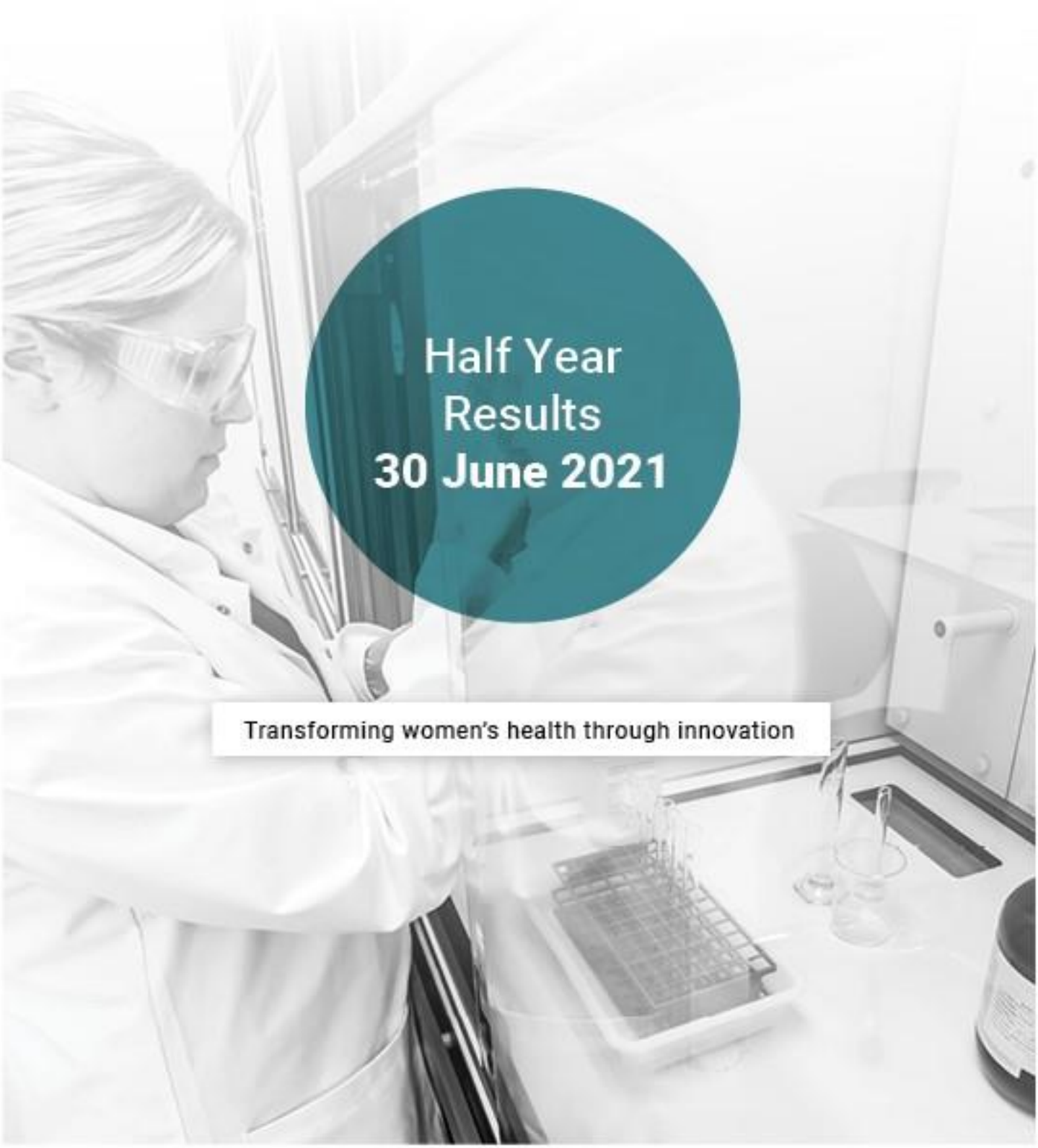
mithra
Women's Health



Half Year Results 30 June 2021

Transforming women's health through innovation

Interim Financial Report
as at 30 June 2021

This report is prepared in accordance with article 13 of the Royal Decree of 14 November 2007.

Mithra Pharmaceuticals SA (hereinafter “Mithra” or the “Company”) has prepared its interim financial report in French and in English. In case of discrepancies between both versions, the French version shall prevail.

Mithra Pharmaceuticals SA/NV,

A limited liability company (société anonyme / naamloze vennootschap) incorporated under Belgian law, with its registered office at rue Saint-Georges 5, 4000 Liège (enterprise number 0466.526.646)

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1. Corporate presentation

Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by providing them, through innovation, new choices with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their lifespan. To do so, Mithra explores the potential of Estetrol, a unique native estrogen, in a wide range of applications including women's health and much more (Covid-19, neuroprotection…). At its technological platform - Mithra CDMO -, Mithra develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. A variety of resources that enable it to offer a complete spectrum of research, development and specialist manufacturing to partners.

Active in more than 100 countries around the world, Mithra has an approximate headcount of 300 staff members and is a limited liability company headquartered in Liège, Belgium. On 30 June 2015, The Group launched its Initial Public Offering on Euronext Brussels.

2. Operational Highlights including post-period end

Mithra has achieved a series of milestones in the first six months of 2021 both with regards to its E4 (Estetrol) unique native estrogen pipeline and its Complex Therapeutics business.

- Marketing authorization for Estelle® obtained in Canada (March), United States (April), Europe (May) and Russia (September). Estetrol is the first new estrogen introduced in over 50 years.
- Successful commercial launch of Estelle® in the United States by Mayne Pharma (June) and in Canada by Searchlight Pharma (September) under the trademark Nextstellis®. Marketing exclusivity granted for five years by the FDA as a new chemical entity (NCE).
- Launch of Estelle® phased European commercialization by Richter under the trademark Drovelis® in Germany, Hungary, Poland and Austria.
- Phase III Donesta®: recruitment completion of American study and additional recruitment in the European study. Primary efficacy data of both studies on track for end of 2021. Depending on the evolution of the Covid-19 situation, study results and regulatory approvals, marketing authorization expected for Donesta® in H1 2024 for the United States/Canada and in H2 2024 for Europe.
- Based on regulatory agencies' feedback, the Board of Directors decided that the initial PeriNesta® development project was no longer timely nor a priority for the Company. Alternative scenarios based on Estelle® and Donesta® could potentially target this perimenopausal market without incurring substantial development costs.
- Topline results of the Coronesta Phase II study, which aimed to assess the safety and efficacy of estetrol (E4) for the treatment of patients who were hospitalized with moderate Covid-19. E4 did not differ from placebo on the primary study endpoint, but the results further support the unique safety profile of estetrol.
- Acquisition of full licensing and distribution rights on Zoreline®, allowing Mithra to significantly increase its margin in some of the most attractive locations outside of Mithra's former geographical scope.
- Launch of an animal PK/PD comparative study for Zoreline® with first results expected by the end of 2021.
- Commercial launch of Myring® in Italy (Farmitalia), Switzerland (Labatec), Poland and France (Zentiva).
- Commercialization agreement for Tibelia® signed with Dampe for Venezuela and additional commercial launches in Chile, Switzerland, UAE and KSA.

- Agreement with ExeVir for the manufacturing at Mithra CDMO's new injectable facility of a novel llama-derived antibody therapies for potential treatment and prevention of Covid-19.
- Renewal of the Board of Directors for a two-year mandate achieving a perfect parity: 5 women directors/5 men directors, as well as 5 independent/5 non-independent directors. Mr. Ajit Shetty succeeds Ms. Patricia van Dijck as Chairman of the Board.
- Appointment of Leon Van Rompay as Chief Executive Officer ad interim.

3. Financial highlights

Figures presented below are management figures[1] :

Thousands of Euro (€)	*30 June 2021*	*30 June 2020*
Revenue	12,142	2,507
Gross profit	**3,897**	**1,176**
Research and development expenses	(32,880)	(25,690)
Other net operating expenses	(2,429)	(2,951)
REBITDA	**(31,412)**	**(27,465)**
Loss from operations	**(36,534)**	**(32,840)**
Net fair value gains/(losses)	(19,164)	(9,551)
Financial result	(4,780)	(2,268)
Loss before taxes	**(60,478)**	**(44,659)**
NET LOSS FOR THE PERIOD	(54,894)	(33,994)

At reporting date, key financial elements can be summarized as follows:

- Revenues mainly driven by EUR 6.3 million first commercial sales of Estelle® during the second quarter of 2021 in the US, Canada and Europe; and an out-licensing revenue of EUR 4 million following the acquisition of full global licensing and distribution rights for Zoreline® allowing a deferred revenue to be recognized as earned revenue on the income statement.
- Cash collection of two major Estelle® out-licensing milestones with Mayne (USD 11 million) and Gedeon Richter (EUR 15 million), without impact on revenue as already recognized as per IFRS15 in 2019.
- R&D expenses (excluding depreciation) increased by 28% to reach EUR 32.9 million compared to EUR 25.7 million in H1 2020. These R&D expenses are of course the result of the ramp-up of activities under the Phase III Donesta®.
- EBITDA stands at EUR -31.9 million compared to EUR -30.0 million at H1 2020, so stable despite the R&D expenses increase.
- Below EBITDA, a net fair value loss on financial assets is reported at EUR -6.4 million which is mainly made of a charge of EUR 8 million related to a contingent receivable with Ceres Pharma, partly compensated by a gain on contract assets (related to the Mayne US deal).
- Reception of second tranche of Mayne shares (an Estelle® out-licensing milestones for the US territory) allowing the Company to become the first shareholder (with 9.57%) of Mayne Pharma Group Ltd, an Australia-listed company on ASX.
- Complete buyout of all earnouts linked to Myring® and Zoreline®, cancelling related amounts reported in the balance sheet in December 2020 (EUR 8.8 million) and thus providing better readability. This deal also allowed the Company to increase the value of Zoreline® IP rights on our balance sheet by EUR 8.5 million.

