures presented below are management figures

Thousands of EUR (€)	FY17 Actual	FY16 Actual
Revenues	46,252	22,468
Cost of sales	(9,095)	(9,029)
<b>Gross profit</b>	<b>37,158</b>	<b>13,439</b>
Research and development expenses	(46,653)	(34,137)
General and administrative expenses	(7,393)	(7,394)
Selling expenses	(4,503)	(7,510)
Other operating income / expenses	3,338	677
<b>Total operating charges</b>	<b>(55,212)</b>	<b>(48,364)</b>
<b>REBITDA<sup>48</sup></b>	<b>(18,053)</b>	<b>(34,926)</b>
Non recurring costs	(373)	-
Depreciations & amortisations	(2,655)	(1,050)
<b>EBIT</b>	<b>(21,081)</b>	<b>(35,976)</b>
Financial result	(25,345)	(4,660)
Share of (loss)/profit of associates		
<b>Result before taxes</b>	<b>(46,426)</b>	<b>(40,635)</b>
Income taxes	11,421	5,548
<b>Net result for the period</b>	<b>(35,006)</b>	<b>(35,087)</b>

Revenues  
increased  
by over  
**100%**

# Financial Highlights

Revenues increased by over 100% to EUR 46.3 million (from EUR 22.5 million in 2016), mainly due to the licensing revenue recognized for partnership agreements with leaders in Women's Health.

R&D expenditures came in below budget and rose to EUR 46.7 million (from EUR 34.1 million in 2016), reflecting targeted investments in the Phase III Estelle® and Phase II Donesta® programs as well as the ramp up at the Mithra CDMO.

Selling expenses amounted to EUR 4.5 million, compared to EUR 7.5 million in 2016. The significant decrease is mainly driven by reduced commercial operations in France and Germany, and the sale of Mithra's French subsidiary in December 2017.

As a result, REBITDA significantly improved to EUR -18.1 million in 2017 compared to EUR -34.9 million in 2016.

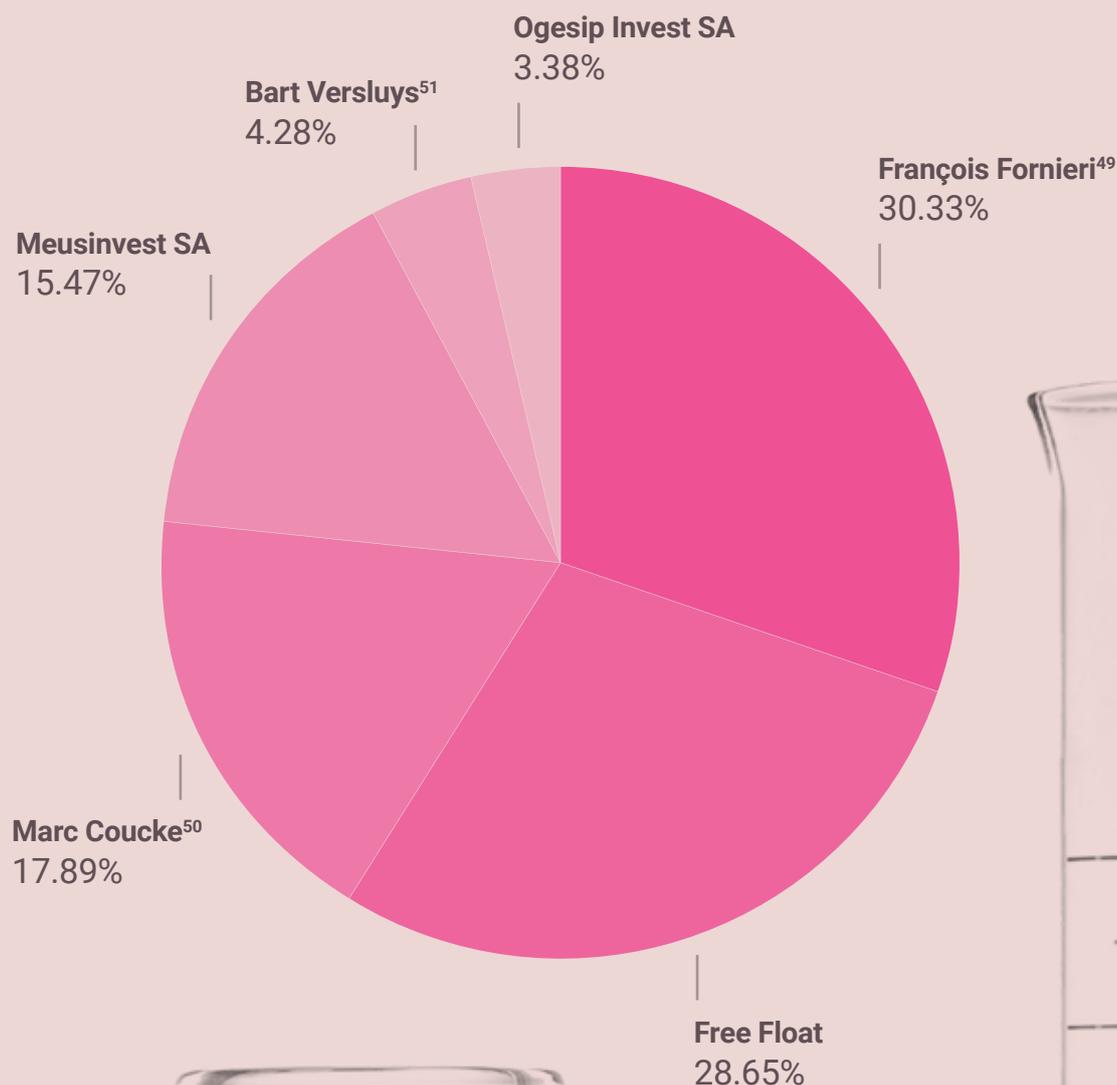
Cash at December 31 2017 came in at EUR 36.2 million (EUR 45.7 million in 2016). In June 2017, the cash position was strengthened by an oversubscribed private placement of EUR 26.1 million.

The financial loss for 2017 amounts to EUR 25.3 million and is driven by changes in the fair value of contingent consideration payable (earn outs) and the remeasurement of the refundable government advances, which are non-cash elements. Regarding the contingent liabilities, this reflects the higher probability of success of our clinical trials and management's higher estimate for future sales revenues.

Although the fair values impacts are significant over 2017, the loss for the period before taxes amounts to EUR 46.4 million, which is an increase of only EUR 5.8 million compared to 2016 thanks to a much better REBITDA in 2017 compared to 2016.

The Group recorded a tax credit of EUR 11.4 million for the year. This is a deferred tax asset to be offset against future taxable income. Taking this tax credit into consideration, the net loss for 2017 was EUR 35 million (loss of EUR 35.1 million for 2016).

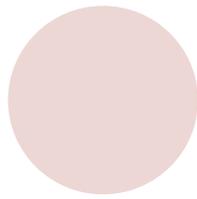
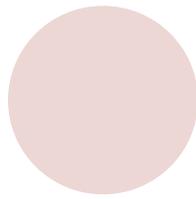
# Shareholder Structure



<sup>49</sup> François Fornieri holds warrants entitling him to subscribe 1,023,000 additional shares of Mithra.

<sup>50</sup> Marc Coucke holds his shareholding partially through Alychlo NV and Mylecke Management Art & Invest NV, which he both controls.

<sup>51</sup> Bart Versluys holds his shareholding through Scorpiaux BVBA, controlled by him.



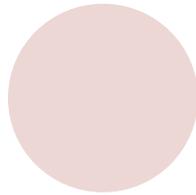
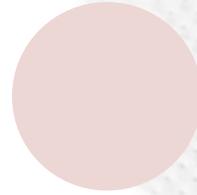
Annual Results 2017



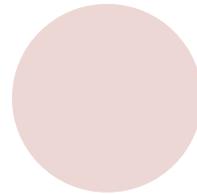
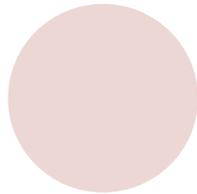
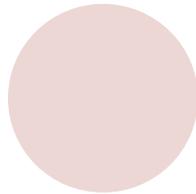
Annual Report 2017  
(available online)



Ordinary General  
Shareholders' Meeting



Half Year 2018 Results

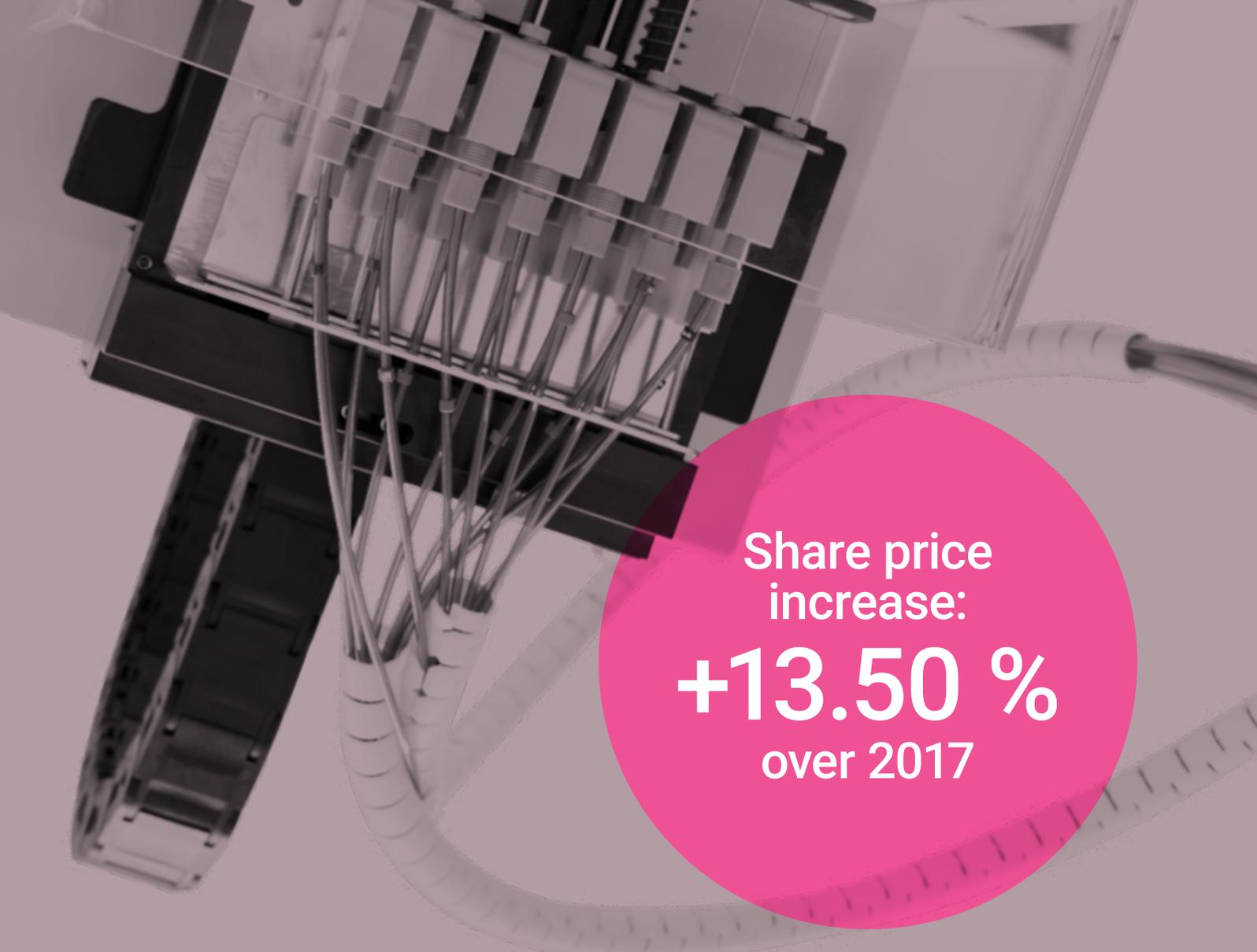


# Financial Calendar 2018

# Stock Exchange Price Evolution in 2017

From 01 January 2017  
to 31 December 2017



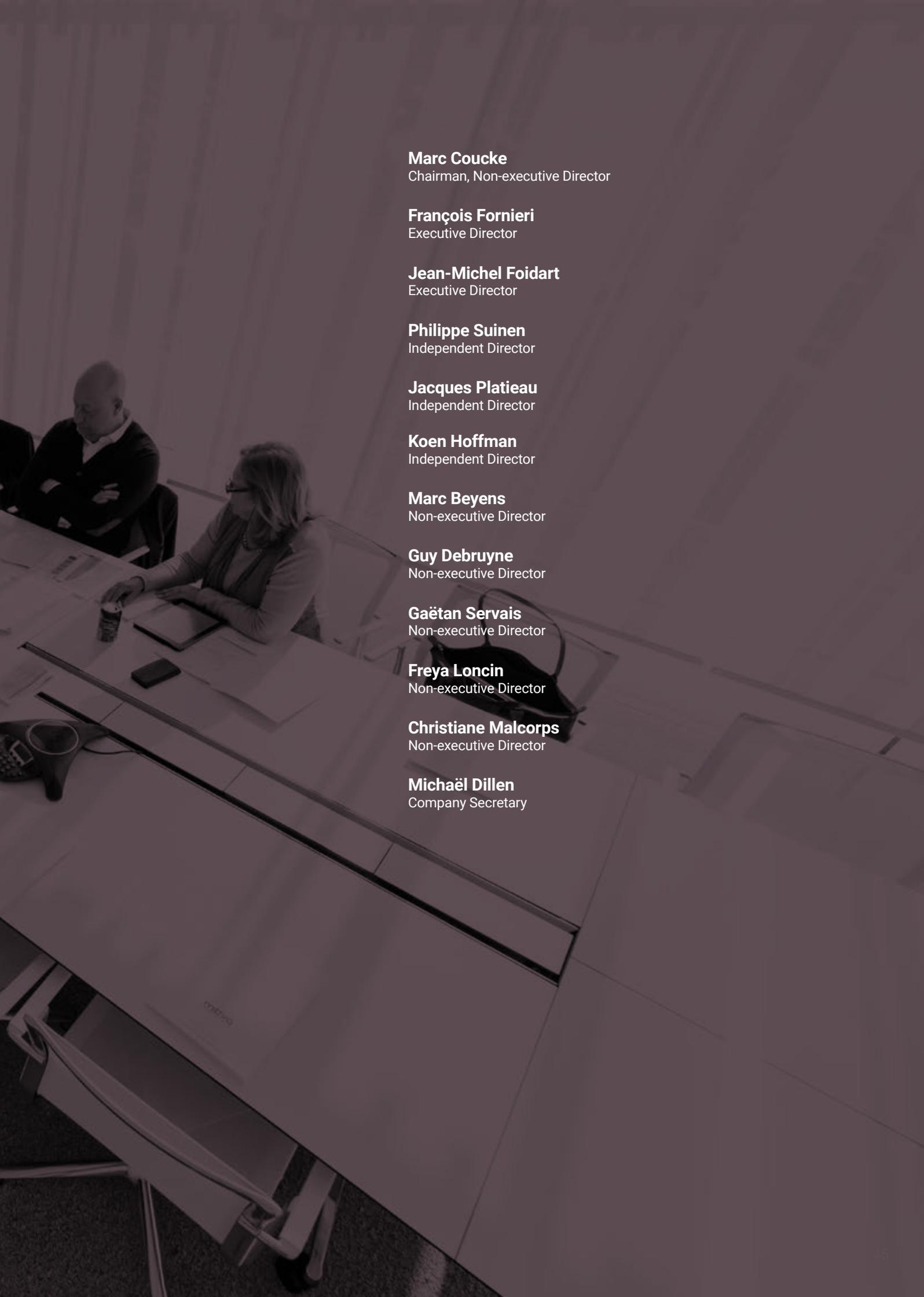


Share price  
increase:  
**+13.50 %**  
over 2017





# Board of Directors



**Marc Coucke**  
Chairman, Non-executive Director

**François Fornieri**  
Executive Director

**Jean-Michel Foidart**  
Executive Director

**Philippe Suinen**  
Independent Director

**Jacques Platieu**  
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

**Michaël Dillen**  
Company Secretary

# Our Executive Management Team



**François Fornieri**

Chief Executive Officer (CEO)

Chief Business Development Officer (CBDO)

Mr François Fornieri has over 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 (CFO)

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, Christophe 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 (CLO)

Mr Michaël Dillen has over 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).



**Valérie Gordenne**  
Chief Scientific Officer (CSO)

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 intra-uterine 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.





**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 Gynecology (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.



**Jan Van der Auwera**  
Chief Marketing Officer (CMO)

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 Sero and Schering.

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



**Geoffroy Dieu**  
Chief Production Officer (CPO)

Mr Geoffroy Dieu has over 15 years of experience in the operational and strategic management of industrial sites, mainly in the food industry. Before joining Mithra, Geoffroy was the General Manager of the Belgian subsidiary of the Firmenich Group. Previously, he was the subsidiary's Plant Manager, in charge of the European projects of Lean Manufacturing and Master Plan aimed at optimizing the Supply Chain. As Product Manager, he also gained significant commercial experience.

Geoffroy obtained a Master in Management at the UCL (Belgium), and started his career in 1999 at PriceWaterhouseCoopers. He further developed his financial competences in subsequent roles as Controller and Finance Manager.

