



2022
Half Year
Results

mithra
Women's Health

Transforming women's health through innovation

2022 Half Year Results

as at 30 June 2022

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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I.
Interim management report

I. Interim management report

1. Corporate presentation

Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, 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 life span. Mithra explores the potential of the unique native estrogen estetrol in a wide range of applications in women health and beyond. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill ESTELLE[®], Mithra is now focusing on its second product DONESTA[®], the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO.

Active in more than 100 countries around the world, Mithra has an approximate headcount of about 300 collaborators and is headquartered in Liège, Belgium.

2. Operational Highlights including post-period end

Mithra has pursued its deliverables' achievements in the first six months of 2022 both with regards to its estetrol unique native estrogen pipeline and its Complex Therapeutics business.

- Successful commercial launch of contraceptive pill ESTELLE[®] in Australia by Mayne Pharma (July) under the trademark NEXTSTELLIS[®].
- Launch of a direct-to-consumer (DTC) campaign in the United States by Mayne Pharma (July) to further increase awareness of NEXTSTELLIS[®] contraceptive in the U.S.
- Positive top-line efficacy results from DONESTA[®] Phase 3 Program, which demonstrated a meaningful reduction in vasomotor symptoms (VSM) from baseline and compared to placebo.
- Launch of the recruitment of 300 additional menopausal non hysterectomised women for the DONESTA[®] European Study (C301), following the decision of the independent Data and Safety Monitoring Board (DSMB).
- Successful commercial launch of vaginal contraceptive ring MYRING[®] in Canada by Searchlight Pharma (February) and reception in August of FDA approval in the U.S. by Mayne Pharma, where MYRING[®] will be commercialized under the trademark HALOETTE[®].
- Collaboration with MedinCell for the development of two long-acting injectable innovative products to address major global healthcare challenges: a 3-month long acting injectable designed as an additional tool to fight Malaria and a long-acting injectable of tacrolimus for transplant patients aiming at improving efficacy, tolerance and patient observance
- Changes within Mithra's Board of Directors: appointment of Mr. Christian Moretti as Chairman and of Mr. Erik Van Den Eynden as Vice-Chairman; resignation of Mr. Ajit Shetty and Mr. François Fornieri.

3. Financial highlights

Key financial figures for the first half of 2022, compared with the first half of 2021, are presented below ¹:

Thousands of Euro (€)	30 June 2022	30 June 2021
Revenue	11,357	12,142
Gross profit	4,516	3,897
Research and development expenses	(22,714)	(32,880)
Other net operating expenses	(3,028)	(2,429)
REBITDA	(21,226)	(31,412)
Loss from operations	(27,537)	(36,534)
Net fair value gains/(losses)	4,332	(19,164)
Financial result	(5,748)	(4,780)
Loss before taxes	(28,952)	(60,478)
NET LOSS FOR THE PERIOD	(31,247)	(54,894)

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

- Revenues stand at EUR 11.4 million mainly driven by Estelle[®]: 3.7 million relates to product sales and EUR 4.0 million relates to an out-licensing revenue in the context of the license and supply agreement with Gedeon Richter for the commercialization of Estelle[®] in Latin America.
- Sales from generic products in our portfolio, at EUR 2.4 million, increased by 30% compared to last year. The majority of it concerns Myring[®] sales in Europe and Canada.
- Cash collection of one Estelle[®] out-licensing milestone relating to Latin America with Gedeon Richter (EUR 1 million), without impact on revenue as it was already recognized as per IFRS15 previously. Still around EUR 288 million cash to be collected for Estelle[®] out-licensing and sales related milestones.
- Research and development expenses (excluding depreciation) decreased by 31% to reach EUR 22.7 million compared to EUR 32.8 million in the first half of 2021. This decrease is attributable to a timing effect as these expenses should accelerate in the second half of 2022.
- REBITDA for the first half 2022 stands at EUR -21.2 million, compared to EUR -31.4 million for the first half 2021, the decrease is mainly explained by the lower expenses incurred in research and development.
- Below REBITDA, the positive impact of EUR 4.3 million booked in the change in fair value gain related to contingent consideration payable relates to Estelle[®]. It is the consequence of a conservative review of the contingent payable, namely the updated discount rate. Concerning this liability, no payment was done during the period to former owners of Uteron Pharma².
- EUR 29.3 million cash position, on the top of which the following facilities are available (subject to conditions):
 - EUR 50 million from the senior secured convertible facilities agreement signed on 8 August 2022 with funds managed by Highbridge Capital and funds managed by Whitebox Advisors for an amount of EUR 100 million. The first tranche of EUR 50 million was received upon signing of the agreement, with around 29 million used to repurchase outstanding convertible bonds of the Company held by the Lenders.