[1] Please refer to note 6.18 Alternative performance measures.

- As contractually agreed (see press release dated 1st October 2019), an earnout of EUR 25 million was paid to former owners of Uteron Pharma. This payment contributed to a reduction of the liability related to such earnouts reported at fair value on the balance sheet (from EUR 115.7 million to EUR 103.6 in December 2020 million in June 2021).
- EUR 56 million cash position which, when added to EUR 67 million capital commitment and credit lines available, is a total amount only exceeded in 2020 after both a capital increase and convertible bond issuance. This shows the Company's financial strength and ability to progress on its Business Development strategy for Donesta® and R&D projects.
- Still around EUR 290 million cash to be collected from Estelle® partners in the form of regulatory and sales related milestone payments under signed out-licensing contracts.
- Equity stands at a strong level of EUR 98 million, logically reduced compared to December 2020 (EUR 157.7 million) by the net loss for the period.

4. Corporate Governance

4.1. Capital and shares

During the period under review, one capital increase took place on 6 May 2021 with the issuance of 1,023,000 new shares for a total amount of EUR 3,500,520 as the result of the exercise of 620 subscription rights (warrants) pursuant to the warrant plan initiated on March 2, 2015. There are no more outstanding warrants arising from this 2015 Warrant Plan.

As of June 30, 2021, following the completion of the above-mentioned capital increase, the Company's capital consisted of a recognized amount of EUR 32,019,708.40 with 43,737,097 fully paid-up ordinary shares (each conferring the same rights).

The shares have no nominal value, but they represent the same fraction of the Company's capital, which is denominated in euros. Each share entitles its holder to one voting right.

In addition, the Company still has a number of subscription rights that are exercisable into ordinary shares, consisting of:

- 1,394,900 subscription rights issued on November 5, 2018, giving the right to subscribe for a total amount of 1,394,900 securities carrying voting rights (see press release dated 06/11/2018);

- 690,000 subscription rights issued on July 23, 2020, giving the right to subscribe for a total number of 690,000 shares in favor of LDA Capital Ltd pursuant to the transaction with LDA Capital Ltd announced by the Company on April 24, 2020 (see press release dated 24/04/2020);

- 300,000 subscription rights issued on September 7, 2020, giving the right to subscribe for a total number of 300,000 shares in favor of the lending shareholders, pursuant to the transaction with LDA Capital Ltd announced by the Company on April 24, 2020 (see press release dated 24/04/2020);

- 74,717 subscription rights issued on November 20, 2020, giving the right to subscribe to a total number of 74,717 securities carrying voting rights (See press release dated 20/11/2020).

Since the end of the reporting period, the Company disclosed on 2 July 2021 the issuance of a second put option notice pursuant to the transaction with LDA Capital Ltd announced by the company on 24 April 2020 (see press release dated 02/07/2021 and 13/08/2021). The first put option notice had been issued on 29 May 2020 and was completed on 5 August 2020 for a total amount of EUR 3,104,869.00, EUR 116,989.58 of which was allocated to the capital and EUR 2,987,879.42 to the share premium account. This capital increase gave rise to the issue of 159,800 new fully paid-up shares without designation of nominal value (see press releases dated 5 June 2020 and 5 August 2020). The completion of this second capital increase is expected to take place in the second half of 2021 (see PR dated 13/08/2021) for a maximum of 428,403 shares.

4.2. Shareholders & Shareholder structure

Based on both the manager's transactions and the transparency declarations the Company has received, the significant shareholders of the Company (i.e. above 3% of the voting rights linked to outstanding shares) as at 30 June 2021 are:

Shareholder	*Address*	*Number of voting rights*	*% of voting rights*[4]
François Fornieri[1]		11,455,605	26,19 %
Marc Coucke[2]		4,894,730	11,19 %
NOSHAQ SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,076,390	11.61 %
Bart Versluys[3]		1,699,496	3.89 %
Ogesip Invest SA	Boulevard du Roi Albert II, 37, B-1030 Bruxelles, Belgium	1,181,700	2.70 %
Free float		19,429,176	44,42 %

1. François Fornieri, Alychlo NV and Noshaq NV jointly holds 300,000 additional warrants.
2. Marc Coucke holds his shareholding partially through Alychlo NV, which he controls
3. Bart Versluys holds his shareholding through himself and through Scorpiaux BVBA, controlled by him.
4. All percentages are calculated on the basis of the current total number of voting rights.

Since the end of the reporting period, additional managers' transactions have occurred. In addition, following the issuance of the second put option notice dated 2 July 2021, and pursuant to the LDA Capital commitment, the share lending shareholders (François Fornieri, Alychlo NV and Noshaq SA) have lent their shares to LDA Capital Ltd for the time period covering the period between the exercise of the second Put Option notice (2 July 2021) and the day on which the new shares will be issued by the Company. More precisely, the day on which the number of shares to be returned by LDA Capital Ltd will be credited by the Company.

Therefore, at the date of the present report, the shareholding of major shareholders is as follows:

Shareholder	*Address*	*Number of voting rights*	*% of voting rights*[4]
François Fornieri[1]		10,991,404	25,13 %
Marc Coucke[2]		4,787,629	10,95 %[6]
NOSHAQ SA[3]	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	4.969,289	11.36 %[7]
Bart Versluys		1,699,496	3.89 %
Ogesip Invest SA	Boulevard du Roi Albert II, 37, B-1030 Bruxelles, Belgium	1,181,700	2.70 %
Free float		20,107, 579	45,97 %

1. François Fornieri, Alychlo NV and Noshaq NV jointly holds 300,000 additional warrants.
2. Marc Coucke holds his shareholding partially through Alychlo NV, which he controls
3. Bart Versluys holds his shareholding through himself and through Scorpiaux BVBA, controlled by him.
4. All percentages are calculated on the basis of the current total number of voting rights.

No other shareholders, alone or in concert with other shareholders, notified the Company of a participation or an agreement to act in concert in relation to 3% or more of the current total existing voting rights attached to the voting securities of the Company.

The most recent transparency declarations, including the abovementioned declarations, are available on the company's website (www.mithra.com).

4.3. Change and/or renewal in the composition of corporate bodies

On 20 May 2021, the Board's composition was renewed:

- 2 Directors have decided not to present their renewal to the General Meeting (Ahok BVBA, with Mr. Koen Hoffman as permanent representative and Selva Luxembourg SA with Mr. Christian Moretti as permanent representative),
- 6 Directors have been renewed. Amongst them, Eva Consulting SRL with Mr Jean -Michel Foidart as permanent representative, Mrs Patricia Van Dijck, Noshaq SA with Mr Gaëtan Servais as permanent representative, Sunathim BV with Mr Ajit Shetty, TicaConsult BV with Mr Erik Van Den Eynden as permanent representative, YIMA SRL with Mr François Fornieri as permanent representative) and finally,
- 4 new Directors have been appointed Alius Modi SRL with Mrs Valérie Gordenne as permanent representative, Mrs Amel Tounsi, Mrs An Cloet, and Mrs Liesbeth Weynants.

Therefore, the new Board of Directors counts 10 Directors and achieve parity with 5 women Directors and 5 men Directors, as well as 5 independent Directors and 5 non-independent Directors.

For further information on the renewal of the Board's composition, please see the press release published by the Company on 20 May 2021. The composition of the Board is as follows:

Name	*Position*	*Term*[1]	*Nature of Mandate*	*Board of Directors Committee Membership*
YIMA SRL (permanent representative: Mr. François Fornieri)	Director	2023	Non-executive	-
Sunathim BV (permanent representative: Mr. Ajit Shetty)	Director Chair	2023	Chair Independent	Nomination and Remuneration Committee
TicaConsult BV (permanent representative: Mr. Erik Van Den Eynden)	Director	2023	Independent	Risk and Audit Committee (Chair)
Noshaq SA (permanent representative: Mr. Gaëtan Servais)	Director	2023	Non-Executive	Risk and Audit Committee
Eva Consulting SRL (permanent representative: Mr. Jean-Michel Foidart)	Director	2023	Executive	
Mrs. Liesbeth Weynants	Director	2023	Independent	
Mrs. An Cloet	Director	2023	Independent	
Mrs. Amel Tounsi	Director	2023	Non-Executive	Nomination and Remuneration Committee
Mrs. Patricia van Dijck	Director	2023	Chair ad interim until 24 June 2021 Independent	Nomination and Remuneration Committee (Chair)
Alius Modi SRL (permanent representative : Mrs. (Valérie Gordenne)	Director	2023	Non-Executive	Risk and Audit Committee

The new composition of the Board has led to a change in the composition the Risk and Audit Committee and the Nomination and Remuneration Committee on 24 June 2021.

The following Directors are members of the Risk and Audit Committee since 24 June 2021: TicaConsult BV (permanent representative: Mr. Erik Van Den Eynden) (Chair), Noshaq SA (permanent representative: Mr. Gaëtan Servais) and Alius Modi SRL (permanent representative: Mrs. Valérie Gordenne). TicaConsult BV (permanent representative: Mr. Erik Van Den Eynden) is an Independent Director.

The following Directors are members of the Nomination and Remuneration Committee since 24 June 2021: Mrs. Patricia van Dijck (Chair), Sunathim BV (permanent representative: Mr. Ajit Shetty) and Mrs. Amel Tounsi. Mrs. Patricia van Dijck and Sunathim BV (permanent representative: Mr. Ajit Shetty) are both Independent Directors.

Given that the duration of the term is two years, the Directors are in office until the General Meeting which shall take place in May 2023.