His career positions him very well for a key role in the further operational and commercial development of the Mithra CDMO.

**Julie Dessart**  
Chief Communication Officer (CCO)

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 was the owner of Sunzi SPRLU, a small company specialized in audiovisual strategy, which develops audiovisual concepts and corporate movies for companies. Julie 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 (PRO)

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 Gijssel**  
Investor Relations Officer (IRO)

Ms Sofie Van Gijssel joined Mithra Pharmaceuticals in February 2017 as Investor Relations Officer. Before joining Mithra, Sofie was Co-CEO of the New York branch of KBC Securities USA.

In this role, Sofie mainly focused on Equity Sales for the Benelux Biotech & Healthcare sector, including for corporate transactions such as IPOs. Sofie 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 (Financial Industry Regulatory Authority) licenses.





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# 1. Report of the Board of Directors

## 1.1. Analysis of results / operations

### *Total income*

Mithra's revenues increased by over 100% from EUR 22.5 million to EUR 46.3 million, mainly due to the licensing revenue recognized for partnership agreements with leaders in Women's Health. In total, and including additional smaller deals, Mithra recognized EUR 29.4 million in licensing agreements revenue in 2017, compared to EUR 5.7 million in 2016. With regard to the Benelux business, Mithra's revenues were EUR 16.8 million in 2017, virtually unchanged from 2016.

Gross margin for 2017 increased by EUR 23.8 million from EUR 13.4 million in 2016 to EUR 37.2 million in 2017. The increase of 177% is due to the licensing agreement deals referred to above.

### *R&D expenses*

R&D expenses increased by EUR 13.9 million from EUR 34.3 million in 2016 to EUR 48.2 million in 2017. This is mainly related to the Phase III of Estelle<sup>®</sup> (EUR 23.7 million in 2017) and the Phase II of Donesta<sup>®</sup> (EUR 5.5 million in 2017), as well as API costs in E4 (EUR 3 million in 2017). R&D expenses for Myring<sup>™</sup>, Zoreline<sup>®</sup> and Tibelia<sup>®</sup> amounted to EUR 4.1 million. The remainder of the R&D expenses relate to payroll and consultancy expenses, and more specifically to expenses at the level of the CDMO.

### *G&A expenses*

G&A expenses are well controlled and have hardly increased by 0.4 million from EUR 8.3 million in 2016 to EUR 8.7 million in 2017.

### *Selling expenses*

Selling expenses have significantly decreased in 2017, mainly driven by reduced commercial operations in France and Germany, and thanks to the sale of Mithra's French subsidiary in early December 2017. As a result, selling expenses came to EUR 4.7 million at 31 December 2017, down from EUR 7.6 million.

### *Financial result*

The financial loss for 2017 amounts to EUR 25.3 million and is driven by changes in the fair value of contingent consideration payable (earn outs) and the remeasurement at amortized cost of the refundable government advances, which are non-cash elements. Regarding the contingent liabilities, this reflects the higher probability of success of our clinical trials and management's higher estimate for future sales revenues.

Although the fair values impacts are significant over 2017, the loss for the period before taxes amounts to EUR 46.4 million, which is an increase of only EUR 5.8 million compared to 2016 thanks to a much better REBITDA in 2017 compared to 2016. For more explanation about the alternative performance measurement REBITDA, refer to note 9.34.

The Group recorded a tax credit of EUR 11.4 million for the year. This is a deferred tax asset to be offset against future taxable income. Taking this tax credit into consideration, the net loss for 2017 was EUR 35 million (loss of EUR 35.1 million for 2016).

### *Branches*

The Company has no branches. Refer to detailed table about the group structure in note 9.31.

## 1.2. Statement of financial position analysis

As of 31 December 2017, the Statement of financial position sheets show a total of EUR 170.5 million in non-current assets, the largest part of which are Other intangible assets (EUR 80.4 million). These Other intangible assets were primarily acquired through business combinations. They principally include scientific assets relating to Estelle<sup>®</sup> for an amount of EUR 30.6 million, to Zoreline<sup>®</sup> for an amount of EUR 24.4 million, to Myring<sup>™</sup> for an amount of

EUR 11.4 million, and to Donesta® for an amount of EUR 8 million. Over 2017, EUR 1.6 million has been added to the Other intangible assets as a result of a capitalization of development costs incurred for the development of the API E4.

In the non-current assets, the Group reported EUR 42.6 million additional net book value of tangible fixed assets (EUR 59.5 million at the end of 2017 vs. EUR 16.9 million in 2016). The increase relates to the construction of the first phase of the new production facility for the manufacturing of pharmaceutical products (Mithra CDMO), where Mithra is preparing the production of Myring™.

Current assets at the end of 2017 represent a value of EUR 74.2 million. The cash position accounts for EUR 36.2 million on 31 December 2017.

The equity position at the end of the year has decreased from EUR 93.0 million in 2016 to EUR 86.9 million in 2017. The decrease is the net result of the loss booked in 2017 as well as the private placement and the warrant exercise.

Non-current liabilities increased to EUR 105.6 million at the end of 2017, compared to EUR 52 million in 2016, primarily due to the leases (+EUR 34 million) and Subordinated financing (+EUR 4.7 million) for the CDMO facility, as well as an increase of the fair values of the contingent considerations payables (+EUR 14.2 million) which are reported under Other loans.

The current liabilities increased to EUR 52.2 million at the end of 2017, compared to EUR 27.7 million in 2016. The increase reported under Short term Other financial liabilities is attributable to an increase of the fair values of some contingent considerations payable (+EUR 6.4 million) and the amortized cost of refundable government advances (+EUR 0.5 million), as well as an increase of bank borrowings granted for the financing of the Mithra CDMO facility (+EUR 3.5 million).

### 1.3. Cash flow analysis

Full year cash flow amounted to EUR -9.6 million, which is composed of:

- *Operating cash flows:* The cash used for operating activities amounts to EUR -34.9 million for the full year 2017. The EBIT of EUR -21.1 million has been adjusted for the non-cash items amounting in net to EUR 13.8 million. These non-cash items relate to depreciation, tax credits, share based payments and development costs capitalizations. Working capital is also impacting the cash used for operating activities amounts as a result of an increase in Trade & other receivables (EUR 25.9 million) which is partially offset by an increase of Trade & other Payables (EUR 8.5 million) and Deferred revenue (EUR 6.7 million).
- *Investing cash flows:* EUR -11.9 Million. The purchase of tangible assets relates predominately to property, plant & equipment acquired at the Mithra CDMO (EUR 10.9 million).
- *Financing cash flows:* EUR 37.2 million. Proceeds from financing primarily refer to the refundable government advances (EUR 8.3 million) and drawdowns on straight loans facilities granted to Mithra CDMO. Proceeds from issuance of shares refer to the Private Placement of EUR 25.4 million closed on 23 June 2017, which strengthened Mithra's financial profile; and the issue of an additional 724,350 ordinary shares for an amount of EUR 2.5 million as a result of the exercise of 439 subscription rights (warrants).

### 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 ([www.corporategovernancecommittee.be](http://www.corporategovernancecommittee.be)).

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 ([www.mithra.com](http://www.mithra.com)), 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 gradually implemented over 2015. The Company has not amended its CGC since then. 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 2017, the share capital of Mithra amounted to EUR 25,599,286.41 as per Belgian GAAP and consists of 34,967,081 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 2017 was 34,967,081.

The number of existing shares and the number of voting rights remain unchanged at 31 December 2017 and on the date of this report.

Since last year's report, an increase of capital through authorized capital took place on the 21<sup>st</sup> of June 2017 by means of which an amount of EUR 2,278,998.89 was contributed in cash to the Company leading to the issuance of 3,112,975 new shares. As a result thereof, and pursuant to provision 501 of the BCC, 439 warrants were exercised on the 29<sup>th</sup> of November 2017 which lead to the issuance of 724,350 new shares representing an amount of EUR 530,294.28, as reflected in the below tables.

Therefore, an amount of 650 warrants representing EUR 1,072,500 are yet to be exercised as from 1 January 2019.

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 2017:**

- There has been no other capital related event in 2017.

## Shareholders & shareholder structure

### Shareholders structure

Based on the transparency declarations the Company has received and the aforementioned capital increase which took place, the significant shareholders of the Company (i.e. above 3% of the outstanding voting rights) as at 31 December 2017 are:

Shareholder	Address	Number of voting rights	% of voting rights
François Fornieri <sup>1</sup>		10,606,757	30.33%
Marc Coucke <sup>2</sup>		6,254,552	17.89%
Meusinvest SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,410,551	15.47%
Ogesip Invest SA	Boulevard du Roi Albert II, 37, B-1030 Bruxelles, Belgium	1,181,700	3.38%
Bart Versluys <sup>3</sup>		1,198,771	3.43%
Free float		10,314,750	29.50%

1. François Fornieri holds warrants entitling him to subscribe 1,023,000 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, both controlled by him. All percentages are calculated on the basis of the current total number of voting rights.

Post-period, the Company received the information that Mr. Versluys had acquired additional voting rights leading to the following shareholding's spread:

Shareholder	Address	Number of voting rights	% of voting rights
François Fornieri <sup>1</sup>		10,606,757	30.33%
Marc Coucke <sup>2</sup>		6,254,552	17.89%
Meusinvest SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,410,551	15.47%
Ogesip Invest SA	Boulevard du Roi Albert II, 37, B-1030 Bruxelles, Belgium	1,181,700	3.38%
Bart Versluys <sup>3</sup>		1,497,921	4.28%
Free float		10,015,600	28.65%

1. François Fornieri holds warrants entitling him to subscribe 1,023,000 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 himself and Scorpiaux BVBA, controlled by him. 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](http://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.

## 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 4 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.

The Board is composed of 10 men and of 2 women. Although the Company did not have a diversity policy during the financial year 2017, it shall ensure its best efforts to set this in place in order to shortly obtain a gender diversity amongst its Board members, at least for the time-line set by provision 518bis of the BCC.

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	Attendance <sup>2</sup> to 2017 Board meetings
<b>YIMA SPRL</b> (permanent representative: Mr. François Fornieri)	Managing director	2019	Executive	-	9/9
<b>Mr François Fornieri</b>	Director	2019	Executive	-	9/9
<b>Mr. Marc Beyens</b>	Director	2019	Non-executive	-	8/9
<b>CG CUBE S.A.</b> (permanent representative: Mr. Guy Debruyne)	Director	2019	Non-executive	-	9/9
<b>Meusinvest SA</b> (permanent representative: Mr. Gaëtan Servais)	Director	2019	Non-executive	Audit Committee	7/9
<b>EVA CONSULTING SPRL</b> (permanent representative Mr. Jean-Michel Foidart)	Director	2019 <sup>3</sup>	Executive	-	9/9
<b>P4MANAGEMENT SPRL</b> (permanent representative: Ms. Christiane Malcorps)	Director	2019 <sup>3</sup>	Independent	Nomination and Remuneration Committee	9/9
<b>Alychlo NV</b> (permanent representative: Mr. Marc Coucke)	Director	2019	President Non-executive	Nomination and Remuneration Committee (Chair)	9/9
<b>Aubisque BVBA</b> (permanent representative Ms. Freya Loncin)	Director	2019 <sup>1</sup>	Non-executive	-	7/9
<b>Ahok BVBA</b> (permanent representative Mr. Koen Hoffman)	Director	2019 <sup>3</sup>	Independent	Audit Committee (Chair)	9/9
<b>P.SUINEN SPRL-S</b> (permanent representative: Mr. Philippe Suinen)	Director	2019	Independent	Audit Committee	9/9
<b>Mr. Jacques Platieu</b>	Director	2019	Independent	Nomination and Remuneration Committee	8/9

4. 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.
5. The number of meetings that could be attended by each Director is due to the nomination of new Directors during the financial year.
6. EVA CONSULTING SPRL, AUBISQUE BVBA and AHOK BVBA have been appointed temporarily as Directors on 24/08/16, and P4MANAGEMENT SPRL on 24/02/17. Their final appointment has been approved and ratified by the Shareholders Meeting held on the 18<sup>th</sup> May 2017.
7. 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. She thus attended one Board meeting as a physical person and eight as permanent representative of P4MANAGEMENT SPRL.

Mr. Fornieri acts both as Director and as permanent representative of YIMA SPRL and thereby 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 2017, nine 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.

Moreover, one specific Board was dedicated to discussions related to a potential increase of capital through authorized capital which ultimately took place on the 21<sup>st</sup> of June 2017. As a result thereof, and pursuant to provision 501 of the BCC, another Board was held to discuss the potential exercise of 439 warrants, which occurred on the 29<sup>th</sup> of November 2017.

Furthermore, Midico BVBA (permanent representative: Mr. Michaël Dillen), was appointed as Compliance Officer and Secretary of the Board, in replacement of Eric Van Traelen.

### 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 with respect to its size, composition, performance and those of its committees, as well as with respect to 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 changing circumstances into account. 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 re-elect 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 reports 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: Mr. Gaëtan Servais). AHOK BVBA (permanent representative: Mr. Koen Hoffman) and P. SUINEN SPRL-S (permanent representative: Mr. Philippe Suinen) are both independent Directors.

No diversity policy has been introduced within this Committee yet due to the fact that the Company has only been listed for eighteen months. However, the Company shall ensure its best efforts to put a diversity policy in place in order to shortly obtain gender diversity amongst its committee members, at least for the time-line set by provision 518 bis of the BCC.

### **Activity report**

The Audit Committee met seven times in 2017. The statutory auditor was present at two of these seven 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. The Audit Committee also debriefed the capital increase which occurred with respect to the cash perspectives and their advice has been requested in the perspective of transactions where conflict of interest arose.

Attendance was as follows: AHOK BVBA (permanent representative: Mr. Koen Hoffman): 7/7, P.SUINEN SPRL-S (permanent representative Mr. Philippe Suinen): 6/7, MEUSINVEST SA (permanent representative: Mr. Gaëtan Servais): 5/7.

### ***Nomination and remuneration committee***

Although the Company did not qualify as a "large" listed company (as defined in Article 526*quater* 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 526*quater* 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 Platieu. P. SUINEN SPRL-S (permanent representative: Mr Philippe Suinen) and Mr Jacques Platieu are independent Directors. Starting from November 2017, P4MANAGEMENT SPRL (permanent representative: Mrs

Christiane Malcorps) was appointed in replacement of Mr Jacques Platieu. P4MANAGEMENT SPRL (permanent representative: Mrs Christiane Malcorps) is also an independent director.

By joining the Nomination and Remuneration Committee, Christiane Malcorps sets the gender diversity of one third of its composition.

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 reports 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 twice in 2017.

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): 2/2, P.SUINEN SPRL-S (permanent representative Mr. Philippe Suinen): 1/2 Mr. Jacques Platieu: 1/2. P4MANAGEMENT SPRL (permanent representative: Mrs Christiane Malcorps) replaced P.SUINEN SPRL-S (permanent representative Mr. Philippe Suinen) as committee member in November 2017 and thus attended 1/2 meeting.

### ***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 eleven members: the Chief Executive Officer (CEO), Chief Business Development Officer (CBDO), 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)
RLD CONSULT SPRL (Mr. Geoffroy Dieu)	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)
Ms. Sofie Van Gijssel	Investor Relations Officer (IRO)

8. 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.

Post-period, the following change occurred in the composition of the Executive Management team:

Mr. Rudi Meurs left his function as Chief Production Officer (CPO) and was replaced by RLD CONSULT SPRL (Mr Geoffroy Dieu) on 1 March 2018.

### 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 2017 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 revise 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. However, the Board did not propose the latter regarding the financial year 2017.

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

#### *Remuneration policy applied during 2017*

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 2017, to the non-executive Directors (in such capacity) was EUR 229.986,3 (gross, excluding VAT), split as follows:

Name	Nature	Remunerations	As member of a committee	As chairman of the board
Marc Beyens	Non-exec	20,000		
CG Cube	Non-exec	20,000		
Meusinvest	Non-exec	20,000	5,000	
Alychlo	Non-exec - Chair	20,000	5,000	20,000
P. Suinen	Independent	20,000	7,500	
Jacques Platieu	Independent	20,000	5,000	
Ahok	Independent	20,000	5,000	
Aubisque	Non-exec	20,000		
Christiane Malcorps	Non-exec	2,958.90		
P4Management	Non-exec	17,027.4	2,500	

The table below provides an overview of the shares and warrants held by the current members of the Board on the 31<sup>st</sup> of December 2017.