¹ These are management figures. Please refer to note 6.18 Alternative performance measures.

² [Mithra's press release_01/10/2019](#)

- EUR 53.8 million in the framework of LDA capital commitment agreement entered in April 2020 with a maturity in April 2025.
- EUR 85 million flexible equity financing agreement contracted with Goldman Sachs International, signed in February 2022 with a maturity in February 2024.
- Equity stands at EUR 36.1 million, compared to EUR 33.8 million end of December 2021: the total comprehensive loss for the period (EUR 47.3 million) was compensated by several capital increases for a total amount of EUR 49.1 million (net of transaction costs):
 - EUR 11.8 million from LDA capital;
 - EUR 13.8 million in the framework of flexible equity financing agreement with Goldman Sachs International;
 - EUR 23.4 million from the private placement completed in June 2022.

4. Corporate Governance

4.1. Capital and shares

During the period under review, several capital increases took place:

- On 4 February 2022, the Company entered into a Master Confirmation Agreement with Goldman Sachs International linked to the Equity Financing Agreement executed on the same date. Pursuant to the later, the Company has increased its capital in principle on basis of the authorized capital to allow the potential issuance of new shares to the benefit of Goldman Sachs International for an aggregate amount of EUR 100,000,000 (including issue premium). At the date of the current request, the Company has utilized EUR 15 million of the aggregate amount and the Company has received three call options from Goldman Sachs International:
 - The first drawing request, exercised on 21 March 2022, amounts to EUR 5 million (including issue premium) and led to the issuance of 377,198 new shares of the Company.
 - The second drawing request, exercised on 20 April 2022, amounts to EUR 5 million (including issue premium) and led to the issuance of 489,686 new shares of the Company.
 - The third drawing request, exercised on 31st May 2022 amounts to EUR 5 million (including issue premium) and led to the issuance of 725,300 new shares of the Company.
- On 14 February 2022, the Company has increased its capital following the third put option notice received from LDA Capital Ltd on the 21 December 2021 for an amount of EUR 8,061,142 (including issue premium) which led to the issuance of 442,191 new shares.
- On 18 April 2022, the Company has extended the capital commitment agreement with LDA Capital Limited ("LDA Capital") for a period of two additional years, as well as the increase of the commitment amount by EUR 25 million. Under the terms of the initial agreement entered into in April 2020, LDA Capital has committed an amount of up to EUR 50 million (the "Capital Commitment") in cash within a maximum of three years in exchange for new ordinary shares in Mithra. This Capital Commitment can be released based on drawdowns by Mithra in the form of put options that Mithra has the right to exercise at its sole discretion.
- On 24th June 2022, the Company has announced completing a private placement for an aggregate amount of EUR 23.5 million leading to the issuance of 3,871,491 new shares.
- On 30th June 2022, the Company announced that it had issued 625,000 new shares today for a total amount of EUR 4,133,933 following the Put Option Notice issued on 13 May 2022 in the framework of LDA capital commitment agreement entered into April 2020 and extended in April 2022.

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);
- 390,717 subscription rights issued on November 20, 2020, giving the right to subscribe to a total number of 390,717 securities carrying voting rights (see press release dated 20/11/2020).

Since the end of the reporting period, the Company announced on the 8th August that it has entered into a senior secured convertible facilities agreement with funds managed by Highbridge Capital Management LLC and fund managed by Whitebox Advisers LLC for a three years term in an amount of up to EUR 100 million to be drawn in three tranches, with a maximum amount outstanding at any time not greater than EUR 65 million or, depending on the satisfaction of certain conditions, EUR 75 million. The first tranche shall be for a maximum amount of EUR 50 million and drawn at the time of execution, and the second and third tranches shall each be for an amount of up to EUR 25 million. The loans will carry interest of in principle 7.50% per annum.