With respect to the Executive Committee, on 3 February 2021, the Board of Directors accepted that Yima SRL (represented by Mr. François Fornieri) take a step back as CEO, until further notice, for a maximum of 12 months and appointed Van Rompay Management BV (permanent representative: Mr. Leon Van Rompay) as CEO until further notice. The members of the Executive Committee as of 30 June 2021 are listed in the table below:

Name/ Designation	*Function*
Van Rompay Management BV (permanent representative: Mr. Leon Van Rompay)	Chief Executive Officer ad interim (Chair)
Eva consulting SRL (permanent representative: Pr. J.M Foidart)	Chair of the Scientific Advisory Board
CMM&C SRL (Mr. Christophe Maréchal)	Chief Financial Officer (CFO)
Novafontis SRL (Mr. Jean-Manuel Fontaine)	Chief Business Officer (CBO)
GD Lifescience SRL (Mr. Graham Dixon)	Chief Scientific Officer (CSO)
BGL Consulting SRL (Mr. Benjamin Brands)	Chief Supply Chain Officer (CSCO)
MAREBA BVBA (Mr. Renaat Baes)	Plant Manager
Benoit Mathieu	Investor Relations Officer (IRO)

5. Principal risks and uncertainties

The Board of Directors considers that the main risk factors summarized in section 1.8 of the 2020 Annual Report, no longer remain relevant as such since the Company has received positive market approvals for its former product candidate Estelle® and has started commercialization in some countries.

The Group's exposure to price risk, credit risk, liquidity risk and cash flow risk are detailed in note 9.3 of the 2020 Annual Report (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 menopause indications as well as other potential indications such as wound healing, NHIE, 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 our former Estetrol-based product candidate Estelle® in the field of oral contraception in several regions (Canada, US, Europe, United-Kingdom, Iceland, Norway and Russia), branded generics, 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 transitions towards a commercial biopharma company in 2021, most focus is on the development portfolio and products' commercial launch.

(i) **Except Estelle®, no Estetrol-based product candidates have been formally registered nor commercialized and the lead product candidate Estelle® is currently approved in Canada, the US, in Europe, United-Kingdom, Iceland, Norway and Russia. Some of these events took place following the analyzed period. Therefore, the successful development of the Group's Estetrol-based other product candidates remain 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.**

Except Estelle® in the abovementioned countries, the Group's other Estetrol-based product candidates have not been approved nor commercialized.

In parallel, the agencies could require a number of additional studies to be conducted other than the pivotal studies which are not expected to have a significant impact on any (potential) marketing authorization approval, although these will play a role in determining the labelling and leaflet restrictions the product candidate would have upon approval (if any). Donesta® is currently in Phase III of clinical trial for use in menopausal hormone therapy. As data support package is shared with Estelle®; the data currently available would seem to suggest (but did not possess the statistical power to demonstrate) that Estetrol decreases hot flushes in a dose-dependent manner. However 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 and the placebo group as well as to confirm the minimum effective dose of E4.

Despite the recent positive opinion/approval on Estelle® in the abovementioned regions, 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 authorization with the relevant regulatory authorities. The Group does not know whether future clinical trials will begin on time, will need to be redesigned or will be completed on schedule. For Estelle® the activities announced for 2020 and during the current reporting period were completed with the filing activities and the obtention of the first market authorizations in significant countries. As for Donesta® and the ongoing Phase 3 clinical trials, providing precise timing estimates for the development and registration (if any) of Donesta® beyond the Phases of clinical development is thus difficult to predict.

At any stage of development, the triggering of certain contingent payments and "royalty payments", may be discontinued based on review of available pre-clinical and clinical data, the estimated costs of continued development, market considerations and other factors such as the development of Estetrol-based product candidates.

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 realize substantial product revenues and, eventually, profitability in line with the investments envisaged will mostly depend on its ability to successfully develop, register and commercialize Estetrol-based product candidates.**

The Group's E4 pipeline currently comprises Estelle®, an original innovative product already approved in significant parts of the globe and one other product candidates which would, upon their marketing authorization, be joining the list of original innovative products. The Group is dedicating the majority of its available cash resources to the development of this innovative Estetrol-based product candidates. If the Group would be unsuccessful in developing, commercializing and/or partnering this innovative original product, this would materially impact the revenue and profitability potential of the Group. In that case, the nature of the Group's pipeline would comprise the commercialization of the Estelle®, capable of generating a future return investment, but also of the development (either directly or indirectly) of Complex Therapeutics and Injectables, both of the later present market opportunities of a level which is significantly lower than the opportunity offered by the development of innovative original products. Both activities have a profile which is more limited in terms of funding needs and growth potential compared to the development of innovative product candidates.

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

The Group has, to date, received market authorizations in significant parts of the globe (see above) for Estelle® but is only starting its commercialization. It still needs to develop its other E4-based products such as Donesta®. Such development, registration and commercialization present significant new challenges.

In preparation, the Group has expanded and continues to expand its organization 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 organization 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 commercialization of the Group's innovative product candidates. This could have a material adverse effect on the Group's business, prospects, financial condition and operations.

(iv) **Complex therapeutics Zoreline® currently under development by the Group has not yet received any regulatory approval. Myring® received regulatory approval for Europe but is still waiting for it in the US. 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® was the first complex therapeutic solution produced by Mithra to demonstrate bioequivalence; for the other products (including Zoreline®), this is not yet the case. Any delays in completing studies, will delay the Group's ability to generate revenues from product sales of complex therapeutical solutions products if any. In case the Group would come late in the market, dependent on the market as of the point when three to five generics have been approved, it will suffer from significantly reduced market share, revenues and cashflows for the relevant generic product.

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

Upon completion of the relevant studies, the Group's products must obtain marketing approval from the European Medicines Agency (EMA), the US Food and Drug Administration (FDA) or competent regulatory authorities in other jurisdictions before the products can be commercialized 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 commercialization and distribution of its products in other regions.**

The Group's product candidates and Estelle® as recently approved in significant parts of the globe (see above) are being developed with the intention of a commercial launch throughout the world. The Company currently has no commercial, marketing and sales organization in place that would allow it 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. In 2020, the Company closed its Brazilian affiliate and the German one is in the process of liquidation.

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 organization elsewhere in the world but will rely for the commercial launch and distribution of its products on license and supply deals with partners.

The Company has not contracted with any new major partners with respect to its product portfolio. Some partners have been identified and some are still to be, but there can be no assurance that the Group will ever find an agreement with them and even identify such un-identified partners. Therefore, its products might not be commercialized in all the markets the Group currently intends to commercialize its products. The Group's

dependence on partners for the commercialization 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 several partnerships involving its CDMO's expertise namely in the injectables' industry, the latest of which concerning a manufacturing collaboration for innovative COVID-19 treatment.

The Company has entered into partnerships regarding sourcing of raw materials including essential active pharmaceutical ingredients such as E4.Therefore the possibility for the Company to meet its production's commitments towards their counterparts depends on its sourcing arrangements and its partners compliance with their own obligations, commitments which may have been impacted by COVID or any other drawbacks that the Company's partners may have faced during these challenging economical times. Notably, the Company has been informed by its E4 sourcing partner that they would have difficulties delivering the contractually defined quantities for the year 2021/2022 to the Company. In order to mitigate these potential delivery delays from our E4 sourcing partner, the Company has already considered other alternatives in order to diversify its E4 supply sources and to meet the increasing sales forecasts of its commercial partners.

(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, Therapeutics MD, Exeltis 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 commercialization 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 will depend in part on its ability to obtain, maintain and enforce its patents and other intellectual property rights for technologies and products in all territories of interest to the Group. The Group directly holds various families of patents for E4/DRSP pill Estelle® and menopause product candidate Donesta®. For Estelle® the initial end date of the patent family covering the use of E4 in a combined oral contraceptive is set in 2022 in Europe and Canada and in 2025 in the Unites States. Extension of the patent end date have been requested based on the first Marketing authorization of E4/DRSP in those territories. The patent families covering the use of Estetrol in menopause will expire in 2022 in Europe and Canada and in 2025 in the United States. New patent applications have been filed to strengthen the protection of the product and product candidate, the outcome and scope of which are still undetermined. The Group also holds five families protecting different synthesis pathways for E4, whose main patents expire in 2032. The Group will also seek to protect market exclusivity once marketing authorization is granted (where applicable) through market/data exclusivity systems (between three and ten years maximum depending on the territory).

(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 (EUR 36.5 million during the first semester of 2021). 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 will result in the Group incurring further significant and increased expenses for the next several years as a result of these activities.

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 depend on the production resources chosen by the Company.

- 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 may require access to additional funding in the future and if the Company fails to obtain such funding, the Company may need to delay, scale back or eliminate the development and commercialization 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 to be made in the future may not occur successfully.

- The Company has obtained significant grants and subsidies (mostly in the form of refundable government advances). The terms of certain of these agreements may hamper the Company in its flexibility to choose a convenient location for its activities.

- The Company has to comply with high standards of manufacturing in accordance with GMPs and other manufacturing regulations. In complying with these regulations, the Company must expend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against the Company, including the seizure of products and shutting down of production. The Company may also be subject to audits by the Competent Authorities. If the Company fails to comply with GMPs or other applicable manufacturing regulations, the Company's ability to develop and commercialize the products could suffer significant interruptions and delay.

(x) The Company or third parties upon whom the Company depends may be adversely affected by natural disasters and/or global health pandemics, and its business, financial condition and results of operations could be adversely affected.

The occurrence of unforeseen or catastrophic events, including extreme weather events and other natural disasters, man-made disasters, or the emergence of epidemics or pandemics, depending on their scale, may cause different degrees of damage to the national and local economies and could cause a disruption in the Company's operations and have a material adverse effect on its financial condition and results of operations. Man-made disasters, pandemics, and other events connected with the regions in which the Company operates could have similar effects. If a natural disaster, health pandemic, or other event beyond its control occurred that prevented the Company from using all or a significant portion of its office and/or lab spaces, damaged critical infrastructure, such as its manufacturing facilities or its manufacturing facilities of its third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult for the Company to continue its business for a substantial period of time.