Share- Warrantholder	Shares	%	Warrants	%	Shares and Warrants	%
<b>YIMA SPRL</b> (permanent representative: Mr François Fornieri) (CEO)	0	0.00%	0	0.00%	0	0.00%
<b>Mr François Fornieri</b> (permanent representative of YIMA SPRL) (together with YIMA SPRL)	10,606,757	30,33%	1,023,000	95.40%	11,629,757	32.27%
<b>Marc Beyens</b>	0	0.00%	0	0.00%	0	0.00%
<b>G CUBE S.A.</b> (permanent representative: Guy Debruyne)	343,200	0.98%	0	0.00%	343,200	0.95%
<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%
<b>AHOK BVBA</b> (permanent representative : Mr Koen Hoffman)	0	0.00%	0	0.00%	0	0.00%
<b>Koen Hoffman</b> (permanent representative of Ahok BVBA) (together with Ahok BVBA)	0	0.00%	0	0.00%	0	0.00%
<b>Meusinvest SA</b> (permanent representative: Gaëtan Servais)	5,410,551	15,47%	0	0.00%	5,410,551	15.01%
<b>Gaëtan Servais</b> (permanent representative of Meusinvest SA)	0	0.00%	0	0.00%	0	0.00%
<b>Aubisque BVBA</b> (permanent representative : Ms Freya Loncin)	0	0.00%	0	0.00%	0	0.00%
<b>Freya Loncin</b> (permanent representative of Aubisque BVBA) (together with Aubisque BVBA)	0	0.00%	0	0.00%	0	0.00%
<b>Marc Coucke</b> (permanent representative of Alychlo NV) (Marc Coucke together with Alychlo NV and Mylecke Management, Art & Invest NV)	6,254,552	17.89%	0	0.00%	6,254,552	17.35%
<b>Eva Consulting SPRL</b> (permanent representative : Jean-Michel Foidart)	0	0.00%	0	0.00%	0	0.00%
<b>Mr Jean-Michel Foidart</b> (permanent representative of Eva Consulting SPRL) (together with Eva Consulting SPRL)	0	0.00%	0	0.00%	0	0.00%
<b>Christiane Malcorps</b>	0	0.00%	0	0.00%	0	0.00%
<b>P.SUINEN SPRL-S</b> (permanent representative: Mr Philippe Suinen)	0	0.00%	0	0.00%	0	0.00%

<b>Philippe Suinen</b> (permanent representative of P.SUINEN SPRL-S) (together with P.SUINEN SPRL-S)	0	0.00%	0	0.00%	0	0.00%
<b>Jacques Platieau</b>	0 0	0.00%	0 0	0.00%	0	0.00%
<b>Subtotal</b>	<b>22,615,060</b>	<b>64.67%</b>	<b>1,023,000</b>	<b>95.40%</b>	<b>23,638,060</b>	<b>65.58%</b>

## Executive Management team

### *Procedure applied in 2017 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 2017*

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 still being elaborated within the Nomination and Remuneration Committee. Such scheme is to be based on objectives which will, in accordance with Article 520bis 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 all members 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, insofar required by law or by the Company's statutes, 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 2017 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	2478	795
Variable Remuneration (*)	0	0
Group Insurance (pension, invalidity, life)	8	0
Other insurance (car, cell phone, hospitalization)	43	0
<b>Total</b>	<b>2529</b>	<b>795</b>

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

Share- / Warranholder	Shares	%	Warrants	%	Shares and Warrants	%
<b>YIMA SPRL</b> (permanent representative: Mr. François Fornieri) (CEO) (together with François Fornieri)	0	0.00%	0	0.00%	0	0.00%
<b>Mr. François Fornieri</b> (permanent representative of YIMA SPRL) (together with YIMA SPRL)	10,606,757	30,33%	1,023,000	95.40%	11,629,757	32.27%
<b>Mr. Christophe Maréchal</b> (representative of and together with CMM&C SPRL BVBA)	0	0.00%	0	0.00%	0	0.00%
<b>Mr. Jean-Michel Foidart</b> (representative of and together with Eva Consulting SPRL)	0	0.00%	0	0.00%	0	0.00%
<b>Ms. Julie Dessart</b> (representative of and together with Sunzi SPRL)	10,922	0.03%	24,750	2.3%	35,672	0.1%
<b>Mr. Jean-Manuel Fontaine</b> (representative of and together with Novafontis SAS)	4,642	0.01%	24,750	2.3%	29,392	0.08%
<b>Mr. Rudi Meurs</b>	58,032	0.16%	0	0.00%	58,032	0.16%
<b>Ms Valérie Gordenne</b> (representative of and together with Alius Modi SPRL)	82,800	0.23%	0	0.00%	82,800	0.22%
<b>Mr. Jan Van der Auwera</b> (representative of and together with TACC BVBA)	4,000	0.01%	0	0.00%	4,000	0.01%
<b>Mr. Michaël Dillen</b> (representative of and together with Midico BVBA)	0	0.00%	0	0.00%	0	0.00%
<b>Ms. Sofie Van Gijssel</b>	0	0,00%	0	0,00%	0	0,00%
<b>Subtotal</b>	<b>10,767,153</b>	<b>30,79%</b>	<b>1,072,500</b>	<b>100,00%</b>	<b>11,839,653</b>	<b>32,85%</b>
<b>Total</b>	<b>34,967,081</b>	<b>100.00%</b>	<b>1,072,500</b>	<b>100.00%</b>	<b>36,039,581</b>	<b>100.00%</b>

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 (1089) 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 31<sup>th</sup> of December 2017, 650 warrants of the initial 1089 remain outstanding. Indeed, an increase of capital through authorized capital took place on the 29<sup>th</sup> of November 2017 by means of which an amount of 439 warrants were exercised pursuant to provision 501 of the BCC which lead to the issuance of 724,350 shares as reflected in the above tables. Therefore, an amount of 650 warrants representing 1,072,500 shares are yet to be exercised as from 1 January 2019.

In 2017, nine members of the Executive Management Team were 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 Executive Management Team is an advisory committee to the Board and the CEO on the day-to-day management of the Company. Each of the members of the Executive Management Team has individually been made responsible for certain aspects of the day-to-day management of the Company and its business (in case of the CEO, by way of a delegation from the Board; in case of the other Executive Management Team members, by way of a delegation from the CEO). In case any decision to be taken by a member could be material to the Company, it shall be presented and discussed at a meeting of the the Executive Management Team. The Executive Management Team is meeting several times per month.

During those Executive Management Meetings, there is a follow-up of the progress of various Group projects, clinical studies, business development deals, and other material matters.

The process of gathering financial information is organized on quarterly, half-year and annual closings and report of such information is done to CEO, the Audit Committee. A central team produces the accounting figures under the supervision of the CFO and Group controller and the books are kept by an ERP (Dynamics AX). The cash and working capital are monitored on a monthly basis. The Company has also selected this ERP to manage the purchase orders, the supply chain, the production, the inventories, the projects and has recently decided to implement its budget module.

The quality of the internal controls is assessed during the course of the financial year and on an ad hoc basis with internal audits (supply chain, IT, PO validation workflows, working capital management, etc.) carried on the basis of potential risks identified. The conclusions are shared and validated with the Audit Committee. During the financial year, the Audit Committee undertakes reviews of the half-year closures and specific accounting treatments. It reviews the disputes and puts all the questions it deemed relevant to the Auditor and the CFO or to the Executive Management in the company.

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 21 May 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). On the 29<sup>th</sup> of November 2017, an increase of capital through authorized capital took place by means of which an amount of 439 warrants were exercised pursuant to provision 501 of the BCC which lead to the issuance of 724,350 new shares. Therefore, an amount of 650 warrants representing 1,072,500 shares are yet to be exercised as from 1 January 2019.

## **1.6. Transactions within the authorized capital**

On the 20<sup>th</sup> of June 2017, the Board gave mandate to a placement committee composed of (i) AHOK BVBA (Mr. Koen Hoffman), (ii) CMM&C BVBA (Mr. Christophe Maréchal), MIDICO BVBA (Mr. Michaël Dillen) and (iv) Ms Sofie Van Gijssel, to determine the terms of an increase of capital by means of a private placement through authorized capital of an amount of EUR 2,278,998.89 excluding issuance premium, representing 3,112,975 new shares.

As this operation equals to less than 10% of the Company's number of shares quoted on Euronext Brussels, it qualifies as an exemption from the Company's obligation to publish a prospectus pursuant to the law of 16<sup>th</sup> June 2006. This increase of capital has been done by suppressing the preferential rights of the existing shareholders in accordance with provision 596 of the BCC and took place on the 21<sup>st</sup> June 2017.

## 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's exposure to price risk, credit risk, liquidity risk and cash flow risk are detailed in note 9.3 (Financial Risk Management). 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 Therapeutics; (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 2017, 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 pre-clinical 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® 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®; 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 Estetrol-based 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 Q2 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<sup>®</sup> (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 Therapeutics 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<sup>™</sup>) currently under development by the Group have received regulatory approval. Complex Therapeutics 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<sup>™</sup> was the first complex therapeutic solution produced by Mithra to demonstrate bioequivalence; for the other products (including Zoreline<sup>®</sup>), 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 its affiliates on hold, it does not plan to build out a commercial organization in these territories.

The Company divested its French subsidiary, Mithra France, in December 2017. The sale consisted in two agreements. A first contract was closed with Laboratoire CCD, a French-based Women's Health player and concerns the transfer of the marketing authorizations (Mas) for four products including Tibelia<sup>®</sup>. Secondly, Mithra concluded a share purchase agreement for Mithra France with Theramex, whereby Theramex has taken over the subsidiary, including its pharmaceutical license.

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 2017 are GSP for Zoreline<sup>®</sup>, Fuji Pharma for Donesta<sup>®</sup> and Estelle<sup>®</sup> (for Japan and ASEAN), Libbs for Estelle<sup>®</sup> (Brazil), Mayne Pharma for Myring<sup>™</sup> in the US, Gynial for Myring<sup>™</sup> in Austria. Post period, the Company entered into an agreement with Adamed for Myring<sup>™</sup> in Czech Republic and Alvogen for Myring<sup>™</sup> in Russia. 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).

The Company has entered into some partnerships regarding sourcing of raw materials. Therefore the possibility for the Company to meet its production's commitments towards their counterparts depend on its sourcing arrangements.

**(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 Allergan, 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 H1 2019) 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, EUR 35 million in 2016, EUR 35 million in 2017. 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 E4 products will be dependent on the successful and timely construction of Phase 2 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). Phase 2 of the construction is scheduled to be finished in H1 2019. The Company is currently working on selecting alternative manufacturing resources. In 2017, the Company announced that as part of the contract with Libbs, the latter will produce Estelle® for the Brazilian market at their own facility.
- 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 E4 (Estetrol) as well as our technologic platform in Complex Therapeutics to develop a diverse and broad portfolio of therapeutic treatments focused on Women's Health.

With regard to E4, most focus is on Mithra's late-stage product candidates, Estelle<sup>®</sup> for contraception (Phase III) and Donesta<sup>®</sup> for menopause (Phase II). Furthermore, Mithra is exploring additional indications in Women's Health (e.g. dysmenorrhea, endometriosis), as well as indications beyond Women's Health, such as wound healing and neuroprotection. In 2017, Mithra capitalized some development costs related to E4 synthesis.

For the Complex Therapeutics, Mithra is preparing for the launch of Myring<sup>™</sup> in Europe as of H2 2018, followed by the US launch in 2019. At the same time, we continue to advance the preclinical work on Zoreline, having obtained supportive 1-month PK results in 2017.

Furthermore, Mithra will pursue the budgeted investments to further advance the technological CDMO facility in terms of performance, applicability and scale; in order to offer third-parties (such as GSP) the opportunity to develop sterile injectables; and to prepare the polymeric forms and hormonal tablets zones for the production of its proprietary products.

In addition, Mithra intends to initiate new discovery programs which might lead to the development and commercialization of drug candidates; and is committed to seek, maintain and expand the know-how, 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 2017, 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 24 February 2017

#### *Board of Directors' Meeting on 24 February 2017 at 5.00pm:*

Mr Jean-Michel Foidart 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 BCC:

Decisions to be taken with regard to consultancy contract to be signed between the Company and Eva Consulting SPRL (represented by Mr Jean-Michel Foidart).

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 interest.

*Minutes of the above Board meeting:*

Point 1

Prior to any discussions, Eva Consulting SPRL (Mr Jean-Michel Foidart) declared a conflict of interest of financial nature, as defined in Article 523 of the Companies Code, in the context of the proposal to discuss the agreement listed in the agenda. Indeed, Eva Consulting SPRL (Mr Jean-Michel Foidart) is on the one hand Director of the Company and, on the other, counterpart to the proposed agreement.

EVA CONSULTING SPRL confirms having informed the statutory auditor of the Company of said conflict of interest and withdraws from the board room, prior to any deliberation and vote on said agenda.

The Chairman of the Nomination and Remuneration Committee goes through the debates which took place within the Committee and the recommendations therefrom.

Taking into consideration the conflict of interest which has been declared and after deliberation, the Board decides to approve the proposed transaction.

The financial consequence of this decision is the monthly payment to EVA CONSULTING SPRL of an amount of EUR HVAT 17.000 during the duration of the contract and the potential payment to EVA CONSULTING SPRL of a unique and flat bonus of EUR HVAT 200.000 should the requirements indicated in the contract be met.

The Board justifies this decision by the fact that the requirements listed herein seem in accordance with the corporate interest of the Company regarding their amount, their appealing character for EVA CONSULTING SPRL, and the stakes related thereto for the Company.

Meeting Board of Directors of 18 September 2017

Mr François Fornieri acting for himself and as permanent representative of SPRL YIMA reported a conflict of interest situation regarding the sole point on the agenda prior to any deliberations, as required by Art. 523 BCC:

Decision to be taken as to the fact that, following the capital increase announced on June 21, 2017, the warrant holders issued in 2015 are entitled to exercise the said warrants and, if applicable, notification of the exercisable nature of said warrants and grant of proxies to negotiate, sign and implement all documents (including notarial deeds)

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 interest.

*Minutes of the above Board meeting:*

Point 1

Prior to any discussions, Mr François Fornieri, acting for himself and as permanent representative of SPRL YIMA, declared a conflict of interest of financial nature, as defined in Article 523 of the Companies Code, in the context of the proposal to discuss the sole point on the agenda, due to the fact that he is (i) warrant holder, (ii) Director of the Company, as well as (iii) permanent representative of SPRL YIMA, which is itself Director of the Company.

He confirms having informed the statutory auditor of the Company of the said conflict of interest and withdraws from the board room, prior to any deliberation and vote on the said agenda.

The discussions were reported within the working group, the implementation of which was decided during the previous Board,

Taking into consideration the conflicts of interest that have been declared, and after deliberation, the Board acts, considering the last paragraph of Article 2.3.7. of the special report of the board which states that "*in the event that the Company carries out a capital increase by contribution in cash before the final date set for the exercise of the warrants, the warrant holders shall be entitled to exercise the warrants on the terms described in this report, without regard to the time fixed for such exercise, and, shall have the right to participate in the capital increase, to the extent where this right would be theirs in accordance with Article 501 of the Companies Code.*" Following the capital increase announced on June 21, 2017, the warrant holders are thus able to exercise their warrants pursuant to the last paragraph of Article 2.3.7. of said conditions.

In order to treat all warrant holders equally, the Board of Directors decides to notify all holders of the possibility of exercising the warrants. For organizational reasons, the Board of Directors decides on a deadline for the exercise of warrants.

The Board of Directors resolves to grant a special power of attorney to Mr. M. Dillen and Mr C. Maréchal to jointly, or individually and with power of substitution, negotiate, finalize, complete and sign in the name and on behalf of the Company any document relating to the exercise of the warrants, as well as to perform any act that they deem necessary or useful for the conversion of the warrants.

The Board considers that the financial consequences of this decision are favorable for the Company to the extent that, in the event of a confirmed financial year, additional liquidity will be available to the Company sooner than it was intended. The Board does not perceive any potentially negative financial consequences for the Company resulting from this decision.

The Board justifies this decision by the above arguments.

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

As disclosed previously, the Audit Committee is composed of the three following members: : (i) two of which satisfy to the independence criterias as set forth by provision 526ter of the BCC, and (ii) all of them meet the expertise requirement of that very article:

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 Independent Director of Fagron SA since August 2016.

AHOK BVBA also satisfies the independence criteria as prescribed by provision 526ter of the BCC.

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.

P. SUINEN SPRL-S also satisfies to the independence criterias as prescribed by provision 526 ter of the BCC.

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. Going concern assessment**

End of 2017, Mithra has a total of EUR 86.4 million accumulated losses on its balance sheet and realized a consolidated net loss of EUR 35 million for the year ended 31 December 2017. The Board of Directors has analyzed the financial statements and accounting policies and based on conservative assumptions, the current cash position of EUR 36.2 million at 31 December 2017 will allow the Group to keep up with operating expenses and capital expenditure requirements at least until the end of 2018. Based on their assessment, the Management and Board of Directors consider it appropriate to prepare the financial statements on a going concern basis. The assessment is based on expected R&D clinical results and further business deals as well as on the monitoring of our funding activities. We are also considering potential capital increase and additional credit facilities to secure liquidity and to support the continuing development of our products.

## 1.14. Appropriation of results

Mithra Pharmaceuticals SA, the parent Company, ended the financial year 2017 with a net loss of EUR 17.257.084,23.

The Board of Directors proposed to appropriate the loss of the year of EUR 17.257.084,23 to accumulated loss. This brings the total amount of retained losses to EUR 50.268.807,98.

## 1.15. Important events after the reporting period

Post-period, Mithra announced two additional agreements for Myring™, its vaginal ring for contraception product candidate: in January 2018, the Company announced a non-exclusive, 10-year license and supply agreement with Adamed Group (Adamed), for the commercialization of the ring in the Czech Republic, a market worth approximately EUR 1.3 million<sup>1</sup>. Adamed is a Polish pharmaceutical and biotechnology company with a focus on gynaecology. Financial details of the agreement were not disclosed. In March 2018, this was followed by an exclusive license and supply Myring™ agreement for the Russian market with Alvogen, a global, privately owned pharmaceutical company focused on developing, manufacturing and selling generic, branded, over-the-counter brands (OTC) and biosimilar products for patients around the world. The Russian market for Myring™ amounts to approximately EUR 13 million<sup>2</sup>. As for its other distribution partners, Gynial (Austria) and Mayne Pharma (US), Mithra will exclusively manufacture and supply the product for Adamed and Alvogen from its CDMO<sup>3</sup> research and manufacturing center.