Following the first drawdown, six conversion notices were sent by Highbridge Capital Management LLC and Whitebox Advisers LLC:

- On 10 August 2022, a first portion of the commitment fee due by the Company was settled in new shares and a first portion of the loans were contributed in kind by the lenders against the issuance of new shares. Following the first drawdown, 238,337 new shares were issued at an issue price of ca. EUR 7.9401 per share, representing 65% of the commitment fees due by the Company. Furthermore, following the drawdown, a portion of the loans (including accrued interest, as relevant, and an option payment amount) was contributed in kind for an aggregate amount of EUR 6,316,288.08 through the issuance of 806,076 new shares at an issue price of ca. EUR 7.84 per share, and an aggregate amount of EUR 1,263,418.02 through the issuance of 155,248 new shares at an issue price of ca. EUR 8.14 per share. Following these contributions in kind, the outstanding principal amount of the loans already drawn is EUR 43,400,000.00;
- On 17 August 2022, another portion of the loans (including accrued interest, as relevant, and an option payment amount) was contributed in kind for an aggregate amount of EUR 402,149.77 through the issuance of 61,913 new shares at an issue price of ca. EUR 6.50 per share;
- On 22 August 2022, other portions of the loans (including accrued interest, as relevant, and an option payment amount) were contributed in kind for an aggregate amount of EUR 4,829,523.30 through the issuance of 799,861 new shares at an issue price of respectively (i) EUR 6.03 per share for the 733,662 shares issued to the profit of Highbridge and (ii) EUR 6.08 per share for the 66,199 shares issued to the profit of Whitebox;
- On 29 August 2022, another portion of the loans (including accrued interest, as relevant, and an option payment amount) was contributed in kind for an aggregate amount of EUR 638,642.12 through the issuance of 103,128 new shares at an issue price of ca. EUR 6.19 per share;
- On 5 September 2022, another portion of the loans (including accrued interest, as relevant, and an option payment amount) was contributed in kind for an aggregate amount of EUR 748,840.19 through the issuance of 118,704 new shares at an issue price of ca. EUR 6.31 per share;

- On 14 September 2022, another portion of the loans (including accrued interest, as relevant, and an option payment amount) was contributed in kind for an aggregate amount of EUR 641,438.27 through the issuance of 97,670 new shares at an issue price of ca. EUR 6.57 per share.

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 2022 are:

Shareholder	Address	Number of voting rights	% of voting rights ^d
François Fornieri ¹		10,993,960	21.73 %
NOSHAQ SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,488,257	10.85 %
Marc Coucke ²		4,474,219	8.85 %
Glenernie Capital Ltd	Smithson Plaza, 13th Floor, 25 St. James's Street, London SW1A 1HA	2,205,776	4.36 %
Bart Versluys ³		2,028,985	4.01%
Free float		25,390,928	50.20 %

1. François Fornieri, Alychlo NV and Noshq 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.

Since the end of the reporting period, due to conversions which occurred in light of the Highbridge/Whitebox facility, the shareholding participations have changed.

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 ^d
François Fornieri ¹		10,993,960	20.76 %
NOSHAQ SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,488,257	10.36%
Marc Coucke ²		4,474,219	8.45%
Glenernie Capital Ltd	Smithson Plaza, 13th Floor, 25 St. James's Street, London SW1A 1HA	2,205,776	4.16 %
Bart Versluys ³		2,028,985	3.83 %
Free float		27,771,865	52.44%

1. François Fornieri, Alychlo NV and Noshq 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 June 2022, Mr. François Fornieri resigned from his non-executive director mandate of the Company. Following the resignation with immediate effect of Mr. Fornieri, Mithra's Board of Directors was composed of 9 directors, including 5 women directors and 4 men directors, 5 independent and 4 non-independent directors. These directors were appointed in May 2021 for a two-year term.