On March 11, 2020 the World Health Organization declared the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. As of the date of this Annual Report, Belgium, where the Company operates, has been impacted by temporary closures. The length or severity of this pandemic cannot be predicted, but the Company currently anticipates that there may be a potential impact from COVID-19 on the planned development activities of the Company.

With COVID-19 and its variants still active in the United States and Europe, the business operations of the Company could be delayed or interrupted, particularly if a large portion of its employees become ill. COVID-19 may also affect employees of third-party organizations located in affected geographies that the Company relies upon to carry out its clinical trials. The spread of COVID-19, or another infectious disease, could also negatively affect the operations at its third-party suppliers, which could result in delays or disruptions in the supply of drug product used in its clinical trials. In addition, the Company is taking temporary precautionary measures intended to help minimize the risk of the virus to its employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for its employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect the Company's business.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics such as COVID-19. For example, many of the Company's

clinical trial sites are located in regions currently being afflicted by COVID-19. Some factors from the COVID-19 outbreak that the Company believes will adversely affect enrollment in its trials at least on a temporary basis include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of physicians serving as Company's clinical trial investigators, hospitals serving as its clinical trial sites and hospital staff supporting the conduct of its clinical trials;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product used in our trials; and
- employee absences that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

The impact of COVID-19 on its business is uncertain at this time and will depend on future developments, which are uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among other things, but prolonged closures or other business disruptions may negatively affect its operations and the operations of its agents, contractors, consultants or collaborators, which could have a material adverse impact its business, results of operations and financial condition.

The Company's premises' (Head Quarter and CDMO) have not been impacted by the natural flood which took place in the Liege area on the 15 and 16 July 2021.

6. Related party transactions

On 24 June 2021, the Company carried on a transaction with related parties in accordance with section 7:97 of the companies and association code. For further information, please see the press release dated 24 June 2021.

II.
Interim condensed consolidated financial statements for the six months ended 30 June 2021

II. Interim condensed consolidated financial statements for the six months ended 30 June 2021

1. Interim consolidated statement of profit or loss

Thousands of Euro (€)		*30 June 2021*	*30 June 2020*
	Notes		
Revenue	6.3.2	12,142	2,507
Cost of sales		(8,246)	(1,331)
Gross profit		**3,897**	**1,176**
Research and development expenses	6.4	(36,756)	(28,183)
General and administrative expenses	6.4	(5,896)	(7,226)
Selling expenses	6.4	(686)	(926)
Other operating income		2,908	2,319
Loss from operations		**(36,534)**	**(32,840)**
Change in the fair value of contingent consideration payable	6.12	(12,813)	(5,803)
Net fair value gains/(losses) on financial assets at fair value through profit or loss	6.12	(6,351)	(3,748)
Financial income		1,310	237
Financial expenses	6.4	(6,090)	(2,504)
Loss before taxes		**(60,478)**	**(44,659)**
Income taxes	6.4	5,584	10,664
NET LOSS FOR THE PERIOD		**(54,894)**	**(33,994)**

Loss per share		
Result for the purpose of basic loss per share, being net loss	**(54,894)**	**(33,994)**
Weighted average number of shares for the purpose of basic loss per share	43,026,680	39,283,621
Basic loss per share (in Euro)	**(1.28)**	**(0.87)**
Diluted loss per share (in Euro)	(1.28)	(0.87)

The accompanying notes are an integral part of these financial statements.

2. Interim consolidated statement of comprehensive loss

Thousands of Euro (€)	*Notes*	*30 June 2021*	*30 June 2020*
Net loss for the period		(54,894)	(33,994)
Other comprehensive income or (loss)		(8,749)	(7,650)
Items that may be reclassified to profit or loss:			
Currency translation differences		-	(12)
Gains/(losses) on cash flow hedges	6.10.2	(5,949)	(4,430)
Income taxes relating to these items		1,487	
Items that will not be reclassified to profit or loss:			
Changes in the fair value of equity investments at fair value through other comprehensive income or loss	6.10.2	(4,287)	(3,208)
Total comprehensive loss for the period		(63,642)	(41,645)
Attributable to			
Owners of the parent		(63,642)	(41,645)
Non-controlling interests		-	-
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		**(63,642)**	**(41,645)**

The accompanying notes are an integral part of these financial statements.

3. Interim consolidated statement of financial position

Thousands of Euro (€)	*Notes*	*30 June 2021*	*31 December 2020*
ASSETS			
Property, plant and equipment	6.6	33,902	29,921
Right-of-use assets	6.6	70,586	69,572
Goodwill	6.5	5,233	5,233
Other intangible assets	6.5	101,452	89,005
Deferred income tax assets	6.14	59,317	50,905
Contracts assets	6.8	-	200
Derivatives financial assets	6.10.2	1,985	6,184
Investments in equity securities	6.12	34,119	18,088
Other non-current assets	6.12	8,218	14,401
Non-current assets		**314,811**	**283,509**
Inventories	6.7	39,422	35,382
Contract assets	6.8	8,831	51,472
Derivatives financial assets	6.10.2	1,654	2,881
Trade and other receivables	6.9	16,047	10,052
Other short-term deposits		-	14
Cash and cash equivalents		55,830	138,675
Current assets		**121,784**	**238,475**
TOTAL ASSETS		436,596	521,985

Thousands of Euro (€)	*Notes*	*30 June 2021*	*31 December 2020*
EQUITY AND LIABILITIES			
Share capital	6.10.1	32,020	31,271
Additional paid-in-capital	6.10.1	335,286	332,535
Other reserves	6.10.2	5,426	13,690
Accumulated deficit		(274,652)	(219,759)
Equity attributable to equity holders		**98,080**	**157,737**
Subordinated loans	6.11	11,962	12,610
Other loans	6.11	112,695	111,898
Lease liabilities	6.11	43,912	44,282
Refundable government advances	6.11	13,476	15,195
Other financial liabilities	6.11, 6.12	103,365	101,180
Contract liabilities	6.8	-	3,706
Provisions	6.16	266	266
Deferred tax liabilities	6.14	5,703	4,363
Non-current liabilities		**291,379**	**293,500**
Current portion of subordinated loans	6.11	1,002	1,002
Current portion of other loans	6.11	10,249	10,475
Current portion of lease liabilities	6.11	6,160	7,315
Current portion of refundable government advances	6.11	1,664	1,259
Current portion of other financial liabilities	6.11, 6.12	8,687	23,424
Derivative financial liabilities	6.10.2	65	-
Trade and other payables		19,310	27,272
Current liabilities		**47,137**	**70,747**
TOTAL EQUITY AND LIABILITIES		436,596	521,985

The accompanying notes are an integral part of these financial statements.

4. Interim consolidated statement of changes in equity

Thousands of Euro (€)	*Share capital*	*Additional paid-in-capital*	*Other reserves*	*Accumulated deficit*	*Total equity*
Balance as at 1 January 2020	28,649	258,898	3,424	(127,673)	163,298
Net loss for the period				(33,994)	(33,994)
Currency translation differences			(12)		(12)
Losses on cash flow hedges			(4,430)		(4,430)
Changes in the fair value of equity investments at fair value through other comprehensive income or loss			(3,208)		(3,208)
Total comprehensive loss for the period	-	-	(7,650)	(33,994)	(41,645)
Capital increase of 23 June 2020, net of transaction costs	2,505	60,813			63,318
Share-based payments expense			2,554		2,554
Balance as at 30 June 2020	31,154	319,711	(1,673)	(161,668)	187,525
Balance as at 1 January 2021	31,271	332,535	13,690	(219,759)	157,737
Net loss for the period				(54,894)	(54,894)
Losses on cash flow hedges			(4,462)		(4,462)
Changes in the fair value of equity investments at fair value through other comprehensive income or loss			(4,287)		(4,287)
Total comprehensive loss for the period	-	-	(8,749)	(54,894)	(63,642)
Capital increase exercise of subscription rights 6 May 2021	749	2,752			3,501
Share-based payments expense			485		485
Balance as at 30 June 2021	**32,020**	**335,286**	**5,426**	**(274,652)**	**98,080**

The accompanying notes are an integral part of these financial statements.

5. Interim consolidated statement of cash flow

Thousands of Euro (€)	*Notes*	*30 June 2021*	*30 June 2020*
CASH FLOWS FROM OPERATING ACTIVITIES			
Result from operations		(36,534)	(32,840)
Adjustments for:			
Depreciation, amortization and impairment charges	6.5, 6.6	4,637	2,820
R&D tax credit		(889)	(723)
Share-based payments	6.15	485	2,554
Realized foreign exchange gains/(losses)		(677)	-
Grant income		(339)	(489)
Gain on derecognition of contingent consideration payable		(366)	-
Subtotal		**(33,683)**	**(28,678)**
Increase/(decrease) in trade and other payables	6.13	(7,884)	(9,143)
(Increase)/decrease in trade and other receivables	6.9	(6,617)	(2,579)
(Increase)/decrease in inventories	6.7	(4,040)	7,850
(Increase)/decrease in contract assets and liabilities	6.8	20,676	(5,598)
Net cash (used in)/ provided by operating activities		(31,548)	(38,148)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payment for acquisition of tangible fixed assets	6.6	(5,298)	(4,442)
Payment for acquisition of intangible fixed assets	6.5	(5,117)	(4,663)
Other financial liabilities payments	6.11, 6.12	(33,500)	-
Net cash (used in)/ provided by investing activities		(43,915)	(9,105)
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of subordinated loans and other loans	6.11	(5,213)	(455)
Repayment of refundable government advances	6.11	(717)	(854)
Proceeds from subordinated loans and other loans	6.11	4,300	715
Proceeds from refundable government advances and other grants		-	160
Lease payments	6.11	(4,732)	(1,268)
Interests paid	6.4	(4,490)	(1,507)
Proceeds from issuance of shares (net of issue costs)	6.10.1	3,501	63,318
Net cash (used in)/provided by financing activities		(7,352)	60,109
Net increase/(decrease) in cash and cash equivalents		(82,815)	12,856
Cash and cash equivalents at beginning of year		138,675	49,720
Effects of exchange rate changes on cash and cash equivalents		(30)	-
Cash and cash equivalents at end of period		**55,830**	**62,576**

6. Notes to interim condensed consolidated financial statements

6.1. Significant changes in the current reporting period

The financial position and performance of the Group was particularly affected by the following events and transactions during the reporting period:

- Estelle® obtained its Marketing authorization in Canada (March), the United States (April), Europe (May) and Russia (September). Thanks to these authorizations, commercial launch of Estelle® has already successfully occurred in the United States, under the trademark Nextstellis®, and in several European countries under the trademark Drovelis®.