Also for Myring™, in March 2018, Mithra and US commercialization partner Mayne Pharma announced that the Abbreviated New Drug Application (ANDA) for the vaginal ring has been accepted for filing by the FDA. This is an important regulatory milestone, putting Mayne Pharma on track for a launch in the US in H1 2019.

Furthermore, post-period, Mithra obtained positive top-line results for its 1-month PK/PD pilot study for Zoreline®, Mithra's product candidate for branded Zoladex® (AstraZeneca). The Zoreline® PK study demonstrates the safety profile of the 1-month (3.6mg) implant as compared to Zoladex®, with results in line with regulatory requirements. Furthermore, the data collected in 58 patients also provide important information on the similar PD activity (efficacy) of the 1-month treatment in Zoladex® and Zoreline®. Mithra continues to work on the reformulation of the 3-month implant, with PK results expected in H2 2018, and is currently evaluating further development steps. Pending positive results for the 3-month product candidate, Mithra could move into a pivotal clinical PD study for both the 1- and 3-month formulation.

Finally, in February 2018, Mithra published very promising top-line results for its hemostasis Phase II study. This substudy, which runs in parallel with the ongoing Phase III studies for Estelle®, analyzes a series of hemostatic, endocrine and metabolic parameters. Data are analyzed for 100 women divided over three treatment groups: 15 mg E4/3 mg DRSP (Estelle®), 30 mcg LNG (Melleva®) and EE/3 mg DRSP (Yaz®). Given the importance of these parameters to help determine the venous thromboembolism (VTE) risk profile of a (combined) oral contraceptive, the results are closely studied by the regulatory bodies and keenly awaited by clinicians and (potential) commercialization partners for Estelle®. The results were presented at the ISGE conference (Florence) on March 8, 2018.

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<sup>1</sup> IMS Analytics Q3 2017

<sup>2</sup> IMS Health Analytics Q3 2017

<sup>3</sup> Contract Development & Manufacturing Organization

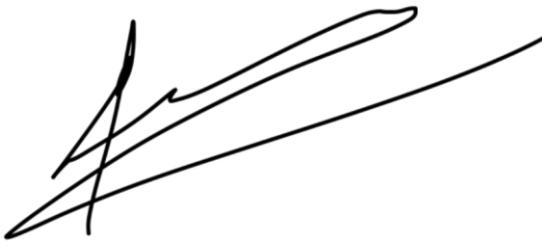
## 1.16. Grant of discharge to the directors and the statutory auditor

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 2017.

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

Liege, 6 April 2018

For the Board of Directors,

A handwritten signature in black ink, consisting of several overlapping, sweeping strokes that form a stylized, abstract shape.

Alychlo NV, represented by  
**Marc Coucke, Chairman**

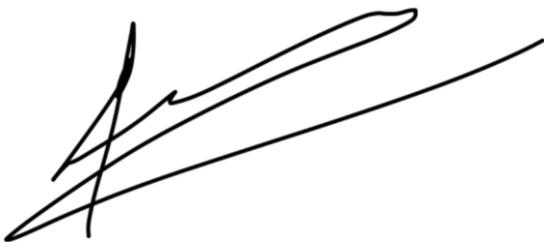
A handwritten signature in black ink, featuring a large, looped initial 'F' followed by the name 'Fornieri' in a cursive script.

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 2017, 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**



CMM&C SPRL, represented by  
**Christophe Maréchal, CFO**

### 3. Auditor report

#### **STATUTORY AUDITOR'S REPORT TO THE GENERAL MEETING OF SHAREHOLDERS OF MITHRA PHARMACEUTICALS S.A. FOR THE YEAR ENDED DECEMBER 31, 2017**

In the context of the statutory audit of the consolidated financial statements of Mithra Pharmaceuticals S.A. (the Company) and its subsidiaries (together referred to as 'the Group'), we hereby present our statutory auditor's report. It includes our report on the audit of the consolidated financial statements as well as our report on the other legal and regulatory requirements. These reports form part of an integrated whole and are indivisible.

We have been appointed as statutory auditor by the general meeting of May 21, 2015, following the proposal formulated by the board of directors issued upon recommendation of the audit committee. Our statutory auditor's mandate expires on the date of the general meeting deliberating on the annual accounts closed on December 31, 2017. We have performed the statutory audit of the consolidated financial statements of Mithra Pharmaceuticals S.A. for thirteen consecutive years.

#### **Report on the audit of the consolidated financial statements**

##### *Unqualified opinion*

We have performed the statutory audit of the Group's consolidated financial statements, which comprise the consolidated statement of financial position as at December 31, 2017, and the consolidated income statement and other comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies and other explanatory information, and which is characterised by a consolidated statement of financial position total of 244.712 (000) EUR and for which consolidated income statement shows a loss for the year of 35.006 (000) EUR.

In our opinion, the consolidated financial statements give a true and fair view of the Group's net equity and financial position as at December 31, 2017, as well as of its consolidated financial performance and its consolidated cash flows for the year then ended, in accordance with International Financial Reporting Standards (IFRS) as adopted by the European Union and with the legal and regulatory requirements applicable in Belgium.

##### *Basis for unqualified opinion*

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the 'Statutory auditor's responsibilities for the audit of the consolidated financial statements' section in this report. We have complied with all the ethical requirements that are relevant to the audit of consolidated financial statements in Belgium, including those concerning independence.

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.

##### *Key audit matters*

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements of the current year. These matters were addressed in the context of our audit of the consolidated accounts as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

## Goodwill and intangible assets impairment

### *Description of the matter*

As described in Notes 9.7 and 9.9 of the consolidated financial statements, the Group is required to annually test its goodwill and other intangible assets for impairment. The Group has significant intangible assets arising from prior acquisitions and is doing its impairment exercises at the level of the identified cash generating units ('CGU'). The management has to conclude about the recoverability of such assets, based on the latest available clinical information and the perspective for further developments.

We consider this area a key audit matter requiring high auditor's attention because of the potential significant impact on the financial statements and the fact that the impairment test contains key judgmental areas due to the inherent uncertainty in forecasting and discounting future cash flows.

### *Procedures performed*

Our audit procedures included, among others, the following:

- We have discussed with the chief scientific officer the current status of the different projects in order to identify potential impairment indicators;
- We have analyzed and reviewed the Company's impairment model including the significant underlying assumptions and checked whether an adequate valuation model was applied;
- We have analyzed the consistency of the underlying data used in the valuation model and compared these with the latest Board approved business plan;
- We consulted a valuation expert in our firm to assess the discount rate applied;
- We reviewed the sensitivity analysis prepared by management to understand the effect of a change in assumptions;
- We considered all available information provided to us by the Company to assess potential additional factors that could trigger impairment;
- We reviewed the completeness and adequacy of the disclosures in Note 9.9 of the Company's Financial Statements.

## Contingent consideration valuation

### *Description of the matter*

As a result of the acquisitions of Estetra SPRL and Novalon SA in 2015, the consolidated financial statements include a contingent consideration towards the previous owners. As disclosed in Note 9.16.3 of the consolidated financial statements, this contingent liability is reported at fair value in the statement of financial position.

We consider this area a key audit matter requiring high auditor's attention because of the fact that the valuation of the contingent consideration is complex, contains key judgmental areas and is strongly affected by assumptions with regards to expected future cash flows and market conditions.

### *Procedures performed*

Our audit procedures included, among others, the following:

- We have analyzed and reviewed the Company's fair value calculation including the significant underlying assumptions and checked whether an adequate valuation model was applied;

- We have analyzed the consistency of the underlying data used in the valuation model and compared these with the latest Board approved business plan;
- We consulted a valuation expert in our firm to assess the methodology, clerical accuracy, long term growth rate and discount rate as applied;
- We have analyzed the consistency of the underlying data used in the valuation model and compared these with the data used in the context of the annual impairment test;
- We have performed an assessment of the reasonableness of key assumptions, notably probabilities of success, discount rate and long term growth rate;
- We reviewed the completeness and adequacy of the disclosures as included in Note 9.16.3 to the consolidated financial statements.

### Revenue recognition

#### *Description of the matter*

As explained in Notes 9.2.18 and 9.19 to the consolidated financial statements, the company has early adopted the new revenue standard, being the IFRS 15. The company has two main revenue streams, which are, on the one hand, sales of product, and, on the other hand, license agreements.

We consider this area a key audit matter requiring high auditor's attention due to the fact that the transition to the new accounting standard (IFRS 15) requires specific technical competences and a high degree of judgments in order to record and disclose revenue properly.

#### *Procedures performed*

Our audit procedures included, among others, the following:

- We have reviewed the comprehensive analysis performed by the company for each relevant contract;
- We have assessed and discussed with management the substance and the economic rational of each relevant license agreement;
- We have evaluated and discussed with the internal legal counsel the legal obligations of the Group towards its customers;
- We have challenged the key judgments made by the management with regards to the determination of the transaction price, its allocation within the performance obligations and the stage of completion of these obligations;
- We reviewed the completeness and adequacy of the disclosures as included in Note 9.19 to the consolidated financial statements.

### Deferred taxes

#### *Description of the matter*

As described in Note 9.24 to the consolidated financial statements, the Group accounts for deferred tax assets on its tax losses carried forward and on the temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the IFRS financial statements to the extent that it is probable that future taxable profits will be realized against which unused tax losses and tax credits can be utilized .

We consider this area a key audit matter requiring high auditor's attention because of their significance to the financial statements and the critical judgment made to confirm the recoverability of the deferred tax assets.

### *Procedures performed*

Our audit procedures included, among others, the following:

- We have checked the consistency of the different tax rates applicable to the relevant statutory entities;
- We have reconciled the total amount of tax losses carried forward available to the Group;
- We have reviewed the taxable impact of the relevant IFRS accounting entries;
- We have challenged the judgment made by the management about the foreseeable taxable future profits;
- We have reviewed the accounting entries;
- We reviewed the completeness and adequacy of the disclosures as included in note 9.24 to the consolidated financial statements.

### *Responsibilities of the board of directors for 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 (IFRS) as adopted by the European Union and with the legal and regulatory provisions applicable in Belgium, and for such internal control as the board of directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

In preparing the consolidated financial statements, the board of directors is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the board of directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

### *Statutory auditor's responsibilities for the audit of the consolidated financial statements*

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue a statutory auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but it is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statement.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control ;
- Obtain an understanding of internal control relevant to the audit 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 Group's internal control ;
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors ;
- Conclude on the appropriateness of the board of directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a

material uncertainty exists, we are required to draw attention in our statutory auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our statutory auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern ;

- Evaluate the overall presentation, structure and content of the consolidated financial statements and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation ;
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the management, the supervision and the performance of the Group audit. We assume full responsibility for the auditor's opinion.

We communicate with the Audit Committee regarding, among other matters, the planned scope and timing of the audit as well as significant audit findings, including any significant deficiencies in internal control identified during the audit.

We also provide the Audit Committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence and, where applicable, related safeguards.

From the matters communicated to the Audit Committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current year, and are therefore the key audit matters. We describe these matters in our statutory auditor's report unless law or regulation precludes public disclosure about the matter.

## **Report on other legal and regulatory requirements**

### *Responsibilities of the board of directors*

The board of directors is responsible for the preparation and the contents of the management report on the consolidated financial statements and for the other information included in the annual report on the consolidated financial statements.

### *Responsibilities of the statutory auditor*

In the context of our mandate and in accordance with the Belgian standard (revised in 2018) that is supplementary to the International Standards on Auditing (ISA), it is our responsibility to verify, in all material aspects, the management report on the consolidated financial statements and the other information included in the annual report on the consolidated financial statements, as well as to report on these elements.

### *Aspects related to the management report on the consolidated financial statements and to the other information included in the annual report on the consolidated financial statements*

In our opinion, after having performed specific procedures in relation to the management report, the management report is consistent with the consolidated financial statements for the same same financial year, and it is prepared in accordance with article 119 of the Company Code.

In the context of our audit of the consolidated financial statements, we are also responsible for considering, in particular based on the knowledge we have obtained during the audit, whether the management report on the consolidated financial statements, and the other information included in the annual report on the consolidated financial statements (Chapter 1 – Report of the Board of Directors) contain a material misstatement, i.e. information which is inadequately disclosed or otherwise misleading. Based on the procedures we have performed, there are no material misstatements we have to report to you.

We do not express any form of assurance whatsoever on the management report on the consolidated financial statements nor on the other information contained in the annual report on the consolidated financial statements.

*Statement concerning independence*

- Our audit firm, and our network, did not provide services which are incompatible with the statutory audit of consolidated financial statements, and we remained independent of the Group throughout the course of our mandate.
- The fees related to additional services which are compatible with the statutory audit as referred to in article 134 of the Company Code were duly itemised and valued in the notes to the consolidated financial statements.

*Other statement*

- This report is in compliance with the contents of our additional report to the audit committee as referred to in article 11 of Regulation (EU) No 537/2014.

Battice, April 16, 2018

A handwritten signature in black ink, consisting of a large, stylized initial 'F' followed by several loops and a final horizontal stroke ending in a small dot.

BDO Réviseurs d'Entreprises Soc. Civ. SCRL

Statutory auditor

Represented by Félix FANK

## 4. Consolidated Income Statement

<i>Thousands of Euro (€)</i>		Year ended 31 December	
CONSOLIDATED INCOME STATEMENT	Notes	2017	2016
<b>Revenues</b>	<b>9.6, 9.19</b>	<b>46,252</b>	<b>22,468</b>
<b>Cost of sales</b>	<b>9.20</b>	<b>(9,095)</b>	<b>(9,029)</b>
<b>Gross profit</b>		<b>37,158</b>	<b>13,439</b>
Research and development expenses	9.20-21	(48,185)	(34,299)
General and administrative expenses	9.20-21	(8,697)	(8,226)
Selling expenses	9.20-21	(4,695)	(7,567)
Other operating income	9.19	3,338	677
<b>Total operating expenses</b>		<b>(58,239)</b>	<b>(49,414)</b>
<b>Operating profit / (loss)</b>		<b>(21,081)</b>	<b>(35,976)</b>
Financial income	9.23	377	165
Financial expense	9.23	(25,722)	(4,793)
Financial result		(25,345)	(4,627)
Share of (loss)/profit of associates and joint ventures accounted for using the equity method	9.10		(32)
<b>Loss before taxes</b>		<b>(46,426)</b>	<b>(40,635)</b>
<b>Income taxes</b>	<b>9.24</b>	<b>11,421</b>	<b>5,548</b>
<b>Net loss for the year</b>		<b>(35,006)</b>	<b>(35,087)</b>
<b>Attributable to</b>			
Owners of the parent		(35,006)	(35,087)
Non-controlling interest			
<b>Profit / (Loss) per share</b>			
Basic earnings per share (euro)	9.25	(1.07)	(1.13)
Diluted earnings per share (euro)	9.25	(1.07)	(1.13)

## 5. Consolidated statement of comprehensive income

<i>Thousands of Euro (€)</i>	<i>Year ended 31 December</i>	
<b>CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME</b>	2017	2016
<b>Net loss for the year</b>	<b>(35,006)</b>	<b>(35,087)</b>
<b>Other comprehensive income</b>	<b>(15)</b>	<b>(20)</b>
Currency translation differences	(15)	(20)
<b>Total comprehensive income/loss for the year</b>	<b>(35,021)</b>	<b>(35,107)</b>
<b>Attributable to</b>		
Owners of the parent	(35,021)	(35,107)
Non-controlling interest		
<b>TOTAL COMPREHENSIVE INCOME/LOSS FOR THE YEAR</b>	<b>(35,021)</b>	<b>(35,107)</b>

## 6. Consolidated Statement of Financial Position

<i>Thousands of Euro (€)</i>		Year ended 31 December	
<b>ASSETS</b>	Notes	2017	2016
Property, plant and equipment	<b>9.8</b>	59,519	16,961
Goodwill	<b>9.9</b>	5,233	5,233
Other Intangible assets	<b>9.7</b>	80,385	79,130
Investments in associates	<b>9.10</b>	-	165
Deferred income tax assets	<b>9.24</b>	22,718	12,193
Other non-current assets		2,644	1,139
<b>Non-current assets</b>		<b>170,500</b>	<b>114,820</b>
Inventories	<b>9.11</b>	4,141	4,170
Trade & other receivables	<b>9.12</b>	33,881	7,955
Other Short Term investments	<b>9.13</b>	-	43,600
Cash & cash equivalents	<b>9.14</b>	36,190	2,150
<b>Current assets</b>		<b>74,212</b>	<b>57,876</b>
<b>TOTAL ASSETS</b>		<b>244,712</b>	<b>172,696</b>