Post period, on 6 July 2022, the Company announced a change in its Board of Directors' Chairmanship. Following the resignation with immediate effect of Sunathim BV (represented by Mr. Ajit Shetty) for personal reasons non-related to the Company, the Board of Directors approved, on the proposal of the outgoing Chairman and the recommendation of the Nomination and Remuneration Committee, the appointment of Selva Luxembourg Sàrl (represented by Mr. Christian Moretti) as Chairman, as well as that of TicaConsult BVBA (represented by Mr. Erik Van Den Eynden) as Vice-Chairman. These functions will be exercised until the next Company's Shareholders Meeting.

Therefore, the new Board of Directors counts 9 Directors: 5 women Directors and 4 men Directors, as well as 4 independent Directors and 5 non-independent Directors.

Until the General Meeting to be held in 2023, the composition of the Board is as follows:

<i>Name</i>	<i>Position</i>	<i>Term¹</i>	<i>Nature of Mandate</i>	<i>Board of Directors Committee Membership</i>
Selva Luxembourg Sàrl (permanent representative : Mr Christian Moretti)	Director Chairman	2023	Non-Executive	Nomination and Remuneration Committee
TicaConsult BV (permanent representative: Mr. Erik Van Den Eynden)	Director (Vice- Chairman)	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	Independent	Nomination and Remuneration Committee (Chair)
Alius Modi SRL (permanent representative: Mrs. Valérie Gordenne)	Director	2023	Non-Executive	Risk and Audit Committee

Additionally, AHOK BVBA (permanent representative: Mr. Koen Hoffman) holds an observer position.

The members of the Executive Committee as of 30 June 2022 are listed in the table below:

<i>Name/ Designation</i>	<i>Function</i>
Van Rompay Management BV (permanent representative: Mr. Leon Van Rompay)	Chief Executive Officer (Chair)
Eva consulting SRL (permanent representative: Pr. J.M Foidart)	Chair of the Scientific Advisory Board
CMM&C SRL (permanent representative: Mr. Christophe Maréchal)	Chief Financial Officer (CFO)
Novafontis SRL (permanent representative: Mr. Jean-Manuel Fontaine)	Chief Commercial and External Affairs Officer (CBO)
GD Lifescience SRL (permanent representative: Mr. Graham Dixon)	Chief Scientific Officer (CSO)
BGL Consulting SRL (permanent representative: Mr. Benjamin Brands)	Chief Supply Chain Officer (CSCO)
MAREBA BVBA (permanent representative: Mr. Renaat Baes)	CDMO Site Director
Mr. Benoit Mathieu	Group Investor Relations Manager (IRO)
Mr. Cédric Darcis	Chief Legal Officer (CLO)
Acta Group SA (permanent representative: Mrs. Laurence Schyns)	Chief Human Resources Officer (CHRO)
Mrs. Maud Vanderthommen	Group Communication Manager
Mr. Frédéric Constant	Group Quality Manager
T Mundi BV (permanent representative: Mr. Stijn Vlamincx)	Group IT Manager

5. Principal risks and uncertainties

The Board of Directors considers that in light of the current global biotech situation, an update on the main risk factors is useful and necessary.

The Group's exposure to price risk, credit risk, liquidity risk and cash flow risk are detailed in note 9.3 of the 2021 Annual Report (Financial Risk Management).

The Group has a business structure; built on:

- ① a development portfolio which includes the development of Estetrol-based product candidates in contraception and menopause indications as well as other potential indications such as wound healing, NHIE, and Complex Therapeutics;

- (ii) the CDMO development and manufacturing facility, and
- (iii) a commercialized portfolio of our Estetrol-based product Estelle® in the field of oral contraception in several regions (Canada, US, Europe, United-Kingdom, Iceland, Norway, Australia, Latam), 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 2022, most focus is on the development portfolio and products' commercial launch.

- **Risks relating to the Estetrol pipeline**

Other than Estelle®, no estetrol-based product candidates have been formally registered or commercialized and the successful development of Mithra's other estetrol-based product candidates remains uncertain due to the complexity and unpredictability of clinical trials.