  Note : For more details about the operations during this period, please refer to 6.11 Financial liabilities, to 6.5 Intangible assets and goodwill and to 6.3 Segment and revenue information.

- In June, Mithra signed an agreement with SVR Invest BV for the buy-back of all contingent payments linked to Myring® and Zoreline® as well as for the acquisition of the full global licensing and distribution rights for the Zoreline® implant.

  Note : For more details about the operations during this period, please refer to 6.11 Financial liabilities, to 6.5 Intangible assets and goodwill and to 6.3 Segment and revenue information.

6.2. Summary of significant accounting policies

6.2.1. Basis of presentation

The condensed consolidated financial statements for the six months ended 30 June 2021 have been prepared in accordance with IAS 34, Interim Financial Reporting as adopted for use in the European Union.

The financial statements do not include all the information required for annual financial statements and should therefore be read in conjunction with the financial statements for the year ended 31 December 2020. The condensed consolidated financial statements are presented in thousands of Euro (unless stated otherwise).

The condensed consolidated financial statements were approved for issue by the board of directors of Mithra on 20 September 2021.

The condensed consolidated interim financial information has been reviewed, not audited, by the statutory auditor.

6.2.2. Significant accounting policies

The interim financial statements have been prepared in accordance with the same accounting policies adopted in the Group's last annual financial statements for the year ended 31 December 2020 and are consistent with those of the previous corresponding interim reporting period.

Following Estelle® Marketing authorization, intellectual property rights and internally generated research and development for this project are now considered as available for use. Amortization is calculated using the straight-line method to allocate the cost of these intangibles on the longest of the patent protection life and the useful life of the product. The estimated useful life and amortization method are reviewed at the end of each reporting period.

The new standards and interpretations effective for the first time for periods beginning on (or after) 1 January 2021 do not impact the Group's interim consolidated financial statements.

The accounting policies have been applied consistently throughout the Group for the purposes of preparation of these interim financial statements.

6.2.3. Use of accounting judgments, estimates and assumptions

When preparing the interim financial statements, management undertakes a number of judgments, estimates and assumptions about recognition and measurement of assets, liabilities, income and expenses. The actual results may differ from the judgments, estimates and assumptions made by management, and will seldom equal the estimated results.

The judgments, estimates and assumptions applied in the interim financial statements, including the uncertainty around key sources of estimation uncertainty, were the same as those applied in the Group's last annual financial statements for the year ended 31 December 2020.

6.2.4. Changes in accounting policies and disclosures

A number of amended standards became applicable for the current reporting period. The group did not have to change its accounting policies or make retrospective adjustments as a result of adopting these amended standards.

The Group has not applied any new IFRS requirements that are not yet effective as per June 30, 2021.

Furthermore, the new standards and interpretations as well as the amendments to the current standards established by the IASB that will be applicable for the first time in the next 2021 annual accounts should not impact the company's EU-IFRS accounts either because they are not relevant to the company or because the current valuation rules are already adapted in relation to these new developments.

6.3. Segment and revenue information

6.3.1. Description of segments

The Group has identified three reportable segments of its business : Product sales for the sales related to Mithra's complex therapeutic products (Myring®), E4 products and the remaining portfolio of generic products, Out-licensing business for partnership deals and Others for the R&D services rendered to third parties. Hence, a distinction is being made in the information provided regularly to the chief operating decision maker, being the Chief Executive Officer.

6.3.2. Revenue

Thousands of Euro (€)	*30 June 2021*	*30 June 2020*
Product sales	8,185	1,920
Out-licensing	3,957	587
Others	-	-
Total revenue	**12,142**	**2,507**

Product sales were largely driven by our first deliveries of Estelle® (EUR 6.3 million) to our European, US and Canadian partners. Sales from generic products in our portfolio, at EUR 1.9 million, remained steady compared to last year.

Out-licensing revenue, at EUR 4.0 million, are essentially Zoreline® milestones, previously invoiced and paid, that could be recognized in line with the agreement signed with SVR Invest BV for the full global licensing and distribution rights for the Zoreline® implant, terminating the former agreement with GSP and delivering Mithra from any performance obligation. Otherwise, no new significant partnership was signed during 2021 first semester and no triggering event on our portfolio of signed contracts meant that no additional performance obligations could be recognized in our accounts.

Disaggregation of revenue

The tables below show the segment information for the reportable segments for the half-year ended 30 June 2021 and 2020, as well as the basis on which revenue is recognized:

Thousands of Euro (€)		*30 June 2021*
	Product sales	Out-licensing
Primary Geographic Markets		
Europe	2,707	3,862
Outside Europe	5,478	95
Total	8,185	3,957
Product type		
Generics	1,875	3,957
E4 Contraception	6,310	-
E4 Menopause	-	-
Total	8,185	3,957
Timing of transfer of goods and services		
At a point in time	8,185	3,957
Over time	-	-
Total	**8,185**	**3,957**

Thousands of Euro (€)		*30 June 2020*
	Product sales	Out-licensing
Primary Geographic Markets		
Europe	1,370	27
Outside Europe	549	560
Total	1,920	587
Product type		
Generics	1,920	587
E4 Contraception	-	-
E4 Menopause	-	-
Total	1,920	587
Timing of transfer of goods and services		
At a point in time	1,920	587
Over time	-	-
Total	**1,920**	**587**

6.4. Profit and loss information

The Group reported a net loss of EUR 54.9 million for the first six months of 2021, compared to a net loss of EUR 34.0 million for the first six months of 2020.

Product sales were largely driven by our first deliveries of Estelle® (EUR 6.3 million) to our European, US and Canadian partners. Sales from generic products in our portfolio, at EUR 1.9 million, remained steady compared to last year.

Out-licensing revenue, at EUR 4.0 million, are essentially Zoreline® milestones, previously invoices and paid, that could be recognized in line with the agreement signed with SVR Invest BV for the full global licensing and distribution rights for the Zoreline® implant. Otherwise, no new significant partnership was signed during 2021 first semester and no triggering event on our portfolio of signed contracts meant that no additional performance obligations could be recognized in our accounts.

As anticipated, R&D expenses increased by 30% compared to last year due to Donesta® Phase III clinical studies and, to a lesser extent, Coronesta studies.

G&A and sales expenses decreased by 19%, essentially due to a much lower impact of share-based payments accounting entries (charge of EUR 0.5 million compared to EUR 2.6 million for June 2020). Not considering this non-cash impact, G&A expenses would have remained stable despite the ramp-up of our activities.

Estelle® approval led to a review of the different scenarios and probabilities related to contingent consideration payable, hence the EUR 12.8 million change in fair value charge recorded in our first semester 2021 accounts.

Fair value loss on financial assets is mainly made of the charge of EUR 8.0 million related to contingent receivable with CERES, partially compensated by a fair value gain on contract assets (reevaluation of Mayne's shares up to their issuance in May 2021) for EUR 1.6 million.

Increase of net financial expenses is mostly driven by the interest charge of the EUR 125 million convertible bond negotiated in December 2020.

The group recorded a tax income of EUR 5.6 million for the six months that mainly results from the recognition of tax losses of the period in several entities as deferred tax assets, which are to be offset against future taxable income.

6.5. Intangible assets and goodwill

Goodwill results entirely from the acquisition of Estetra (EUR 3.8 million) and Novalon (EUR 1.4 million).

Intangible assets primarily include the acquisition of Estetra (EUR 30.7 million), Novalon (EUR 39.3 million) and the Donesta® asset deal (EUR 8.0 million). Other intangible assets consist mainly of a portfolio of acquired product rights, market access fees and development costs. The rights were acquired from 1999 onwards from different pharmaceutical companies. The intangibles also include intellectual property rights for a new formulation of Tibolone for use in Tibelia®.

The increase in intangible assets during the first semester of 2021 (for EUR 13.6 million) is explained by the acquisition of full licensing and distribution rights of Zoreline® held by SVR Invest, including important territories such as China, Canada and Australia for an amount of EUR 8.5 million, as well as internally generated E4 assets arising from development for EUR 4.7 million.

Following Estelle® Marketing authorization, intellectual property rights and internally generated research and development for this project are now considered as available for use. Amortization is calculated using the straight-line method to allocate the cost of these intangibles on the longest of the patent protection life and the useful life of the product. The estimated useful life and amortization method are reviewed at the end of each reporting period.

6.6. Property, plant and equipment and right of use assets

During the period, the Group recorded EUR 8.5 million of additions to tangible fixed assets which were mainly related to machinery and equipment of the new production facility for the manufacturing of pharmaceuticals products (Mithra CDMO) and their related development costs for EUR 4.0 million. In order to finance these machines, the Group entered into several leases. Right-of-use assets additions amount to EUR 3.1 million.