<i>Thousands of Euro (€)</i>		Year ended 31 December	
<b>EQUITY AND LIABILITIES</b>	Notes	2017	2016
<b>Equity</b>			
Share capital	<b>7, 9.15</b>	25,036	22,613
Share premium	<b>7, 9.15</b>	148,279	122,830
Retained earnings	<b>7</b>	(86,374)	(52,384)
Translation differences	<b>7</b>	(59)	(44)
<b>Equity attributable to equity holders</b>		<b>86,882</b>	<b>93,015</b>
Subordinated loans	<b>9.16</b>	11,158	6,431
Bank borrowings	<b>9.16</b>	37,578	1,061
Refundable government advances	<b>9.16</b>	7,785	8,255
Other loans	<b>9.16</b>	46,727	32,495
Provisions		266	266
Deferred tax liabilities	<b>9.24</b>	2,099	3,469
<b>Non-current liabilities</b>		<b>105,612</b>	<b>51,977</b>
Current portion of financial loan	<b>9.16</b>	167	945
Short term financial debts	<b>9.16</b>	16,070	6,010
Trade payables and other current liabilities	<b>9.17</b>	24,174	15,682
Corporate tax payable		(4)	73
Accrued charges & Deferred income	<b>9.17</b>	11,811	4,995
<b>Current liabilities</b>		<b>52,217</b>	<b>27,705</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>244,712</b>	<b>172,696</b>

## 7. Consolidated statement of changes in Equity

<i>Thousands of Euro (€)</i>	Share Capital	Share Premium	Retained Earnings	CTA	Share based payments	Total Equity
<i>Notes</i>	9.15	9.15			9.26	
<b>Balance as at 1 January 2016</b>	<b>22,613</b>	<b>122,830</b>	<b>(18,646)</b>	<b>(24)</b>	<b>621</b>	<b>127,394</b>
Result for the year	-	-	(35,087)			(35,087)
Currency translation differences	-	-		(20)		(20)
Share-based payments	-	-	-	-	728	728
<b>Balance as at 31 December 2016</b>	<b>22,613</b>	<b>122,830</b>	<b>(53,733)</b>	<b>(44)</b>	<b>1,349</b>	<b>93,015</b>
Result for the year			(35,006)			(35,006)
Currency translation differences				(15)		(15)
Capital increase of 21 June 2017	1,957	24,177				26,134
Capital increase warrants NOV 2017	530	1,948				2,479
Transaction costs for equity issue	(65)	(676)	(5)			(746)
Share-based payments					1,021	1,021
<b>Balance as at 31 December 2017</b>	<b>25,036</b>	<b>148,279</b>	<b>(88,744)</b>	<b>(59)</b>	<b>2,370</b>	<b>86,882</b>

## 8. Consolidated Cash Flow statement

<i>Thousands of Euro (€)</i>	Year ended 31 December	
	2017	2016
<b>Cash Flow from operating activities</b>		
<b>Operating result</b>	<b>(21,081)</b>	<b>(35,976)</b>
Depreciation, amortisation and impairment	2,156	1,050
Development costs capitalized	(3,860)	-
R&D Tax credit receivable	(2,406)	-
Share based payments	1,020	728
Taxes paid	(85)	(1,096)
<b>Subtotal</b>	<b>(24,256)</b>	<b>(35,294)</b>
<b>Changes in working capital</b>		
Increase/ (decrease) in Trade payables and other current liabilities	8,493	11,689
(Increase) / decrease in Trade receivables and other receivables	(25,925)	1,543
(Increase) / decrease in Inventories	29	(1,374)
(Increase)/decrease in deferred revenue and others	6,739	23
<b>Net cash provided by/ (used in) operating activities</b>	<b>(34,921)</b>	<b>(23,412)</b>
<b>Cash Flow from investing activities</b>		
Business combinations	-	(8,500)
Payment for acquisition of tangible fixed assets	(10,943)	(13,795)
Payment for acquisition of intangible fixed assets	(1,255)	(2,309)
Disposal of assets	312	36
Contingent liabilities payments	-	(1,264)
Investment in other non-current assets	-	(6)
<b>Net cash provided by/ (used in) investing activities</b>	<b>(11,886)</b>	<b>(25,838)</b>
<b>Cash Flow from financing activities</b>		
Payments on financial loan	(574)	(17,148)
Proceeds from financial loan & government advances	11,204	15,628
Interest paid	(1,271)	(274)
Proceeds from issuance of shares (net of issue costs)	27,887	-
<b>Net cash provided by/ (used in) financing activities</b>	<b>37,246</b>	<b>(1,794)</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>(9,560)</b>	<b>(51,043)</b>
Cash & cash equivalents at beginning of the year	45,750	96,794
Cash & cash equivalents at end of the year	36,190	45,750

## 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, manufacture and markets Complex Therapeutics 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 are presented in thousands of euro (unless stated otherwise). The consolidated financial statements for the financial year ended 31 December 2017 have been approved for issue on 6 April 2018 as decided by the Board of Directors of 27 March 2018. The financial statements have been prepared on historical cost basis. 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 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 2017**

During the current financial year, the Group has adopted all the new and revised Standards and Interpretations issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC) of the IASB as adopted by the European Union and effective for the accounting year starting on January 1, 2017. The Group has early adopted the following new IFRS requirements that are not yet effective as per December 31, 2017.

- IFRS 15 Revenue from Contracts with Customers (Original issue May 2014 and subsequent amendments)
- IFRS 15 Revenue from Contracts with Customers – Clarifications (Original issue April 2016)

For more details, refer to the notes 9.19 (Revenue and others operating income) and 9.2.19 (Revenue recognition accounting policy).

While IFRS 15 is normally applicable for accounting periods beginning on or after 1 January 2018, management has early adopted the Standard for the preparation of the 2017 financial statements. The Group has conducted a detailed analysis of its contracts and concluded that adoption of IFRS 15 does not affect revenues that were reported for 2016 and the half year ended June 30, 2017. The Group has accordingly decided to apply retrospectively to each prior reporting period.

The following new Standards, Interpretations and Amendments issued by the IASB and the IFRIC as adopted by the European Union are effective for the current year<sup>4</sup>.

- IAS 7 Cash flow statement – Amendments as result of the Disclosure initiative (January 2016), refer to note 9.16
- IAS 12 Income taxes – Amendments regarding the recognition of deferred tax assets for unrealized losses (January 2016) – this amendment did not have any significant impact on amounts reported in prior and the current periods and is not expected to significantly affect future periods.

The adoption of these new standards and amendments has not led to major changes in the Group's accounting policies<sup>5</sup>.

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

The Group elected not to early adopt the following new Standards, Interpretations and Amendments, which have been issued by the IASB and the IFRIC but are not yet effective as per December 31, 2017 and/or not yet adopted by the European Union as per December 31, 2017 and for which the impact might be relevant:

- Annual Improvements to IFRSs 2014-2016 Cycle (December 2016) \*
- Annual Improvements to IFRSs 2015-2017 Cycle (December 2017) \*
- IFRS 2 Share-based Payment – Amendments to clarify the classification and measurement of share-based payment transactions (June 2016) \*
- IFRS 7 Financial Instruments: Disclosures (Amendments December 2011) – Deferral of mandatory effective date of IFRS 9 and amendments to transition disclosures
- IFRS 7 Financial Instruments: Disclosures (Amendment November 2013) – Additional hedge accounting disclosures (and consequential amendments) resulting from the introduction of the hedge accounting chapter in IFRS 9
- IFRS 9 Financial Instruments – Classification and Measurement (Original issue July 2014, and subsequent amendments)
- IFRS 9 Financial Instruments – Amendments regarding prepayment features with negative compensation (October 2017) \*
- IFRS 16 Leases (Original issue January 2016)
- IAS 39 Financial Instruments: Recognition and Measurement – Amendments for continuation of hedge accounting (fair value hedge of interest rate exposure) when IFRS 9 is applied (November 2013)
- IFRIC 23 Uncertainty over Income Tax Treatments (June 2017) \*

\* Not yet endorsed by the EU as of December 31, 2017

The following new standards, interpretations and amendments, which have not been applied in these financial statements, will or may have an effect on the Group's future financial statements:

None of the other new standards, interpretations and amendments, which are effective for years beginning after January 1, 2017 which have been issued by the IASB and the IFRIC but are not yet effective as per December 31, 2017 and/or not yet adopted by the European Union as per December 31, 2017, are expected to have a material effect on the Group's future financial statements.

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<sup>4</sup>Please only consider the Standards relevant to the activities of the company

<sup>5</sup>To amend in case of major impact of these changes in the Group's accounting policies

### 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 the investee.

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 statement of financial position respectively.

#### **b) Associates**

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 acquiree 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 allocation 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. Some of its products which are capitalized as from current year do not require any regulatory approval.

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 and components: 15-30 years
- Machinery: 5-15 years
- Vehicles: 3-5 years
- Furniture and equipment: 5-8 years
- ICT and other equipment: 3-5 years

Specific machines are depreciated using unit of production depreciation method.

The acquisition value of the assets have been analyzed by component and specific useful lives and residual values were applied to each of them. The residual value of the building is estimated to correspond to the cost of the structure of the building. 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 (FIFO) 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.

Write-offs are done based on the shelf life of the products.

### **9.2.10. *Trade receivables***

Tradereceivables are amounts due from customers for merchandise sold or services performed in the ordinary course of business and are recognized initially at fair value and subsequently measured at amortised cost using the effective interest method less provision for impairment.

### **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.

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

### 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 it 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 or credit 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. *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.

### 9.2.18. Revenue recognition

While IFRS 15 is normally applicable for accounting periods beginning on or after 1 January 2018, management has early adopted the Standard for the preparation of the 2017 financial statements. The Group has conducted a detailed analysis of its contracts and concluded that adoption of IFRS 15 does not affect revenues that were reported for 2016 and the half year ended June 30, 2017. The Group has accordingly decided to apply retrospectively to each prior reporting period.

Net sales encompass revenue recognized resulting from transferring control over products sold to customers.

- In addition, the Group has entered into a number of contracts through which it “out-licenses” to customers the IP it developed related to drugs that have not yet received regulatory approval. Generally, under the terms of the license, the licensee can further develop the IP, and manufacture and/or sell the resulting commercialized product. The Group typically receives an upfront fee, milestone payments for specific clinical or other development-based outcomes, and sales-based milestones or royalties as consideration for the license. Some arrangements also include ongoing involvement by the Group, who may provide R&D and/or manufacturing services relating to the licensed IP.

- Licenses coupled with other services, such as R&D, must be assessed to determine if the license is distinct (that is, the customer must be able to benefit from the IP on its own or together with other resources that are readily available to the customer, and the Group’s promise to transfer the IP must be separately identifiable from other promises in the contract). If the license is not distinct, then the license is combined with other goods or services into a single performance obligation. Revenue is then recognized as the Group satisfies the combined performance obligation.

- If the license is distinct, revenue is recognized at *the point in time* the license is granted to the extent that the license provides the customer a “right to use” of a company’s IP as it then exists. Revenue from a distinct license is recognized *over time* if and only if the license is qualified as “right to access”, which is the case when the three following criteria are met:

- a) The entity (is reasonably expected to) undertakes activities that will significantly affect the IP to which the customer has rights;
- b) The customer’s rights to the IP expose it to the positive/negative effects of the activities that the entity undertakes in (a);
- c) No goods or services are transferred to customer as the entity undertakes the activities in (a).

- Milestone payments represent a form of variable consideration as the payments are contingent on the occurrence of future events. Milestone payments are estimated and included in the transaction price based on either the expected value (probability-weighted estimate) or most likely amount approach. The most likely amount is the most predictive for milestone payments with a binary outcome (i.e., the Group receives all or none of the milestone payment). Variable consideration is only recognized as revenue when the related performance obligation is satisfied and the company determines that it is highly probable that there will not be a significant reversal of cumulative revenue recognized in future periods. This then results in a catch up of revenue at that moment for any performance obligations satisfied until that moment. Sales-based royalties received in connection with the license of IP are not included in the transaction price until the customer’s subsequent sales occur.

- For R&D services agreement where no license is granted, the related revenues is recognized over time using the output methods for determining the stage of completion of the services.

- For manufacture and supply agreement, the revenue is recognized at a point in time when the transfer of control over the related products is completed.

- The Group has taken advantage of the practical exemptions (i) not to account for significant financing components where the time difference between receiving consideration and transferring control of goods (or services) to its

customers is one year or less and (ii) expense the incremental costs of obtaining a contract when the amortization period of the asset otherwise recognized would have been one year or less.

#### 9.2.19. *Government grants and advances*

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 cumulative catch-up approach under which the carrying amount of the liability is adjusted to the present value of the future estimated cash flows, discounted at the liability's original effective interest rate. The resulting adjustment is recognized within profit or loss. 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.

#### 9.2.20. *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.

If the entity cancels or settles a grant of equity instruments during the vesting period (other than a grant cancelled by forfeiture when the vesting conditions are not satisfied), the entity account for the cancellation or settlement as an acceleration of vesting, and shall recognise immediately the amount that otherwise would have been recognised for services received over the remainder of the vesting period.

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

#### 9.2.21. *R&D tax credit*

Companies that invest in research and development of new environmentally friendly products and advanced technologies can enjoy increased investment incentives or a tax credit following Belgian tax law, according to each company's choice. The tax credit may be calculated either as a one-shot credit or spread over the depreciation period. Excess tax credit is carried forward, and the remaining balance after five years is refunded, which may result in a cash benefit. The tax credit applies to tangible and intangible fixed assets used for R&D of new products and technologies that do not have a negative impact on the environment (green investments), including R&D expenses capitalized under Belgian GAAP.

The tax credit should be claimed in the year in which the investment takes place.

Regarding the accounting treatment, the Group follows the IAS 20 after assessing its situation carefully because the tax credit can be directly settled in cash and some conditions not related to taxes for receiving the tax credit are existing.

## 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, but the current interest rate environment in Europe is rather stable and even with negative interest 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 (€)		Past due but not impaired					
Year	Carrying amount	Neither impaired nor past due	0-60 days	61-90 days	91-120 days	>120 days	
2017	25,428	19,175	5,551	249	63	390	
2016	3,510	2,529	414	237	6	325	

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.

The overall collectability risk for the remaining can be considered as immaterial.

The credit risk on cash investments or cash available on banks accounts 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 AA- (so upper-medium grade) and are thus considered as low credit risk.

### c) Liquidity risk

Thanks to the successful IPO, and to the capital increase as well as new leases taken in 2017, the Group maintains sufficient cash to conduct its clinical trials. 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 contingent and deferred consideration payable in relation to 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
<b>At 31 December 2017</b>	<b>36,135</b>	<b>9,111</b>	<b>2,699</b>	<b>12,569</b>	<b>12,569</b>	<b>93,983</b>
Subordinated Loan & Bank Borrowings	149	9,111	1,330	3,985	9,362	23,986
Finance lease liabilities	-	-	1,369	8,585	24,106	34,059
Trade and other payables	24,174	-	-	-	-	35,986
<b>At 31 December 2016</b>	<b>20,927</b>	<b>5,957</b>	<b>599</b>	<b>7,934</b>	<b>1,934</b>	<b>37,351</b>
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

The EUR 8.660k 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).

For more details on borrowings and other financial liabilities, refer to notes 9.16. (Borrowings) and 9.16.3. (Other financial liabilities).

### 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 be in a position to provide returns for shareholders in the future 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 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 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) Going concern**

The financial statements have been prepared on a going concern basis and in accordance with the main accounting principles set out above. For the evaluation of the company's ability to continue in operations for the foreseeable future, refer to point 1.13 (Going concern assessment).

#### **b) Out-licensing contracts with customers**

Revenue from licensing contracts should be accounted for based on the substance of the agreements between the entity and its business partners. The new revenue standard (IFRS 15) requires the management to exercise its judgment, notably in the following key areas:

- a) Determine if the license is distinct from other performance obligation or not;
- b) Determine the transaction price to consider, including the estimates of the agreed variable considerations, taking into account the constraining limit of the "highly probable" criteria;
- c) Determine if the performance obligation are satisfied or not at reporting date.

The Management makes its judgments taking into account all information available about clinical status of the underlying projects at the reporting date and the legal analysis of the contracts performed by its legal counsel.

#### **c) R&D capitalization**

R&D capitalization involves a great deal of judgment linked to evaluating whether all conditions to capitalized development costs have been met or not. This analysis is done on a project basis and with the involvement of internal project managers.

#### **d) 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. This involves the identification of potential impairment indicators and the use of significant assumptions including future cash flows, discount rate and probabilities of success. These estimates are performed taking into account all information available about the clinical status of the underlying project, some external benchmark and the relevant market economic conditions at reporting date.

#### **e) 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 foreseeable future taxable profits. We refer to section 9.24 Income tax expense.

#### **f) 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.

#### **g) 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 best estimate of the amount that would be 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. Both residual value and useful life are determined based upon discussions with local engineers.

#### **h) Contingent consideration payable 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; the main assumptions and variables used are future cash flows per projects, likelihood of approval (LOA), discount rate and

long term growth rate. These assumptions are based on external benchmarks, management's estimates based on experience of the entity and on internal analysis.

#### i) Refundable cash advances measurement

The remeasurement of refundable cash advances using the cumulative catch up method requires periodic re-estimation of the contractual cash flows required to repay the liability towards the wallon Region.

## 9.5. Business combinations and asset deals

These business combinations dates from 2015 but are still published in the 2017 Annual Report. 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 2500k.

An additional consideration to the former Uteron Pharma shareholders of EUR 25,000k or 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**
	<b>54,582</b>	<b>28,226</b>

\* includes USD 25,000k. Nominal amount to be increased with the nominal amount of future variable royalty payments

\*\* 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.