Other than Estelle®, which has been approved to date in various countries worldwide, mainly in North America and Europe, Mithra's estetrol-based product candidates have not been approved or commercialized. Notwithstanding the approval of Estelle® in these jurisdictions, all of Mithra's estetrol-based product candidates will be subject to extensive pre-clinical and clinical trials to demonstrate safety and efficacy in humans before Mithra can apply for the necessary regulatory approval potentially to obtain marketing authorizations from the relevant regulatory authorities. In particular, Mithra's Donesta® Phase 3 Clinical Program is ongoing, with topline efficacy results having been reported in January and in April 2022 and primary safety data anticipated by the end of 2022 for the C302 trial (North America) and the end of the second half of 2023 for the C301 trial (EU, Russia, Latin America, United States and Canada).

Prior to initiating a clinical trial, Mithra requires regulatory and ethical approval from the competent authority in each relevant country. Mithra and the relevant regulatory authorities may not agree on a clinical trial design or, if a clinical trial design is accepted, one or more clinical trial endpoints may not be achieved, and that may undermine support for regulatory approval. Clinical trials remain subject to ongoing review and monitoring throughout their duration, and with certain exceptions, changes made to the trial protocols after approval is received must also be approved prior to implementation. Failure to obtain or maintain the approvals required to conduct a clinical trial for Donesta® or any other estetrol-based products could significantly delay or prevent the completion of such trials, necessitate additional testing or a re-design of the clinical trial, incur significant additional time and costs and/or prevent Mithra from achieving or maintaining profitability.

Regulators may also require Mithra to amend ongoing trials or perform additional trials, which could result in significant delays and additional costs or may be unsuccessful.

Furthermore, clinical trials may not produce the anticipated clinical efficacy outcomes or may uncover previously unknown safety issues or risks. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. Further trials may uncover issues not yet discovered by previous pre-clinical or clinical testing, which could lead to delays or suspension of the clinical trials.

Mithra cannot predict with certainty how long it will take to complete necessary clinical trials or obtain regulatory approvals of its current or future products. The time needed to complete clinical trials and obtain regulatory approvals varies by product, indication, and country.

If Mithra's clinical trials are delayed, or if they do not produce the anticipated clinical efficacy outcomes, this could prevent it from achieving the commercialization of Donesta® or any of its other estetrol-based products in the expected timeframe, which would in turn delay the timing of expected revenues from these products or prevent Mithra from ever earning revenues from these products.

Even if Mithra obtains marketing authorizations for Donesta® or any other estetrol-based products, future clinical trials may uncover previously unknown safety issues or risks or suggest that these products do not significantly improve clinical outcomes. Such results would slow or possibly stop the adoption of these products, or potentially lead to market authorization suspension or withdrawal by regulatory authorities.

Further trials designed to support additional indications for an authorized product may not achieve targeted clinical outcomes. This would jeopardize anticipated further/wider adoption of the product.

If Mithra experiences delays or difficulties in the recruitment of Investigators, obtaining necessary approvals from trial sites or the enrolment of subjects in clinical trials, or trial sites failure to adhere to trial protocols and good clinical practices (GCP) regulations or similar regulations its receipt of necessary regulatory approvals could be delayed or prevented.

Performing clinical trials requires the engagement of many hospitals, clinics, and clinicians. In particular, Mithra must engage a physician at each clinical trial centre to maintain overall responsibility for conduct of the clinical trial. Each Investigator may have additional physicians working under his or her direction to conduct a trial. Furthermore, Mithra is required to obtain necessary approvals from the trial sites where it conducts its clinical trials, including approvals from institutional review boards ("IRBs")/ethics committees ("ECs") and local competent agencies ("CAs"), which are required for clinical trials such as the trials related to Donesta[®].

Mithra may not be able to attract sufficient qualified Investigators to conduct clinical trials within an adequate timeframe, and those investigators may not be able to attract or enrol sufficient subjects to meet Mithra's clinical trial objectives. Any difficulties in enrolling a sufficient number of subjects, failure to conduct the clinical trial in accordance with regulatory requirements or the approved trial protocols or difficulty obtaining approvals from trial sites for any of its clinical trials could result in significant delays or suspension of the trial and could require Mithra to abandon one or more clinical trials altogether. Any such delays may result in increased development costs that may exceed the resources available to Mithra and in delays to commercially launching Donesta[®] and/or any future products in target markets, if approved.