6.7. Inventories

Thousands of Euro (€)	*30 June 2021*	*31 December 2020*
Raw materials & consumables	37,876	32,442
Semi-finished goods	1,541	2,915
Finished goods	5	25
Total	**39,422**	**35,382**
Write-down / write-back of inventories during the period	(657)	150

Raw material inventories are still increasing in line with Estelle® commercial launch and forthcoming FDA approval for Myring® in the USA.

6.8. Contract assets and liabilities

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 also contain other performances such as manufacture and supply obligations, which are distinct to the license grant.

An analysis has been conducted in order to determine whether the single performance obligation was satisfied as at 30 June 2021.

6.8.1. Contract assets

The table below presents the roll forward of the related contract assets:

Thousands of Euro (€)	*Contracts assets*
Balance as at 1 January 2021	**51,672**
Fair value gain through profit or loss	1,648
Share issuance - transfer to investments in equity securities	(20,318)
Revenue billed during the period already recognized in previous years	(24,457)
Currency translation differences	285
Balance as at 30 June 2021	**8,831**

As a result of receiving FDA and EMA approval for Estelle®, previously unbilled revenue was invoiced, leading to a cash collection about EUR 24.5 million. Additionally, Mayne Pharma issued 85.8 million ordinary shares to the intention of the Company. Contract asset related to Mayne shares receivable was reversed and the EUR 20.3 million (value of shares at the emission date) booked under equity securities.

As at 30 June 2021, the balance of contract assets takes into account unbilled revenue for EUR 8.8 million, among which EUR 7.6 million related to Mayne Pharma for Myring™ and 1 million related to Gedeon Richter for Estelle® in Latin America.

6.8.2. Contract liabilities

The contract liabilities were the result of amounts already invoiced (and paid by customer) in the context of Zoreline® license agreement but not recognized in revenue as the related performance obligations were not yet satisfied as at 31 December 2020.

The table below presents the roll forward of the contract liabilities:

Thousands of Euro (€)	*Contract liabilities*
Balance as at 1 January 2021	**3,706**
Reclassification to revenue	(3,706)
Balance as at 30 June 2021	**-**

Zoreline® milestones, could be recognized in line with the agreement signed with SVR Invest BV in June 2021 for the full global licensing and distribution rights for the Zoreline® implant, terminating the former agreement with GSP and delivering Mithra from any performance obligation. Indeed, the renegotiation of earnouts relating to Complex Therapeutics extinguished the previous performance obligation of the Company.

6.9. Trade and other receivables

Trade and other receivables increased by EUR 6.0 million, which is mainly the result of the launch of Estelle® product sales and higher VAT receivables at the end of the reporting period.

6.10. Equity

6.10.1. Share capital and additional paid-in capital

During the period under review, one capital increase took place on 6 May 2021 with the issuance of 1,023,000 new shares for a total amount of EUR 3,500,520 as the result of the exercise of 620 subscription rights (warrants) pursuant to the warrant plan initiated on March 2, 2015. There are no more outstanding warrants arising from this 2015 Warrant Plan.

As of June 30, 2021, following the completion of the above-mentioned capital increase, the Company's capital consisted of a recognized amount of EUR 32,019,708.40 with 43,737,097 fully paid-up ordinary shares (each conferring the same rights).

The shares have no nominal value, but they represent the same fraction of the Company's capital, which is denominated in euros. Each share entitles its holder to one voting right.

In addition, the Company has still a number of subscription rights, that are exercisable into ordinary shares. We refer to section 4 and note 6.15.

The change in the number of shares during the periods ending on 30 June 2021 is as follows:

Thousands of Euro (€)	*Number of shares*	*Share capital*	*Additional paid-in-capital*	*Total*
Balance as at 31 December 2020	42,714,097	31,271	332,535	363,806
Capital increase exercise of subscription rights 6 May 2021	1,023,000	749	2,752	3,501
Balance at 30 June 2021	**43,737,097**	**32,020**	**335,287**	**367,306**

6.10.2. Other reserves

The table below presents the breakdown of other reserves within equity:

Thousands of Euro (€)	*Share-based payment reserve*	*Financial assets at FVOCI and foreign currency translation reserves*	*Cash flow hedge reserve*	*Total other reserves*
Balance as at 1 January 2020	**8,448**	**(5,024)**	**-**	**3,424**
Currency translation differences		(12)		(12)
Losses on cash flow hedges			(4,430)	(4,430)
Changes in the fair value of equity investments at fair value through other comprehensive income or loss		(3,208)		(3,208)
Total comprehensive loss for the period	**-**	**(3,220)**	**(4,430)**	**(7,650)**
Share-based payments expense	2,554			2,554
Balance as at 30 June 2020	**11,001**	**(8,244)**	**(4,430)**	**(1,673)**
Balance as at 1 January 2021	**15,714**	**(9,862)**	**7,838**	**13,690**
Losses on cash flow hedges			(4,462)	(4,462)
Changes in the fair value of equity investments at fair value through other comprehensive income or loss		(4,287)		(4,287)
Total comprehensive loss for the period	**15,714**	**(14,149)**	**3,376**	**(8,749)**
Share-based payments expense	485			485
Balance as at 30 June 2021	**16,199**	**(14,149)**	**3,376**	**5,426**

▪ Share-based payment reserve

Please refer to note 6.15.

▪ Financial assets at fair value through other comprehensive income or loss

The group has elected to recognize changes in the fair value of certain investments in equity securities in Other comprehensive income or loss, as explained in note 9.17 under Financial Instruments in the 2020 annual report. These changes are accumulated through other comprehensive income or loss and other reserves within equity. The group transfers amounts from this reserve to retained earnings when the relevant equity securities are derecognized.

As at June 30, 2021, the other reserves contain the cumulative changes in fair value of financial assets through other comprehensive income or loss (Mayne shares) for EUR 14.1 million.

▪ Cash flow hedge reserve

In the first quarter of 2020, the Group entered into derivative financial instruments to manage its exposure to foreign exchange rate risk arising from operational activities (cash flow hedges). The effective portion of changes in the fair value of derivative financial instruments qualifying as cash flow hedges is deferred to equity. Amounts deferred in equity are subsequently released to the income statement in the periods in which the hedged transaction impacts the income statement.

As at June 30, 2021, the cash flow hedge reserve contains the cumulative changes in fair value of hedge instruments for EUR 3.4 million.

The maturity table for the foreign currency hedges (forward sale of USD against EUR) is the following:

Time to maturity	*Hedged Amounts (kUSD)*	*Average Hedge Rate*
< 1 year	38,460	1.133
1-2 years	68,500	1.195
2-5 years	110,000	1.237
As at 30 June 2021	**216,960**	**1.188**

6.11. Financial liabilities

An overview of the financial liabilities is shown below.

			30 June 2021			*31 December 2020*
Thousands of Euro (€)	Total	Current	Non-Current	Total	Current	Non-Current
Subordinated loans	12,964	1,002	11,962	13,612	1,002	12,610
Other loans	122,945	10,249	112,695	122,373	10,475	111,898
Bank loans	*10,462*	*5,183*	*5,278*	*10,713*	*5,162*	*5,551*
Convertible bond	*112,483*	*5,066*	*107,417*	*111,310*	*5,313*	*105,997*
Capital grants	-	-	-	*350*	-	*350*
Lease liabilities	50,072	6,160	43,912	51,597	7,315	44,282
Refundable government advances	15,139	1,664	13,476	16,454	1,259	15,195
Sub-total liabilities arising from financing activities	**201,120**	**19,075**	**182,045**	**204,036**	**20,051**	**183,985**
Other financial liabilities	112,052	8,687	103,365	124,604	23,424	101,180
Derivative financial liabilities	65	65	-	-	-	-
Total financial liabilities	**313,237**	**27,827**	**285,410**	**328,640**	**43,475**	**285,165**

No new credit facilities were negotiated during the first semester 2021 : cash inflows came from existing credit facilities.

The decrease in financial liabilities is mainly explained by Other financial liabilities movements. Please refer to the note 6.12 for more details.

Additionally, here is the roll forward of liabilities arising from financing activities:

		Cash flow		*Non-cash changes*				
Thousands of Euro (€)	*31 December 2020*	*Inflow*	*Outflow*	*Additions*	*Reclassification*	*Classification of part of the proceeds in grant income*	*Amortized costs adjustments*	*30 June 2021*
Subordinated loans	13,612	-	(648)	-	-	-	-	12,964
Other loans	122,373	4,300	(7,236)	-	(61)	(261)	3,830	122,945
Bank loans	*10,713*	*4,300*	*(4,551)*	-	-	-	-	*10,462*
Convertible bond	*111,310*	-	*(2,656)*	-	-	-	*3,830*	*112,483*
Capital grants	*350*	-	*(28)*	-	*(61)*	*(261)*	-	-
Lease liabilities	51,597	-	(4,732)	3,207	-	-	-	50,072
Refundable government advances	16,454	-	(717)	-	61	-	(658)	15,139
Total	**204,036**	**4,300**	**(13,332)**	**3,207**	**-**	**(261)**	**3,171**	**201,120**

The debt component of convertible bond issued in December 2020 is the present value of all cash flows (coupons and redemption) discounted. Cash outflow for this debt consists in an interest payment during the period.