<i>Thousands of Euro (€)</i>	<i>Estetra SPRL</i>
<b>Current assets</b>	<b>500</b>
Cash and & cash equivalents	434
Trade and other receivables	66
<b>Non-current assets</b>	<b>30,725</b>
Property, plant and equipment	33
Intangible assets	30,686
Other non-current assets	6
<b>Liabilities</b>	<b>(6,813)</b>
Trade and other payables	(751)
Government loans	(6,062)
<b>Total identifiable net assets</b>	<b>24,412</b>
Goodwill	3,814
<b>Total</b>	<b>28,226</b>

The intangible assets represent the Entrepreneurial Right, which is the collection of assets that allows Estetra to further develop and commercialize the Estelle<sup>®</sup> 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<sup>®</sup> products and other related knowledge and know-how. The amortization will be determined 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.

We refer to note 9.16.3. for a description of the update computation of these debts.

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<sup>®</sup>). 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® and Myring™) 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
<b>Consideration</b>	<b>17,900</b>

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
<b>At 1 January 2014</b>	<b>-</b>
Acquisition 25% share	2,000
Loss of the period (25%) - equity accounting	(35)
<b>At 31 December 2014</b>	<b>1,965</b>
Step-up from 25% to 50%	1,500
Capital increase	300
Loss of the period - equity accounting till Dec 2015	(2,709)
<b>At 8 December 2015 - at acquisition</b>	<b>1,056</b>
Gain as a result of step-up accounting under IFRS	3,717
Consideration paid for step-up to 100%	17,900
<b>Total participation Novalon 31/12/2015</b>	<b>22,673</b>

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

<i>Thousands of Euro (€)</i>	Novalon SA
<b>Current assets</b>	<b>684</b>
Cash and & cash equivalents	242
Trade and other receivables	442
<b>Non-current assets</b>	<b>37,205</b>
Property, plant and equipment	71
Intangible assets	36,262
Other non-current assets	871
<b>Liabilities</b>	<b>(19,419)</b>
Trade and other payables	(1,523)
Current accounts	(3,698)
Deferred tax liabilities	(5,692)
Fair value contractual obligations	(7,763)
Government loans	(743)
<b>Total identifiable net assets</b>	<b>18,470</b>
Goodwill	4,204
<b>Total</b>	<b>22,673</b>

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 will start 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.

We refer to note 9.16.3. for a description of the update computation of these debts.

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 December 2017, due to the increasing volume of new licensing deals, operating activities are since 2017 being reviewed at two levels: Benelux business for product sales and Out-licensing business for partnership deals within Mithra and hence, a distinction is being made in the information provided regularly to the chief operating decision maker, François Fornieri. Moreover, some key figures can be displayed geographically within the Benelux Business model

### *Geographical information*

<i>Thousands of Euro (€)</i>	Year ended 31 December	
	2017	2016
<b>Product sales</b>	<b>16,852</b>	<b>16,728</b>
Belgium	13,588	12,899
The Netherlands	811	1,505
Luxembourg	419	443
Sales others countries	2,034	1,882
<b>Out-licensing</b>	<b>29,400</b>	<b>5,740</b>
Out-Licensing worldwide	29,400	5,740
<b>Total Net Sales</b>	<b>46,252</b>	<b>22,468</b>

For more details on the sales and license fees, please refer to section 9.19. Revenue and other operating income.

In 2017, two major customers represented respectively 32% and 22% of total revenue were identified in the “out-licensing” segment. No other customer represented more than 10% of total revenue .

### *Non-current assets*

<i>Thousands of Euro (€)</i>	Year ended 31 December	
	2017	2016
Belgium	162,005	106,300
Brazil	478	465
Luxembourg	9	20
The Netherlands	7,998	7,998
France	0	25
Germany	10	12
<b>Total</b>	<b>170,500</b>	<b>114,820</b>

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 and some minor assets in Brazil, Luxemburg and Germany.

## 9.7. Other Intangible Assets

Thousands of Euro (€)	Operating license	Intellectual property rights	Software licences	R&D Expenses	Total
<b>Cost</b>					
<b>At 31 December 2015</b>	<b>464</b>	<b>80,709</b>	<b>193</b>	<b>-</b>	<b>81,366</b>
Additions	2	2,057	250	-	2,309
Acquisitions through business combination	-	(782)	(18)	-	(800)
<b>At 31 December 2016</b>	<b>466</b>	<b>81,984</b>	<b>425</b>	<b>-</b>	<b>82,875</b>
Additions	281	-	219	1,575	2,075
Disposals	110	-	(310)	-	(200)
<b>At 31 December 2017</b>	<b>857</b>	<b>81,984</b>	<b>334</b>	<b>1,575</b>	<b>84,750</b>
<b>Accumulated amortisation</b>					
<b>At 31 December 2015</b>	<b>-</b>	<b>3,130</b>	<b>2</b>	<b>-</b>	<b>3,132</b>
Amortisation expense	-	535	78	-	613
<b>At 31 December 2016</b>	<b>-</b>	<b>3,665</b>	<b>81</b>	<b>-</b>	<b>3,745</b>
Amortisation expense	506	-	114	-	620
<b>At 31 December 2017</b>	<b>506</b>	<b>3,665</b>	<b>195</b>	<b>-</b>	<b>4,365</b>
<b>Net Book Value</b>					
<b>At 31 December 2015</b>	<b>464</b>	<b>77,579</b>	<b>191</b>	<b>-</b>	<b>78,234</b>
Cost	466	81,984	425	-	82,875
Accumulated amortisation and impairment	-	3,665	81	-	3,745
<b>At 31 December 2016</b>	<b>466</b>	<b>78,320</b>	<b>345</b>	<b>-</b>	<b>79,130</b>
Cost	857	81,984	334	1,575	84,750
Accumulated amortisation and impairment	506	3,665	195	-	4,365
<b>At 31 December 2017</b>	<b>351</b>	<b>78,320</b>	<b>139</b>	<b>1,575</b>	<b>80,385</b>

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 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.

The IP rights are not yet amortised because not yet available for use. No impairment indicators were identified as at December 31, 2017.

The increase in intangible assets during 2017 is primarily explained by the development costs capitalization in Estetra related to the project "E4 synthesis" (for EUR 1,575k), which entered into the development phase since 2017.

## 9.8. Property, plant and equipment

<i>Thousands of Euro (€)</i>	Land and buildings	Fixtures and equipment	Motor Vehicles	Total
<b>Cost</b>				
<b>At 31 December 2015</b>	<b>2,879</b>	<b>1,791</b>	<b>135</b>	<b>4,805</b>
Additions	11,023	2,752	21	13,795
Disposals	-	(35)		(35)
<b>At 31 December 2016</b>	<b>13,902</b>	<b>4,507</b>	<b>156</b>	<b>18,565</b>
Additions	38,444	5,846	34	44,285
Disposals	-	(69)	(36)	(105)
<b>At 31 December 2017</b>	<b>52,347</b>	<b>10,284</b>	<b>154</b>	<b>62,785</b>
<b>Accumulated amortisation</b>				
<b>At 31 December 2015</b>	<b>393</b>	<b>759</b>	<b>79</b>	<b>1,232</b>
Disposals	-	-	(1)	(1)
Amortisation expense	62	312	(1)	373
<b>At 31 December 2016</b>	<b>456</b>	<b>1,071</b>	<b>77</b>	<b>1,604</b>
Disposals	-	-	-	-
Amortisation expense	1,295	377	(11)	1,661
<b>At 31 December 2017</b>	<b>1,751</b>	<b>1,448</b>	<b>66</b>	<b>3,265</b>
<b>Net Book Value</b>				
<b>At 31 December 2015</b>	<b>2,486</b>	<b>1,031</b>	<b>56</b>	<b>3,573</b>
Cost	52,347	4,507	156	18,565
Accumulated amortisation and impairment	456	1,071	77	1,604
<b>At 31 December 2016</b>	<b>51,891</b>	<b>3,436</b>	<b>79</b>	<b>6,961</b>
Cost	52,347	10,284	154	62,785
Accumulated amortisation and impairment	1,751	1,448	66	3,265
<b>At 31 December 2017</b>	<b>50,596</b>	<b>8,836</b>	<b>88</b>	<b>59,519</b>

In November 2014, Mithra laid the first stone of its future integrated R&D and manufacturing technological platform called CDMO (Contract Development and Manufacturing Organization).

During the period, the Group recorded EUR 44,285k 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).

The acquisition value of the building has been analyzed by component and specific useful lives and residual values were applied to each of them. Depreciation by component is provided for lifetimes ranging between 5 and 30 years and CDMO building components from Phase 1 are depreciated as from April 2017.

The second and final phase of the CDMO construction (Phase 2) is underway and on track to be completed in H1 2019 within the allocated budget (EUR 25.8 million). This second phase is dedicated to tablet manufacturing, and is supported by the Walloon Region by a nonrefundable investment grant.

The machines acquired within the CDMO investment are not depreciated in 2017 because these assets are not yet available for use.

## 9.9. Goodwill & IP R&D

Goodwill results entirely from the acquisition of Estetra (EUR 3,814k) and Novalon (EUR 1,420k).

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 which is no longer required, that the WACC is slightly increased, 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 was identified. The same applies for Donesta<sup>®</sup> and the Novalon products.

More specifically, the assets related to Estetra and Novalon products are tested for impairment in groups of assets described as three different cash-generating units (CGUs), being Estelle<sup>®</sup>, Myring<sup>™</sup> and Zoreline<sup>®</sup>.

The recoverable amounts are based on the fair value less cost to sell methodology which use some risk-adjusted discounted cash flow models for a period of 10 years. If any terminal value is included, further cash flows are extrapolated using a negative long term growth rate. Probabilities of success are also different by CGU and are updated based on latest information about clinical results. The discount rate applied was updated at 13,23% and is the same for all three models. Management's assessment is that the recoverable amounts exceeds their carrying value and that no impairment are required.

Actually, a sensitivity analysis of impairment test has been done in case of adverse changes in assumptions. Mithra tested reasonable sensitivity to changes in the discount rate and a simulated increase of up to 1 percentage point in the discount rate used would not change the findings of the Group's analysis.

## 9.10. Investments in associates

<i>Thousands of Euro (€)</i>	Targetome	Total
<b>At 31 December 2015</b>	<b>198</b>	<b>198</b>
Loss of the period - equity accounting *	(33)	(33)
<b>At 31 December 2016</b>	<b>165</b>	<b>165</b>
Loss of the period - equity accounting *	0	0
Derecognition of investment in associate	(165)	(165)
<b>At 31 December 2017</b>	<b>0</b>	<b>0</b>

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

End of 2017, the Board of Directors of Targetome decided to terminate its activities. Further decisions regarding the future of the company are expected so that its value was derecognized for the current financial year.

## 9.11. Inventories

<i>Thousands of Euro (€)</i>	As at 31 December	
	2017	2016
Raw materials & consumables	2,180	147
Finished goods	2,350	4,148
<b>Total at cost</b>	<b>4,530</b>	<b>4,295</b>
Cumulated amounts written off at the beginning of the period	(125)	-
Write-down of inventories recognized as an expense in the period	(264)	(125)
Cumulated amounts written off at the end of the period	(389)	(125)
<b>Total net carrying amount</b>	<b>4,141</b>	<b>4,170</b>

In 2017, it has been decided to write-down the total net value of Gedeon (146k) and Desogestrel (118k) products in the inventory of Mithra Pharmaceuticals SA.

The variance from the inventory cost is booked within the cost of sales area and the write-down charges are booked within the operating expenses area of the income statement.

## 9.12. Trade Receivables and other current assets

Thousands of Euro (€)	As at 31 December	
	2017	2016
Trade receivables	25,428	3,510
Recoverable VAT	6,270	3,331
Prepayments	558	414
Other	1,624	701
<b>Total Trade receivables</b>	<b>33,881</b>	<b>7,955</b>

The increase in Trade receivables is mainly explained by the recognition of the invoices issued for the license upfront fees. The major part of the recoverable VAT stated at December 2017 closing has been collected at the end of Q1 2018.

## 9.13. Other short term investments

Thousands of Euro (€)	As at 31 December	
	2017	2016
Term deposits > 3 months	-	43,600
<b>Other short-term deposits</b>	<b>-</b>	<b>43,600</b>

These are no more term deposits with banks.

## 9.14. Cash and cash equivalents

Thousands of Euro (€)	As at 31 December	
	2017	2016
Cash at bank and in hand	36,190	2,150
<b>Total cash and cash equivalents</b>	<b>36,190</b>	<b>2,150</b>

## 9.15. Share capital

These shares are fully paid and have no nominal value.

### 9.15.1. General

At 31 December 2017 and 31 December 2016, the Company's share capital was represented by the following number of shares (units).

	As at 31 December	
	2017	2016
<b>Number of shares (issued and fully paid)</b>	<b>34,967,081</b>	<b>31,129,756</b>

These shares are fully paid and have no nominal value. There is no shares categories within the company; i.e. all shares entitle their owner to the same rights. There are no treasury shares as at end of December 2017.

There are some shares reserved for issuance under options, which are warrants to be exercised as from 1<sup>st</sup> January 2019. Refer to notes 1.4 and 9.26.

### 9.15.2. *Changes in capital*

The change of the number of shares during each of the periods ending on 31 December 2017 and 31 December 2016 is as follows:

Thousands of Euro (€)	Number of Shares	Issued Capital	Share premium	Total
<b>Balance at 31 December 2015</b>	<b>31,129,756</b>	<b>22,613</b>	<b>122,830</b>	<b>145,443</b>
Nihil				
<b>Balance at 31 December 2016</b>	<b>31,129,756</b>	<b>22,613</b>	<b>122,830</b>	<b>145,443</b>
- Incorporation in capital of retained earnings	3,112,975	1,957	24,177	26,134
- Capital increase by subscription rights	724,350	530	1,948	2,479
- Transaction costs for equity issue		(65)	(676)	(741)
<b>Balance at 31 December 2017</b>	<b>34,967,081</b>	<b>25,036</b>	<b>148,279</b>	<b>173,315</b>

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

The following capital transactions took place between 1 January 2017 and 31 December 2017:

- By resolution of a Board of directors' meeting held on 21 June 2017, a capital increase took place by means of authorized capital which was closed on 23 June 2017, resulting in the issue of 3,112,975 new shares at an issue price of EUR 8.4 per share, i.e. EUR 26.134k in the aggregate, of which EUR 1.957k was incorporated in the capital and EUR 24.177k was booked as issue premium.
- An additional 724,350 ordinary shares have been issued by the Company for an amount of EUR 2,478 k as the result of the exercise of 439 subscription rights (warrants).

## 9.16. Borrowings

An overview of the borrowings is shown below.

<i>Thousands of Euro (€)</i>	As at 31 December	
	2017	2016
<b>Subordinated loan</b>	<b>11,158</b>	<b>5,441</b>
<b>Bank borrowings</b>	<b>37,578</b>	<b>4,036</b>
Borrowings	3,519	4,036
Financial lease	34,059	-
<b>Refundable government advances</b>	<b>7,785</b>	<b>8,255</b>
<b>Other loans</b>	<b>46,727</b>	<b>30,510</b>
Capital grants	495	495
Other financial liabilities	46,232	30,015
<b>Non Current</b>	<b>103,247</b>	<b>48,242</b>
Subordinated loan	104	83
Short term bank loans	8,826	5,671
Other borrowings	379	380
Refundable government advances	493	321
Other financial liabilities	6,434	500
<b>Current</b>	<b>16,236</b>	<b>6,955</b>
<b>Total Borrowings</b>	<b>119,483</b>	<b>55,197</b>

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	2017	2016
<b>Subordinated loans (non-current and current)</b>				<b>11,261</b>	<b>6,514</b>
<b>Unsecured subordinated loans</b>				<b>395</b>	<b>458</b>
<b>Non-current</b>				291	375
Development Brazilian/Dutch subsidiary	4,95%	Fixed	2022	291	375
<b>Current</b>				104	83
Development Brazilian/Dutch subsidiary	4,95%	Fixed	2022	104	83
<b>Secured subordinated loans</b>				<b>10,866</b>	<b>6,056</b>
<b>Non-current</b>				<b>10,866</b>	<b>6,056</b>
CDMO Phase 1 Immobilier – prefin.	6,50%	Fixed	2018	7,997	5,576
CDMO Phase 2 Immobilier – prefin.	5,75%	Fixed	2018	1,264	
CDMO Phase 2 Mobilier – prefin.	5,75%	Fixed	2018	1,606	480
<b>Borrowings (non-current and current)</b>				<b>46,785</b>	<b>10,087</b>
<b>Secured borrowings</b>				<b>12,726</b>	<b>10,087</b>
<b>Long term bank loan</b>					
<b>Non-current</b>				<b>895</b>	<b>1,061</b>
Investment loans	2,00%	Fixed	2023	541	640
Working capital funding	5,24%	Fixed	2023	354	421
<b>Current</b>				<b>166</b>	<b>161</b>
Working capital funding	5,24%	Fixed	2023	67	62
Investment loans	2,00%	Fixed	2023	99	99
<b>Short term bank loans</b>					
<b>Current</b>				<b>8,660</b>	<b>5,510</b>
Straight Loans ING - CDMO		Variable	2018	8,660	5,510
<b>Other borrowings</b>					
<b>Non-current</b>				<b>2,625</b>	<b>2,975</b>
Innodem	2,57%	Fixed	2026	2,625	2,975
<b>Current</b>				<b>380</b>	<b>380</b>
Innodem	2,57%	Fixed	2026	380	380
<b>Financial Lease</b>				<b>34,059</b>	<b>-</b>
<b>Non-current</b>				<b>34,059</b>	<b>-</b>
Leasing Intégrale (Immo Phase I)	5,40%	Fixed	2032	25,164	-
Leasing (Phase I Immo)	3,14%	Fixed	2026	829	-
Leasing ING Lease (Mob Phase I)	3,19%	Fixed	2026	8,066	-
<b>Total non-current</b>				<b>48,736</b>	<b>10,467</b>
<b>Total current</b>				<b>9,310</b>	<b>6,134</b>
<b>Total</b>				<b>58,046</b>	<b>16,601</b>

The EUR 8,660k CDMO Straight Loan is referred to 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 “subsides” by Société Publique Wallonne (SPW), whichever occurs first.