The triggering of certain milestone payments and "royalty payments" may be discontinued at any time based on a review of available pre-clinical and clinical data, the estimated costs of continued development, market considerations and other factors.

Mithra has entered into a number of contracts through which it "out-licenses" to customers the intellectual property it has developed related to drugs that have not yet received regulatory approval. Generally, under the terms of these licenses, the licensee can further develop the intellectual property and can manufacture and/or sell the resulting commercialised product. Mithra typically receives an upfront fee, milestone payments for specific clinical or other development-based outcomes, and sales-based milestones or royalties as consideration for the relevant license. Some arrangements also include ongoing involvement by Mithra, which may provide research and development and/or manufacturing services relating to the licensed intellectual property.

During 2021, Mithra collected cash in relation to two major Estelle[®] out-licensing milestones with Mayne Pharma, in the amount of USD 11 million, and Gedeon Richter, in the amount of EUR 15 million, although the revenue was already recognised in 2019 in accordance with IFRS 15. During the year, Mithra also received 85.8 million ordinary shares of Mayne Pharma, resulting in the Company becoming the largest shareholder of Mayne Pharma, an Australia-listed company on ASX. Approximately EUR 288 million in cash remains to be collected for Estelle[®] out-licensing and sales related milestones as at 30 June 2022.

Under the U.S. License and Supply contract signed with Mayne Pharma and well as Mithra's other licensing arrangements, milestone payments can be suspended based on a review of available pre-clinical and clinical data, the estimated costs of continued development, market considerations and other factors. For that reason, if the commercialisation of Estelle[®] does not proceed as anticipated by Mithra, it may not receive the EUR 288 million that remains to be collected under the contract in the timeframe it expects or at all. The achievement of the commercial milestones under the contract will depend on the performance of Mithra's commercial partners in their respective markets, which are described under " — Risks relating to commercialisation". In addition, Mithra is subject to foreign exchange risk in relation to the U.S. License and Supply contract due to the payments thereunder being payable in U.S. Dollars, as well as the Australian listing of Mayne Pharma. See " — Risks relating to Mithra's financial situation — Changes in currency exchange rates could have a material negative impact on the profitability of Mithra".

Mithra is subject to similar risks in relation to its future product candidates, including Donesta[®], with respect to which it is considering entering into a licensing agreement to fund its future clinical development.

Mithra depends on third party suppliers for manufacturing, pharmaceutical ingredients and other raw materials and any disruption of the supply chain or unavailability of third-party services could have a material adverse effect on

Mithra. Currently Mithra relies on a key E4 tolling supplier and it has signed binding heads of terms in order to secure alternative options for the transformation of estetrol in the future. If current negotiations do not result in commercially favourable terms for Mithra, this could impact its cost of goods and thus the profitability of Estelle[®]. Moreover, if the difficult market conditions arising from the outbreak of COVID-19 and the conflict in Ukraine persist and impact its supply prices or if this results in a shortage of raw materials, Mithra might not be able to comply with its supply commitments regarding its partners. See “ – Risks relating to the Mithra’s dependence on third parties and on key personnel”.

If Mithra is unable to enter into a partnership or strategic alliance for the further development and commercialization of Donesta[®] or its other product candidates, it may incur additional costs, and/or the development of these products might be delayed.

Mithra does not have a commercial organisation in place to launch its product candidates on its own. Before the commercialisation of Estelle[®], Mithra had never marketed a product outside of the Benelux region and it therefore has limited experience in sales, marketing and distribution in other markets. Mithra does currently not intend to deploy itself as a sales and distribution organisation anywhere in the world and will rely for the distribution of its products on license and supply deals with commercial partners.

Moreover, Mithra plans to enter into a strategic alliance or commercial partnership for the further development and commercialisation of Donesta[®] as well as its future product candidates. Such arrangements may require Mithra to incur additional expenses, increase its capital expenditures, issue securities that dilute its shareholders or disrupt its management and business. In addition, Mithra faces significant competition in seeking appropriate strategic partners and the negotiation process can with such parties be time consuming and complex. Additionally, Mithra may not be successful in its efforts to establish a partnership or other strategic alliance for Donesta[®] or its other future product candidates because these products may be deemed to be at too early development stage for collaborative effort and third parties may hence not view them as having the requisite potential. Furthermore, Mithra cannot be certain that, following any strategic alliance or commercial partnership, it will achieve the level of revenues that would justify such an agreement. Any delays in entering into new strategic partnership agreements related to Donesta[®] and/or future product candidates could also delay their development and commercialisation and reduce their competitiveness even if they reach the market.