6.12. Fair value measurement of financial instruments

The following table presents the Company's financial assets and financial liabilities measured and recognized or unrecognized at fair value at 30 June 2021 :

Thousands of Euro (€)	*Balance as at 30 June 2021*	*Recognized fair value measurements*	*Fair value measurement hierarchy*	*Unrecognized fair value measurements*
Financial assets				
Financial assets at fair value through profit and loss				
Other non-current assets – contingent consideration receivable	-	-	Level 3	-
Contract assets – Mayne shares receivable	-	-	Level 1	-
Derivatives financial assets	-	-	Level 2	-
Financial assets at fair value through other comprehensive income				
Investments in equity securities	34,119	34,119	Level 1	-
Derivatives financial assets	3,639	3,639	Level 2	-
Financial assets at amortised cost				
Other non-current assets - other than above	8,218	-	-	8,218
Contract assets - other than above	8,831	-	-	8,831
Trade and other receivables	16,047	-	-	16,047
Cash and cash equivalents	55,830	-	-	55,830
Financial liabilities				
Financial liabilities at fair value through profit and loss				
Other financial liabilities - Estelle ®	103,552	103,552	Level 3	-
Financial liabilities at fair value through other comprehensive income				
Derivative financial liabilities	65	65	Level 2	-
Liabilities at amortized cost				
Subordinated loans	12,964	-	-	12,964
Other loans	122,945	-	-	122,945
Lease liabilities	50,072	-	-	50,072
Refundable government advances	15,139	-	-	15,139
Trade and other payables	19,310	-	-	19,310
Other financial liabilities - Zoreline ®	8,500	-	-	8,500

The following table presents the Company's financial assets and financial liabilities measured and recognized or unrecognized at fair value at 31 December 2020 :

Thousands of Euro (€)	*Balance at 31 December 2020*	*Recognized fair value measurements*	*Fair value measurement hierarchy*	*Unrecognized fair value measurements*
Financial assets				
Financial assets at fair value through profit and loss				
Other non-current assets – contingent consideration receivable	7,999	7,999	Level 3	-
Contract assets – Mayne shares receivable	18,670	18,670	Level 1	-
Derivatives financial assets	14	14	Level 2	-
Financial assets at fair value through other comprehensive income				
Investments in equity securities	18,088	18,088	Level 1	-
Derivatives financial assets	9,051	9,051	Level 2	-
Financial assets at amortized cost				
Other non-current assets - other than above	6,402	-	-	6,402
Contract assets - other than above	33,002	-	-	33,002
Trade and other receivables	10,052	-	-	10,052
Other short-term deposits	14	-	-	14
Cash and cash equivalents	138,675	-	-	138,675
Financial liabilities				
Financial liabilities at fair value through profit and loss				
Other financial liabilities	124,604	124,604	Level 3	-
Liabilities at amortized cost				
Subordinated loans	13,467	-	-	13,467
Other loans	122,466	-	-	122,466
Lease liabilities	51,650	-	-	51,650
Refundable government advances	16,454	-	-	16,454
Trade and other payables	27,272	-	-	27,272

6.12.1. Financial assets and liabilities not accounted for at fair value:

▪ Financial assets:

Fair value of trade and other receivables, other short-term deposits and cash and cash equivalents does not materially differ from carrying amounts. Fair value would typically be measured as Level 2. The fact that their carrying value approximates their fair value is due to the short maturity of these assets.

▪ Financial liabilities:

For a significant part of the loans, the fair values are not materially different to their carrying amounts, since the interest payable on those loans is close to current market rates because they are recent, or the loans have short maturities. For Lease liabilities the incremental borrowing rate has been determined at transition to IFRS 16 on 1 January 2019.

6.12.2. Financial assets and liabilities accounted for at fair value

▪ Fair value hierarchy:

Fair values are measured according to the following hierarchies:

- 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:

There are four categories of financial assets: Contingent consideration receivables, Contract assets, Derivative financial assets and Investments in equity securities.

Thousands of Euro (€)	*Fair value measurement hierarchy*	*Assets recognized or disclosed at fair value*
Other non-current assets – contingent consideration receivable	Level 3	-
Contract assets – Mayne shares receivable	Level 1	-
Derivatives financial assets	Level 2	3,639
Investments in equity securities	Level 1	34,119
Assets recognized or disclosed at fair value		**37,758**

Other non-current assets – contingent consideration receivable

Thousands of Euro (€)	*Other non-current assets – contingent consideration receivable*
Balance as at 1 January 2021	**7,999**
Fair value loss through profit or loss	(7,999)
Balance as at 30 June 2021	**-**

Further to the recent acquisition of Ceres Pharma by Naxicap Partners and latest financial info received from Ceres, it is currently deemed unlikely that necessary financial performance of the assets sold will be met in order to receive the contingent consideration receivables of two times EUR 5 million (discounted) by 2023.

Obviously, expected financial performance of the assets sold will be followed closely and regularly and part or whole of the contingent consideration receivable may very well be reinstated if considered as likely.

Contract assets – Mayne shares receivable

Regarding the contract assets, the variability associated with the Mayne share price gives rise to an embedded derivative so that in accordance with IFRS 9, the receivable should be classified as fair value through profit or loss.

As a result of receiving FDA approval for Estelle®, Mayne Pharma issued 85.8 million ordinary shares to the intention of the Company. Contract assets related to Mayne shares receivable were reversed and the EUR 20.3 million (value of shares at the emission date) booked under equity securities.

Until the issuance of shares in May 2021, the variability of Mayne share price led to a gain through profit or loss of EUR 1.6 million.

The roll forward of contract assets related to Mayne shares is as follow:

Thousands of Euro (€)	*Contract assets – Mayne shares receivable*
Balance as at 1 January 2021	**18,670**
Fair value gain through profit or loss	1,648
Share issuance - transfer to investments in equity securities	(20,318)
Balance as at 30 June 2021	**-**

Derivatives financial assets

The Group entered into derivative financial instruments to manage its exposure to foreign exchange rate risk arising from operational activities (cash flow hedges). The effective portion of changes in the fair value of derivative financial instruments qualifying as cash flow hedges is deferred to equity. Amounts deferred in equity are subsequently released to the income statement in the periods in which the hedged transaction impacts the income statement.

Thousands of Euro (€)	*Derivatives financial assets*
Balance as at 1 January 2021	**9,065**
Fair value loss through profit or loss	(14)
Fair value loss through other comprehensive income	(5,413)
Balance as at 30 June 2021	**3,639**

Investments in equity securities

Financial assets at fair value through other comprehensive income (FVOCI) comprise equity securities which are not held for trading, and which the group has irrevocably elected at initial recognition to recognize in this category. These are strategic investments and the group considers this classification to be more relevant.

Changes in Investments in equity securities relating to Mayne shares are explained by the issuance of the second tranche of shares and decreases in Mayne's share price as well as the AUD / EUR conversion rate as of June 30, 2021.

Thousands of Euro (€)	*Investments in equity securities*
Balance as at 1 January 2021	**18,088**
Share issuance - transfer from contract assets	20,318
Fair value loss through other comprehensive income	(4,287)
Balance as at 30 June 2021	**34,119**

▪ Financial liabilities:

There are two categories of financial liabilities: Other financial liabilities and Derivative financial liabilities. We considered a level 2 or 3 under the fair value measurement hierarchy.

Thousands of Euro (€)	*Fair value measurement hierarchy*	*Liabilities recognized or disclosed at fair value*
Other financial liabilities	Level 3	103,552
Derivative financial liabilities	Level 2	65
Liabilities recognized or disclosed at fair value		**103,617**

Other financial liabilities

The roll forward of other financial liabilities measured at fair value is as follow:

Thousands of Euro (€)	*Other financial liabilities*
Balance as at 1 January 2021	**124,604**
Payments related to Estelle ®	(25,000)
Payment related to Zoreline ® and Myring ®	(8,500)
Gain on derecognition of contingent consideration payable	(366)
Fair value loss through profit or loss	12,813
Balance as at 30 June 2021	**103,552**

As at June 30, 2021, other financial liabilities at fair value relates only to Estelle®. In June 2021, the Group renegotiated the earnouts relating to Zoreline® and Myring®, with the complete buyout of all remaining contingent payments obligation. In this context, Zoreline® financial liability following the acquisition of full licensing and distribution rights is accounted at amortized cost (EUR 8.5 million liability spread over the next four years).

The fair value of the contingent payments has been determined using a probability weighting approach applied to discounted cash flows. When relevant, a risk-adjusted discounted cash flow model was used where all future cash flows are probabilized and then discounted.

June 2021 assumptions for Estelle®:

Contingent considerations relating to Estelle®	*Total cash-out until 2028*	*Partial cash-out until 2028*	*Net Present Value*
Alternative 1	60%	40%	94,616
Alternative 2	**67%**	**33%**	**103,552**
Alternative 3	80%	20%	116,003
Alternative 4	100%	0%	130,064

Alternatives 1, 3 and 4 are not used for the measurement of the liability but are to be used for disclosing sensitivity of the value to the probability factors used (a level 3 input). Alternative 2 used for the measurement of the liability foresees a weight of 67% on scenarios modelling a complete cash out of the outstanding balance as at reporting date (EUR 185million) and 33% on scenarios modelling a partial cash out of this amount (cases where a cash position would be insufficient until 2028).

The increase of fair value for the contingent consideration for Estelle® of EUR 12.8 million is mainly due the review of management estimate following Estelle market approvals obtained in April and May 2021, and in a lesser extent to timing effect. The WACC used in June 2021 is 11.87% and was not changed since 31th December 2020.

December 2020 assumptions for Estelle®:

Contingent considerations relating to Estelle®	*Total cash-out until 2028*	*Partial cash-out until 2028*	*Net Present Value*
Alternative 1	50%	50%	107,921
Alternative 2	**60%**	**40%**	**115,739**
Alternative 3	70%	30%	125,087

6.13. Trade and other payables

Trade and other payables decreased by EUR 8.0 million, which is mainly the result of invoice and payment timing.

6.14. Deferred tax assets and liabilities

Thousands of Euro (€)	*Balance as at 30 June 2021*	*Balance as at 31 December 2020*
Deferred tax asset to be recovered after more than 12 months	59,317	50,905
Deferred tax assets	**59,317**	**50,905**

Increase of deferred tax assets is mostly due to recognition of tax losses of the period in several subsidiaries of the Group.