Securities given by the Company primarily consist of Receivable pledges (of EUR 7,200k) and pledges on future receivables related to subsidies from the Walloon Region given as securities for the loans referred to in the above table as Straight Loans ING – CDMO; plus receivable pledge mandates (of EUR 6,000k) and mortgage mandates in respect of the office building owned by the Company (of EUR 1,450k) which were both given as securities for mixed credit facilities (straight loans, bank guarantees and documentary credits) under which there was no straight loan drawdowns at year-end.

Reconciliation of liabilities arising from financing activities following IAS 7:

Thousands of Euro (€)	2016	Cash flows	Non-cash changes Acquisitions	2017
Unsecured subordinated loans	458	(63)		395
Secured subordinated loans	6,056			10,866
Long term bank loan	1,222	(161)		1,061
Short term bank loans	5,510		3,150	8,660
Other borrowings	3,355	(350)		3,005
Financial Lease	-		34,059	34,059
<b>Total</b>	<b>16,601</b>	<b>(574)</b>	<b>42,019</b>	<b>58,046</b>

#### 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.

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
Refundable government advances Estetra	5,887	7,072
Other refundable government advances	2,390	1,504
<b>Total refundable government advances</b>	<b>8,278</b>	<b>8,576</b>

The below table gives the details of refundable governments advances granted to the group and repayments done in 2017:

Thousands of Euro (€)	Amount of grant	Decision year on fixed repayments part	% of fixed repayment part	% applied on turnover for variable repayment part	Maximum repayment amount	Amount reimbursed 2017
AR 7410 - Zoreline 2	5.265.000	01-05-2015	30%	3,57%	200%	-
AR 7585 - Development EVA	1.188.000	01-04-2016	30%	0,21%	200%	-
AR 6137 - Zoreline	1.825.884	01-10-2009	30%	3,30%	200%	44.700
AR 6138 - Drosperinone Novalon	625.800	01-12-2009	30%	0,50%	200%	16.000
AR 7492 - VMS	2.898.000	01-05-2015	30%	0,10%	200%	-
AR 7551 - Bio Synthesis	747.000	01-10-2016	30%	0,26%	200%	-
AR 6139 - Estelle	2.820.000	01-10-2009	30%	0,50%	200%	80.000
AR 6926 - Estelle	2.009.000	01-10-2012	30%	0,20%	200%	15.000
AR 6875 - Estelle	5.400.000	01-10-2011	30%	0,60%	200%	80.000
AR 7411 - Co-extrusion CDMO	441.000	01-05-2015	30%	0,40%	200%	-
AR 1510597 - Septime	206.466	01-07-2016	30%	0,01%	200%	-
<b>Total</b>	<b>23.426.150</b>					<b>235.700</b>

The amounts of refundable government advances measurements have increased since we updated the future sales expectations on the related projects. Indeed, the determination of the amount to be eventually paid to the Walloon Region under the signed agreement is subject to a high degree of uncertainty as it depends on the amount of the future sales that Mithra will generate (or not) in the future.

Product/projects related to the refundable advances	Amount granted	Probability of success		WACC
		Phase 2	Phase 3	
Estelle®	10,229	100%	38%	13.8%
Donesta®	2,898	27%	38%	12.48%
	Amount granted	R&D	Commercial	
Zoreline®	7,091	30%	55%	13.88%
Others	3,208	90%	25%	13.88%/12.48%
<b>Total refundable government advances</b>	<b>23,426</b>			<b>8,279</b>

### 9.16.3. Other financial liabilities

Other non-current financial liabilities primarily include the fair value of the contingent consideration for Estetra (EUR 41,811k) as well as the fair value of contingent payments relating to certain contractual obligations with respect to the acquired Zoreline® and Myring™ products (EUR 10,855k). 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 Estetra (EUR 41,811k in 2017 compared to EUR 22,418k in 2016) is the result of an increase of internal management estimates about likelihood of approval (the multiplication of probabilities of success of Phase 2 and Phase 3 clinical

trials) and higher expected future revenue, notably due to downpayments for deals for which some specific higher probabilities were considered. The discount rate update had no significant impact.

<i>Thousands of Euro (€)</i>	Year ended 31 December	
	2017	2016
Fair value Earn-out Estetra	41,811	22,418
Fair value Earn-out Myring™	1,958	1,569
Fair value Earn-out Zoreline	2,463	5,533
<b>Non current</b>	<b>46,232</b>	<b>29,520</b>
Fair value Earn-out Myring™	6,434	500
<b>Current</b>	<b>6,434</b>	<b>500</b>
<b>Total Other financial liabilities</b>	<b>52,666</b>	<b>30,020</b>

A sensitivity analysis has been performed on the fair value of the contingent considerations, see note 9.18. Financial instruments.

## 9.17. Trade payables and other current liabilities

<i>Thousands of Euro (€)</i>	As at 31 December	
	2017	2016
Trade account payables	16,141	9,312
Invoices to receive	7,241	5,727
VAT payable	(7)	25
Salaries and social security payable	794	600
Deferred income & accrued charges	11,811	4,994
Other debts	5	18
<b>Trade payables and other current liabilities</b>	<b>35,986</b>	<b>20,676</b>

The increase in trade accounts payables is explained by higher activities on clinical studies at the end of the year. In 2017, the total accrued charges amounts to EUR 2,489k.

The deferred income meets the definition of “contract liabilities” and is disclosed as required by IFRS 15.116 (a) for a total amount of EUR 14,300 k. The increase in deferred income is the deferred revenue recognition of the Estelle® deal for which Mithra still had a EUR 6 million invoice in the trade receivables, EUR 1 million of which has been recognized as revenue (EUR 5 million deferred licensing agreements revenues), and EUR 4.9 million invoiced late December for a R&D service agreement and milestones on Zoreline® development that have been fully deferred under IFRS 15 guidance. On the same deals, other parts of the license amount 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 are carried at amortized cost. Given the current nature of the other financial assets and liabilities involved, 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 on 31 December 2017 and 2016:

<i>Thousands of Euro (€)</i>	As at 31 December		
	2017	2016	
<b>Non Current liabilities</b>	<b>54,017</b>	<b>37,775</b>	
Other financial liabilities	46,232	29,520	Level 3
<b>Current liabilities</b>	<b>6,927</b>	<b>821</b>	
Other financial liabilities	6,434	500	Level 3

For the majority of the borrowings, the fair values are not materially different to their carrying amounts, since the interest payable on those borrowings is either close to current market rates or the borrowings are of a short-term nature.

The fair values of non-current borrowings are based on discounted cash flows using a current borrowing rate. They are classified as level 3 fair values in the fair value hierarchy due to the use of unobservable inputs, including own credit risk.

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

<i>Thousands of Euro (€)</i>	Other financial Liabilities
<b>Balance at 31 December 2015</b>	<b>26,653</b>
New government advances	-
Charged/(credited) to income statement	3,367
Settlements	
Other	-
<b>Balance at 31 December 2016</b>	<b>30,020</b>
New government advances	-
Charged/(credited) to income statement	21,999
Settlements	(636)
Other	-
<b>Balance at 31 December 2017</b>	<b>52,665</b>

The fair value of the contingent payments has been determined using a probability weighting approach based on the discounted cash flows as described above. A risk-adjusted discounted cash flow model was used, where all future cash flow are probabilized using statistical data gathered from the biotech sector and then discounted using the updated WACC applicable to Mithra.

The increase has already been explained in the note 9.16.3. Other financial liabilities.

A 1% increase in the discount rate used would lead to a decrease of the fair value of the contingent liabilities payments of EUR 2,058k while a 5% increase in the probability used would lead to an increase of EUR 7,951k.

## 9.19. Revenue and other operating income

### Revenue

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

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
<b>Product sales</b>	<b>16,852</b>	<b>16,728</b>
Belgium	13,588	12,899
The Netherlands	811	1,505
Luxembourg	419	443
Others countries	2,034	1,882
<b>Out-licensing</b>	<b>29,400</b>	<b>5,740</b>
Out-Licensing (worldwide)	29,400	5,740
<b>Total Revenues</b>	<b>46,252</b>	<b>22,468</b>

While the product sales segment remained stable during 2017, the revenues from License sales has increased compared to last year thanks to the recognition of upfront and milestone payments in the context of several new partnership deals.

The Group has early adopted IFRS 15 for the preparation of its consolidated financial statements 2017. IFRS 15 Revenue from Contracts with Customers (applied by the Group as from January 1<sup>st</sup> 2017) establishes a new comprehensive framework for determining whether, how much and when revenue is recognised. It replaces existing revenue recognition standards, including IAS 18 Revenue, IAS 11 Construction Contracts, IFRIC 18 Transfers of Assets from Customers and IFRIC 13 Customer Loyalty Programmes. The Group chooses to apply IFRS 15 using the full retrospective approach (being to restate comparative figures with the IFRS 15 requirements) and has conducted a detailed analysis of its contracts and concluded that adoption of IFRS 15 does not affect revenues that were reported for 2016 and the half year ended June 30, 2017.

Here below is a disclosure applying IFRS 15 versus IAS 18 that shows that there are no differences which are impacting the revenue recognition in 2016:

Thousands of Euro (€)	Year ended 31 December 2016		
	Under IAS 18	Restated under IFRS 15	Difference
Product sales	16,728	16,728	-
Out-Licensing revenue	5,740	5,740	-
<b>Total revenues</b>	<b>22,468</b>	<b>22,468</b>	<b>-</b>

### Disaggregation of revenue

The Group has disaggregated revenue into various categories in the following table which is intended to:

- Detail how the nature, amount, timing are affected by the change of method from IAS 18 to IFRS 15; and
- Enable users to understand the relationship with revenue segment information provided in note 9.6

Disaggregation of revenue 2017 :

Year ended 31 December 2017		
Thousands of Euro (€)	Product sales	Out-licensing
<b>Primary Geographic Markets</b>		
Europe	15,306	400
Outside Europe	1,546	29,000
<b>Total</b>	<b>16,852</b>	<b>29,400</b>
<b>Product type</b>		
Product sales	16,852	-
License grant	-	29,400
Manufacture and supply	-	-
R&D services	-	-
<b>Total</b>	<b>16,852</b>	<b>29,400</b>
<b>Timing of transfer of goods and services</b>		
Point in time	16,852	29,400
Over time	-	-
<b>Total</b>	<b>16,852</b>	<b>29,400</b>

Disaggregation of revenue 2016 :

Year ended 31 December 2016		
Thousands of Euro (€)	Product sales	Out-licensing
<b>Primary Geographic Markets</b>		
Europe	14,846	240
Outside Europe	1,882	5,500
<b>Total</b>	<b>16,728</b>	<b>5,740</b>
<b>Product type</b>		
Product sales	16,728	-
License grant	-	5,740
Manufacture and supply	-	-
R&D services	-	-
<b>Total</b>	<b>16,728</b>	<b>5,740</b>
<b>Timing of transfer of goods and services</b>		
Point in time	16,728	5,740
Over time	-	-
<b>Total</b>	<b>16,728</b>	<b>5,740</b>

Mithra's revenues increased 106% from EUR 22,468k to EUR 46,252k. The main reasons for the increase in revenue were the Donesta® deal with Japanese market leader Fuji Pharma for which EUR 4,000k was recognized, the Estelle® deal with Libbs for EUR 15,000 k and the commercialization deal with Mayne Pharma for Myring™ in the US for EUR 10,000 k. In total, and including additional smaller deals, Mithra recognized EUR 29,400k in licensing agreements revenue in 2017, compared to EUR 5,740k in 2016. Additional payments were received related to licensing agreements for which revenue recognition was deferred to future periods (refer to Statement of financial position section). With regard to the product sales in the Benelux, Mithra's revenues were EUR 16,852k in 2017, virtually unchanged from 2016.

### *Revenue from out-licensing contracts*

Amounts received or milestones to be received in the near future have been recognized as revenue to the extent that it is highly probable that no reversal will be done in the future.

Most of the out-licensing contracts have a single performance obligation which is the grant of the license. Some contracts contain also other performances such as manufacture and supply obligations, which are distinct of the license.

An analysis has been conducted in order to determine whether the single performance obligation was satisfied or not as at 31 December 2017.

#### *Summary table for revenue recognition and amounts deferred per type of payments:*

Year ended 31 December 2017	Revenue recognised	Balance in Deferred Income
Non refundable downpayments	14,300	1,110
Milestones payments	15,100	13,190
Sales	-	-
<b>Total</b>	<b>29,400</b>	<b>14,300</b>

The deferred income is the result of some amounts already invoiced to partners but not recognized in revenue as the related performance obligations were not yet completed as at December 31, 2017. The details are as follows:

- Two Estelle® deals for a total of EUR 9,500k to be recognized when the Phase III will be entirely achieved;
- Downpayments related to R&D services still to be performed for EUR 1,110k;
- Milestones received in the context of the Zoreline® license agreement, amounts being contingent to the regulatory approvals in the different countries of the partner' territory.

As at December 31, 2017, no significant financing component was identified on any of the existing customers contracts.

## Other operating income

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
R&D Tax credit	2,406	-
Recharged expenses	-	71
Other revenues	932	606
<b>Other operating income</b>	<b>3,338</b>	<b>677</b>

Item "Other revenues" is mainly referring to exemption from the withholding tax on professional income and to the gain on asset disposal related to the sale of Mithra France for EUR 200 k.

In 2016, the "Other revenues" were mainly referring to a regularization of exemption from the withholding tax on professional income.

For explanation on the item "R&D tax credit", refer to note 9.2.21 as we applied for an investment deduction mechanism for energy efficient investments and R&D investments which have no impact or reduce the impact on the environment.

## 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.

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
<b>Costs by nature</b>		
Trade goods, raw materials and consumables	9,095	9,029
Employee benefit expenses	10,657	10,039
External service providers	42,144	29,055
Other expenses	4,415	8,099
Corporate branding expenses	1,142	760
Depreciation, amortization and impairment charges	2,655	985
Commissions	242	850
Operating lease payments	321	302
<b>Total costs by nature</b>	<b>70,671</b>	<b>59,120</b>
<b>Costs by type</b>		
Cost of sales	9,095	9,029
Research and development expenses	48,185	34,299
General and administrative expenses	8,697	8,226
Selling expenses	4,695	7,567
<b>Total costs by type</b>	<b>70,671</b>	<b>59,120</b>

Investments in Mithra's innovative product portfolio, start of the phase III studies for Estelle<sup>®</sup> and phase II for Donesta<sup>®</sup>, together with Myring<sup>™</sup> and Zoreline<sup>®</sup> development, has driven the increase in R&D expenses by EUR 34,299k to EUR 48,185k in 2017.

## 9.21. Employee benefit expenses

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

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
Wages, salaries, fees & bonuses	9,204	8,945
Pension costs: defined contribution plan	156	137
Pension costs: defined benefit plan	0	0
Share based payments	1,021	728
Other	277	229
<b>Total</b>	<b>10,657</b>	<b>10,039</b>

In 2017, the Group employed at year-end 104 FTE's (80 FTE's in 2016) which can be allocated to the following departments:

Number of employees	As at 31 December	
	2017	2016
R&D Staff	44	39
G&A Staff	44	23
Sales staff	16	18
<b>Total</b>	<b>104</b>	<b>80</b>

## 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 1,75% on employer contributions and 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

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
Interest income	8	122
Other financial income	370	43
<b>Total financial income</b>	<b>377</b>	<b>165</b>

Other financial income in 2017 included the gain realised on the sale of Mithra France shares for 112k.

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
Interest expenses	(1,710)	(175)
Other financial expenses	(24,012)	(4,618)
<b>Total financial expense</b>	<b>(25,722)</b>	<b>(4,793)</b>

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 19,393k in 2017 and 3,537k in 2016) and in the amortized cost of the refundable government advances. In 2017, 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, mainly explained by the increase of probability of success of our clinical trials and Management's higher estimate for future license revenues, downypayments, milestone payments and product sales revenues.

## 9.24. Income tax expense

The tax expenses consist of:

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
Current tax income / (expense)	1,046	(126)
Deferred tax income/(expense) related to temporary differences and tax losses	10,525	6,674
Withholding tax income / (expense)	(150)	(1,000)
<b>Total</b>	<b>11,421</b>	<b>5,548</b>

The income taxes in 2016 and 2017 are still the result of temporary differences and taxes losses carried forward, and is thus a non cash item.

Withholding taxes of EUR 150k relates to the Fuji Pharma downpayments, see also notes 9.17 and 9.19 for this license sale contract.

The Group recorded a total deferred tax of EUR 11,400 k for the year. This is a deferred tax to be offset against future taxable income.

### *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	
	2017	2016
Income / Loss (-) before tax	(46,426)	(40,635)
Country's statutory tax rate	33,99%	33,99%
Tax expenses / income (-) (theoretical)	(15,780)	(13,812)
Tax expenses / income (-) in income statement (effective)	(11,421)	(5,548)
<b>Difference in tax expenses / income (-) to explain</b>	<b>4,360</b>	<b>8,264</b>
- Tax credit 2017 for R&D investments	(818)	-
- Temporary differences with different tax rates	(1,724)	1,651
- Tax losses for which no deferred tax income was recognised	246	251
- Belgian tax law reform impact on losses carried forward	1,803	-
- Tax losses for which no deferred Tax was recognised at lower %	-	5,592
- Permanent difference for which no deferred tax was recognized	95	-
- Withholding taxes	150	1,000
- Other	604	(281)
- Tax losses recognized with different tax rates	4,004	50
	<b>4,360</b>	<b>8,264</b>

## Deferred tax assets

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

Thousands of Euro (€)	As at 31 December	
	2017	2016
Deferred tax asset to be recovered after more than 12 months	22,718	12,193
Deferred tax asset to be recovered within 12 months	-	-
<b>Deferred tax assets</b>	<b>22,718</b>	<b>12,193</b>

The increase of EUR 10,525 k is mainly explained by the temporary difference arising from the recognition of a deferred tax asset on the fair values of the Estetra earn-out for EUR 8.527 k in 2017.

Actually concerning the Estetra acquisition done in 2015, 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 the probability criterion for recognizing a net deferred tax asset was not met at the previous reporting date.

Since second semester, the estimation of the management changed mainly because of a significant out-licensing deal that has been signed at the end of the last semester. As a consequence, management increased the probability of success of our clinical trials and its higher estimate for future sales revenues was a trigger to recognize a deferred tax impact in 2017.

The deferred tax asset relates also to fiscal losses carried forward at the level of Mithra, Estetra and Novalon and to the temporary difference arising from the differences in accounting principles at the level of Mithra, Estetra and Novalon. 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:

Thousands of Euro (€)	Temporary Differences				Total
	Contingent consideration	Expensed R&D costs	Other	Tax Losses	
At 1 January 2016	-	324	(20)	5,041	5,345
(Charged) / credited to income statement	-	(1)	(779)	7,628	6,848
At 31 December 2016	-	323	(799)	12,669	12,193
(Charged) / credited to income statement	8,527	-	11	1,988	10,525
At 31 December 2017	8,527	323	(788)	14,657	22,718

## Deferred tax Liabilities

The deferred tax liabilities (EUR 2,099k in 2017 and EUR 3,469k in 2016 ) result from temporary differences arising from the difference between the fair values of assets acquired at the acquisition date and their tax bases. DTA and DTL are offsetted by legal entity.

## 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.

Diluted loss per share is calculated including all the outstanding warrants that are in the money at the closing date.

Thousands of Euro (€)	Year ended 31 December	
	2017	2016
Result for the purpose of basic loss per share, being net loss	(35,006)	(35,087)
Weighted average number of shares for the purpose of basic loss per share	32,660,197	31,129,756
Basic loss per share (in Euro)	(1.07)	(1.13)
Diluted loss per share (in Euro)	(1.07)	(1.13)

## 9.26. Share-based payments

By a decision of the extraordinary shareholders' meeting of 2 March 2015 the Company issued 1089 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 2,789k

In 2017, there has been an exercise of 439 subscription rights (warrants) end of November. These warrants were settled during the vesting period which was accounted for as an acceleration of vesting by immediately recognizing the amount that otherwise would have been recognized for services received over the remainder of the vesting period.

650 warrants are still outstanding at 31 December 2017.

During the reporting period EUR 1,021k 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 alleged 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.

### *Control dispute*

A pending litigation exists between Mithra and Contrel Europe, arising out of a dispute 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 non-compliance 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 section 9.16.3.

## **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 2 construction 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 Phase III clinical trials on its product candidate Estelle®, a combined oral contraceptive, composed of 15 mg of Estetrol (E4) and 3 mg of drospirenone (DRSP) for a total budget of EUR 60 million to be paid by Mithra.

For the 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 2017, 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);
- Eva Consulting SPRL (an entity controlled by M. Jean-Michel Foidart), a Director and member of the key management of 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 Gaëtan Servais (permanent representative of Meusinvest SA, director of the Company) indirectly acts as Director);

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 has been included as related party.

### *Assets acquired from related parties*

In January 2015, Mithra acquired Estetra of which Mr Fornieri was a shareholder. The total consideration for the Estetra SPRL shares includes a payment of EUR 1 to the Watson Actavis Group (now Allergan) 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.

### *Key management compensation*

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

Thousands of Euro (€)	Dec 2017	Dec 2016
Base Salary	2,478	2,508
Variable Remuneration	-	-
Group Insurance (pension, invalidity, life)	8	4
Other (car, cell phone, hospitalization) insurance	36	20
Share based compensations (*)	1,021	728
<b>Total</b>	<b>3,542</b>	<b>3,260</b>

\* We also refer to section 9.26 on share based payments in which the Company indicated that François Fornieri exercised an amount of 114 warrants corresponding to the issuance of 188,100 new shares.

### *Sales/Purchase of other services and goods*

Thousands of Euro	Type of services	2017	2016
<b>Total services rendered to entities controlled by or with significant influence from key management / directors</b>		<b>0</b>	<b>0</b>
Vesteco	Reinvoicing IT expense	0	0
<b>Total services purchased from entities controlled by or with significant influence from key management / directors</b>		<b>130</b>	<b>156</b>
Yima sprl	Rental services building Foulons	122	119
Vitamine Event	Event organisation	0	28
Bocholtz	Event organisation - rent meeting rooms	8	10

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

Thousands of Euro (€)	2017	2016
Receivables from entities controlled by or with significant influence from key management / directors	0	10
Payables to entities controlled by or with significant influence from key management / directors	180	126
Payables to other related parties	0	0

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

Thousands of Euro (€)	2017	2016
Loan from / to entities controlled by key management / directors	0	0

### Transactions with non-executive Directors

The total amount of the remunerations and the benefits paid in 2017 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		
Meusinvest	Non-exec	20,000	5,000	
Alychlo	Non-exec - Chair	20,000	5,000	20,000
P. Suinen	Independent	20,000	7,500	
Jacques Platieu	Independent	20,000	5,000	
Ahok	Independent	20,000	5,000	
Eva Consulting <sup>6</sup>				
Aubisque	Non-exec	20,000		
Christiane Malcorps	Non-exec	2,958.90		
P4Management	Non-exec	17,027.4	2,500	

## 9.30. Events after the balance sheet

Post-period, Mithra announced two additional agreements for Myring™, its vaginal ring for contraception product candidate: in January 2018, the Company announced a non-exclusive, 10-year license and supply agreement with Adamed Group (Adamed), for the commercialization of the ring in the Czech Republic, a market worth approximately EUR 1.3 million<sup>7</sup>. Adamed is a Polish pharmaceutical and biotechnology company with a focus on gynaecology. Financial details of the agreement were not disclosed. In March 2018, this was followed by an exclusive license and supply Myring™ agreement for the Russian market with Alvogen, a global, privately owned pharmaceutical company focused on developing, manufacturing and selling generic, brand, over-the-counter brands (OTC) and biosimilar products for patients around the world. The Russian market for Myring™ amounts to approximately EUR 13 million<sup>8</sup>.

<sup>6</sup> The remuneration of Eva Consulting SPRL as executive member of the Board has been disclosed in the key management compensation table (see above).

<sup>7</sup> IMS Health Analytics Q3 2017

<sup>8</sup> IMS Health Analytics Q3 2017

As for its other distribution partners, Gynial (Austria) and Mayne Pharma (US), Mithra will exclusively manufacture and supply the product for Adamed and Alvogen from its CDMO<sup>9</sup> research and manufacturing center.

Also for Myring™, in March 2018, Mithra and US commercialization partner Mayne Pharma announced that the Abbreviated New Drug Application (ANDA) for the vaginal ring has been accepted for filing by the FDA. This is an important regulatory milestone, putting Mayne Pharma on track for launch in the US in H1 2019.

Furthermore, post-period, Mithra obtained positive top-line results for its 1-month PK/PD pilot study for Zoreline®, Mithra's product candidate for branded Zoladex® (AstraZeneca). The Zoreline® PK study demonstrates the safety profile of the 1-month (3.6mg) implant as compared to Zoladex®, with results in line with regulatory requirements. Furthermore, the data collected in 58 patients also provide important information on the similar PD activity (efficacy) of the 1-month treatment in Zoladex® and Zoreline®. Mithra continues to work on the reformulation of the 3-month implant, with PK results expected in H2 2018, and is currently evaluating further development steps. Pending positive results for the 3-month product candidate, Mithra could move into a pivotal clinical PD study for both the 1- and 3-month formulation.

Finally, in February 2018, Mithra published very promising top-line results for its hemostasis Phase II study. This substudy, which runs in parallel with the ongoing Phase III studies for Estelle®, analyzes a series of hemostatic, endocrine and metabolic parameters. Data are analyzed for 100 women divided over three treatment groups: 15 mg E4/3 mg DRSP (Estelle®), 30 mcg LNG (Melleva®) and EE/3 mg DRSP (Yaz®). Given the importance of these parameters to help determine the venous thromboembolism (VTE) risk profile of a (combined) oral contraceptive, the results are closely studied by the regulatory bodies and keenly awaited by clinicians and (potential) commercialization partners for Estelle®. The results were presented at the ISGE conference (Florence) at March 8, 2018, and the full CSR is expected early Q2 2018.

## 9.31. Mithra Pharmaceuticals companies consolidation scope

### Subsidiaries

The Group's financial statements consolidate those of the following undertakings<sup>10</sup>:

The Company has the following subsidiaries	2017 Ownership %	2016 Ownership %
<b>Mithra Recherche et Développement SA</b>	<b>100%</b>	<b>100%</b>
Registered office	Rue Saint-Georges 5 4000 Liège	
Incorporation Date	13/06/2013	
Company registration n°	534.909.666	
<b>Fund SA</b>	<b>100%</b>	<b>100%</b>
Registered office	Rue Saint-Georges 5 4000 Liège	
Incorporation Date	1/07/2013	
Company registration n°	0535.840.470	
<b>Mithra Lëtzebuerg SA</b>	<b>100%</b>	<b>100%</b>
Registered office	Boulevard de la Petrusse 124, 2330 Luxembourg	
Incorporation Date	27/12/2012	
Company registration n°	LU25909011	

<sup>9</sup> Contract Development & Manufacturing Organization

<sup>10</sup> Please note that the shareholding percentage is considered at a consolidated level. Therefore, the 100% are held by the Company or one of its subsidiaries.

The Company has the following subsidiaries	2017 Ownership %	2016 Ownership %
<b>Mithra Pharmaceuticals CDMO SA</b>	<b>100%</b>	<b>100%</b>
Registered office	Rue Saint-Georges 5 4000 Liège	
Incorporation Date	13/06/2013	
Company registration n°	534.912.933	
<b>Mithra Pharmaceuticals GmbH</b>	<b>100%</b>	<b>100%</b>
Registered office	Promenade 3-9 Raumm 22 DE - 52076 Aachen Germany	
Incorporation Date	27/12/2013	
Company registration n°	DE 295257855	
<b>Mithra Farmacêutica do Brasil Ltda</b>	<b>100%</b>	<b>100%</b>
Registered office	Rua Ibituruna N° 764 Saúde, São Paulo Brésil	
Incorporation Date	28/02/2014	
Company registration n°	NIRE N°35.220.476.861	
<b>WeCare Pharmaceuticals BV</b>	<b>100%</b>	<b>100%</b>
Registered office	Lagedijk 1-3, NL -1541 KA Koog aan de Zaan	
Incorporation Date	23/09/2013	
Company registration n°	NL08165405B01	
<b>Novalon SA</b>	<b>100%</b>	<b>100%</b>
Registered office	Rue Saint-Georges 5 4000 Liège	
Incorporation Date	17/11/2005	
Company registration n°	877.126.557	
<b>Estetra SPRL</b>	<b>100%</b>	<b>100%</b>
Registered office	Rue Saint Georges, 5 4000 Liège	
Incorporation Date	01/09/2009	
Company registration n°	818.257.356	
<b>Donesta Bioscience BV</b>	<b>100%</b>	<b>100%</b>
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 following associates		2017 Ownership %	2016 Ownership %
<b>Targetome SA</b>			
Registered office	Avenue Pré-Ailly 4, 4031 Angleur		
Incorporation Date	15/07/2010	<b>25,13%</b>	<b>25,13%</b>
Company registration n°	827,564,705		

As indicated, on 27<sup>th</sup> June 2017, the Ordinary General Meeting of Targetome decided to terminate the companies' activities and to initiate the legal proceedings related to the liquidation of the company so that its value was derecognized for the current financial year.

## 9.32. Disclosure audit fees

In Euro (€)	
Auditor's fees	88,110
Fees for exceptional services or special missions (audit related)	20,700
Tax consultancy (audit related)	-
Fees for exceptional services or special missions (external to audit)	-
Tax consultancy (external to audit)	-
Total	108,810

### 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 2017 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.

Assets as at (in K EUR)	2017	2016
<b>Fixed assets</b>	<b>88,817</b>	<b>39,798</b>
Intangible fixed assets	3,309	4,114
Tangible fixed assets	1,558	1,834
Financial fixed assets	83,950	33,849
<b>Current assets</b>	<b>88,623</b>	<b>106,659</b>
Amounts receivable	57,066	53,385
Inventory	4,207	3,660
Current investments	-	-
Cash at bank and in hand	27,038	44,951
Deferred charges and accrued income	312	4,663
<b>Total assets</b>	<b>177,440</b>	<b>146,457</b>

Liabilities as at (in K EUR)	2017	2016
<b>Equity</b>	<b>127,307</b>	<b>116,040</b>
Capital	25,599	22,790
Share premium account	151,379	125,561
Reserves	598	598
Accumulated profits (losses)	(50,269)	(33,012)
Grants	-	104
<b>Provisions</b>	<b>266</b>	<b>266</b>
<b>Amounts payable after more than one year</b>	<b>3,811</b>	<b>4,411</b>
<b>Current liabilities</b>	<b>46,057</b>	<b>25,740</b>
Short term debts	-	-
Short term portion of LT debts	650	624
Amounts payable within one year	45,407	20,584
Deferred charges and accrued income	-	4,532
<b>Total Liabilities</b>	<b>177,440</b>	<b>146,457</b>

Summary income statement (in K EUR)	2017	2016
<b>Operating income</b>	<b>51,740</b>	<b>21,578</b>
Turnover	49,630	21,126
Other operating income	2,109	451
<b>Operating charges</b>	<b>69,435</b>	<b>35,572</b>
Cost of goods sold	8,711	8,214
Services and other goods	53,193	21,895
Remuneration, social security costs and pensions	3,859	3,801
Depreciations of and amounts written off formation expenses, intangible and tangible fixed assets	3,464	1,289
Other operating charges	208	373
<b>Operating profit</b>	<b>(17,696)</b>	<b>(13,995)</b>
<b>Financial result</b>	<b>654</b>	<b>517</b>
Financial income	1,263	747
Financial charges	609	230
<b>(Profit) loss for the year before taxes</b>	<b>(17,041)</b>	<b>(13,478)</b>
Taxes	216	1,024
<b>Profit (loss) for the period available for appropriation</b>	<b>(17,257)</b>	<b>(14,501)</b>

Capital statement (in K EUR)	2017	2016
<b>A. Capital</b>		
1. Issued capital		
- At the end of the previous year	22,790	22,790
- Changes during the year	2,809	-
- At the end of this year	25,599	22,790
2. Capital representation		
2.1 Shares without par value		
- bearer and dematerialised	34,967,081	31,129,756
<b>B. Own shares held by</b>		
<b>C. Commitment to issue shares</b>		
<b>D. Authorised capital not issued</b>		

## 9.34. Alternative performance measure

Mithra decided to use some alternative performance measures (APMs) that are not defined in IFRS but that provide helpful additional information to assess clearer how the business has performed over the period. Mithra decided to use REBITDA in order to provide information on recurring items but this measure should not be viewed in isolation or as an alternative to the measures presented in accordance with IFRS.

REBITDA is an alternative performance measure calculated by excluding the non-recurring items and the depreciations & amortisations from EBIT (operating loss) from the consolidated statement of income prepared in accordance with IFRS. The Group considers one-off items and exceptional items as non-recurring items.

Refer to note on Financial Highlights and table below for the reconciliation to EBIT:

Thousands of EUR (€)	FY17 Actual	FY16 Actual
Revenues	46,252	22,468
Cost of sales	(9,095)	(9,029)
Gross profit	37,158	13,439
Research and development expenses	(46,653)	(34,137)
General and administrative expenses	(7,393)	(7,394)
Selling expenses	(4,503)	(7,510)
Other operating income / expenses	3,338	677
Total operating charges	(55,212)	(48,364)
REBITDA	(18,053)	(34,926)
Non recurring costs	(373)	-
Depreciations & amortisations	(2,655)	(1,050)
EBIT (operating loss)	(21,081)	(35,976)

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