Management is convinced that foreseeable future taxable profit will be more than sufficient to recover the tax losses carried forward and therefore justify the recognition of such deferred tax assets.

The deferred tax liabilities (EUR 5.703k in H1 2021 and EUR 4,363k in 2020) result from temporary differences arising from the difference between the fair value of assets acquired at the acquisition date and their tax bases. DTA and DTL are offset by legal entity.

6.15. Share-based payments

The roll forward of the number of warrants is as follow:

	30 June 2021		31 December 2020	
	Weighted average exercise price (in Euro)	*Number of warrants*	*Weighted average exercise price (in Euro)*	*Number of warrants*
Outstanding and granted as of 1st January	18.8	2,701,520	15.7	1,307,825
Granted			24.8	1,393,695
Forfeited				
Exercised	5,646.0	(620)		
Expired				
	24.3	**2,700,900**	**18.8**	**2,701,520**

The fair value of each option is estimated using the Black & Scholes model based on the following assumptions:

	Plan 2018 (Grant 1 - 70%)	*Plan 2018 (Grant 1 - 30%)*	*Plan 2018 (Grant 2 - 100%)*	*Plan 2018 (Grant 3 - 100%)*
Number of warrants granted	**866,837**	**371,502**	**97,695**	**67,528**
Exercise price per warrant	EUR 24,05-24,09	EUR 24,05-24,09	EUR 24,09-25,72	EUR 25,5-27,5
Expected dividend yield	**-**	**-**	**-**	**-**
Expected stock price volatility	37.50%	37.50%	37.50%	37.50%
Risk-free interest rate	**0.36%**	**0.36%**	**0.36%**	**0.36%**
Expected duration	5 years	5 years	5 years	5 years
Fair value at grant date	**EUR 6,705k**	**EUR 2,918k**	**EUR 753k**	**EUR 586k**
Discount related to market condition	-	14.37%	-	

	Plan 2018 (Grant 4 - 100%)	*Plan 2020 (LDA)*	*Plan 2020 (LDA)*	*Plan 2020 (Mgmt)*
Number of warrants granted	87,695	690,000	300,000	316,000
Exercise price per warrant	**EUR 16,54**	**EUR 27**	**EUR 27**	**EUR 17,87**
Expected dividend yield	-	-	-	-
Expected stock price volatility	**37.50%**	**37.50%**	**37.50%**	**37.50%**
Risk-free interest rate	0.36%	0.36%	0.36%	0.36%
Expected duration	**5 years**	**3 years**	**3 years**	**10 years**
Fair value at grant date	EUR 479k	EUR 1581k	EUR 608k	EUR 2552k

During the period, a charge of EUR 485k has been recognized at the consolidated statement of income.

No new warrant plan was issued during the first semester of 2021.

6.16. Commitments

Dohme NV (previously Organon NV) /Merck patent dispute

Since 2008, Mithra is involved in a legal proceeding against Organon NV (now Merck Sharp and Dohme BV). The proceeding concerns the alleged patent infringement caused by the commercialization by Mithra and its partner DocPharma BVBA (now Mylan) of a generic drug named Heria. Currently, Organon is claiming for provisional damages of EUR 2,770k including actual loss of profit as well as the reimbursement of cost for establishing the infringement attorney's fees and expert's expenses. A first instance judgement was rendered on 11 December 2015 that concluded in a partial infringement of Organon's patent. An expert was appointed by Commercial Court to advise on the damages suffered by Organon and Merck because of the partial infringement. A final report of the judicial expert dated November 22, 2019 assessed that damage at EUR 551k. That amount is, however, questionable in the light of several objective factors. The case is pending at the appeal level and the hearing has not yet been fixed. A provision of EUR 341k has been recorded in the accounts in accordance with management's assessment of the liability that can result.

6.17. Events after reporting period

In July 2021, Mithra announced the issuance of a put option notice, according to the terms of the capital agreement signed with LDA Capital Limited on April 24, 2020. This is the second put option notice related to this agreement, after the first one issued on May 29, 2020. In August 2021, Mithra extended the pricing period for a minimum of 30 additional consecutive trading days, up to a maximum of 60 additional consecutive trading days.

In July 2021, Mithra also concluded a collaboration with ExeVir for the manufacturing of ExeVir's novel llama-derived antibody therapies for potential treatment and prevention of Covid-19. Under the terms of this agreement, Mithra will be responsible for upscaling and manufacturing services for filling thee drug substance in support of clinical and commercial supply.

In September, Mithra obtained Estelle® approval in Russia. The product will be marketed in Russia by Gedeon Richter under the brand name Esteretta®. Currently, the Russian contraceptives market is valued at approximately EUR 190 million annually with an average growth of 3% per year. Russia represents the third largest market in Europe, after Italy and Germany.

In September, Mithra announced the recruitment completion of the American Phase III Donesta® study and additional recruitment in the European study. The primary efficacy data of both North American and European studies are on track for end of 2021. Depending on the evolution of the Covid-19 situation, study results and regulatory approvals, Mithra believes it could achieve marketing authorization for Donesta® in H1 2024 for the United States/Canada and in H2 2024 for Europe.

Following a strategic meeting held on September 20 & 21, 2021, the Board of Directors analyzed both regulatory agencies' feedback as for the initial development project of PeriNesta®, as well as the additional budget required to achieve this development in accordance with the regulatory expectations compared to the initial EUR 20 million. Accordingly, the Board decided that the initial PeriNesta® development project was no longer timely nor a priority for the Company and that alternative scenarios based on Estelle® and Donesta® could potentially target this perimenopausal market without incurring substantial development costs. Therefore, the targeted market authorization initially planned for 2023 is no longer achievable in this opportunistic development project.

On September 24th, Mithra announced the topline results of the Coronesta Phase II study, which aimed to assess the safety and efficacy of estetrol (E4) for the treatment of patients who were hospitalized with moderate Covid-19. E4 did not differ from placebo on the primary study endpoint, but the results further support the unique safety profile of estetrol.

There has been no other subsequent event which occurred between the end of the six-month period ended on June 30, 2021 and the date of approval of these interim financial statements by the Board of Directors.

6.18. Alternative performance measures

Mithra decided to use some alternative performance measures (APMs) that are not defined in IFRS but that provide helpful additional information to better assess how the business has performed over the period. Mithra decided to use REBITDA[2] and EBITDA in order to provide information on recurring items, but those measures 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 depreciation & amortization from EBIT (operating loss) from the consolidated statement of income prepared in accordance with IFRS. The Group considers one-off item, share-based payments as non-recurring item.

EBITDA is an alternative performance measure calculated by excluding the depreciation and amortization from EBIT (operating loss) from the consolidated statement of income prepared in accordance with IFRS.

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

Thousands of Euro (€)	*30 June 2021*	*30 June 2020*
Loss from operations	**(36,534)**	**(32,840)**
Depreciation	4,637	2,820
Share-based payments	485	2,554
REBITDA	**(31,412)**	**(27,465)**
Share-based payments	(485)	(2,554)
EBITDA	**(31,897)**	**(30,019)**

[2] Recurring earnings before interest, taxes, depreciation and amortization

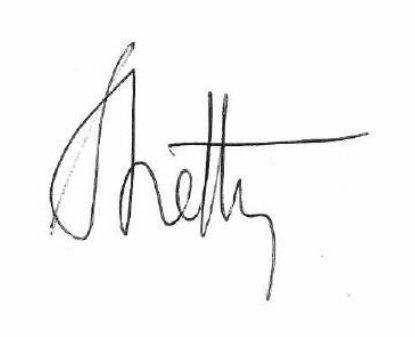
III.
Statement of the responsible persons

III. Statement of the responsible persons

The board of directors of Mithra, represented by all its members, declares that, to its knowledge:

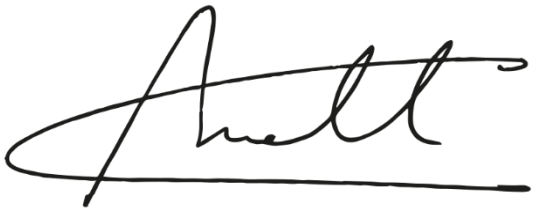
- The condensed financial statements, prepared in accordance with the applicable accounting standards, give a true and fair view of the assets, the financial position and the results of Mithra and of its consolidated entities; and
- The interim management report contains a fair description of the important events and main transactions between related parties which occurred during the first 6 months of the financial period and on their incidence on the condensed financial statements, as well as a description of the main risks and uncertainties for the remaining months of the financial period.

On behalf of the Board of Directors



SUNATHIM BV, represented by
Ajit Shetty, Chairman

Van Rompay Management BV, represented by
Leon Van Rompay, CEO ad interim



CMM&C SPRL, represented by
Christophe Maréchal, CFO

IV.
Statutory auditor’s report to the Board of Directors on the review of consolidated interim financial information

IV. Statutory auditor's report

Statutory auditor's report to the Board of Directors of MITHRA PHARMACEUTICALS SA on the review of consolidated interim financial information for the six-month period ended 30 June 2021

Introduction

We have reviewed the accompanying interim consolidated statement of financial position of MITHRA PHARMACEUTICALS SA as of 30 June 2021 and the related interim consolidated statements of comprehensive income, cash flows and changes in equity for the six-month period then ended, as well as the explanatory notes. The Board of Directors is responsible for the preparation and presentation of this consolidated interim financial information in accordance with IAS 34 "Interim Financial Reporting", as adopted by the European Union. Our responsibility is to express a conclusion on this consolidated interim financial information based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the accompanying consolidated interim financial information is not prepared, in all material respects, in accordance with IAS 34 "Interim Financial Reporting", as adopted by the European Union.

Battice, September 23, 2021

BDO Réviseurs d'Entreprises SRL
Statutory auditor
Represented by *Cédric ANTONELLI*

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mithra
Women's Health