If Mithra is unable to identify a strategic alliance or commercial partnership for a particular product, it would need to complete the clinical and manufacturing development, proceed with the associated regulatory filings on its own and commercialise the product through its own sales force. In that event, Mithra might need to invest significant financial and management resources. Furthermore, its sales force might not be well equipped to market these products, which could adversely affect the revenues Mithra is able to earn from them.

Mithra is currently heavily focused on, and investing in, the development of its estetrol-based product candidates. Its ability to realise substantial product revenues and, eventually, profitability in line with the investments envisaged will significantly depend on its ability to successfully develop, register and commercialise estetrol-based product candidates.

Mithra has, to date, received approvals for Estelle[®] in various countries worldwide, mainly in North America and Europe and the product is being commercialised progressively around the world. Nevertheless, it remains at the early stages of commercialisation. Furthermore, Mithra is still pursuing the development of its other estetrol-based products, such as its development programs in menopause, neuroprotection for the treatment of hypoxic-ischaemic encephalopathy (“HIE”) in neonates and wound healing. Mithra is dedicating the majority of its available cash resources to the development of its product candidates. The development, registration and commercialisation of these products present significant new challenges. In preparation, Mithra has expanded and continues to expand its organisation and has attracted and continues to attract a number of experienced collaborators. However, it may not be able to successfully integrate their experience and know-how, and to continue to further successfully expand its organisation and successfully conclude every development step. Any failure to do so could cause delays in the clinical development and/or the regulatory approval process for these products, which could ultimately delay or even prevent the commercialisation of Mithra’s innovative product candidates.

If Mithra is unsuccessful in developing, commercialising and/or identifying partners with respect to its estetrol-based products, the nature of Mithra’s pipeline would comprise the continued commercialisation of Estelle[®], as well as the development (either directly or indirectly) of complex therapeutics products and injectables. The market opportunities for these products is significantly more limited in scope than the market opportunity offered by Mithra’s

estetrol pipeline. Accordingly, if Mithra is forced to shift its focus to complex therapeutics and injectables and away from estetrol-based products, management expects that Mithra's revenues and profitability would be severely impacted.

- **Risk related to the financial situation**

Should Mithra not have sufficient working capital to meet its present requirements and cover its working capital needs for a period of at least 12 months as at the date of this Report, it will require additional funds beyond this period in order to meet its operating and capital expenditure needs.

On 23 April 2020, the Company, LDA Capital (as defined below), LDA Capital, LLC, and the Share Lending Shareholders (as defined below) entered into the LDA Put Option Agreement (as defined below), pursuant to which (as amended), LDA Capital agreed to commit a maximum amount of EUR 75,000,000.00 in cash within a maximum of five years in exchange for new ordinary Shares in the Company. This amount is to be released, based on drawdowns by the Company in the form of put options which the Company has the right to exercise at its sole discretion (via so-called "put option notices"). At the date of this Report, four put options have been exercised and settled (two of which were settled in 2022), for a total amount of EUR 21,027,121.00, the remaining amount committed by LDA Capital under the LDA Put Option Agreement to be (potentially) invested in the Company by LDA Capital being EUR 53,972,879.00. It is, however, noted that, in accordance with the undertakings given by the Company under the GSI Financing Agreement (as defined below), the Company does not in principle intend to send any new put option notice until the expiration of the GSI Financing Agreement, save exceptions and with prior approval of GSI (as defined below).

On 4 February 2022, the Company and GSI entered into the GSI Financing Agreement pursuant to which the Company may require GSI (subject to certain conditions) to provide financing to the Company in an aggregate amount of up to EUR 100,000,000.00, by way of several drawings and against issuance of new Shares. At the date of the Report, two drawdowns have been made and settled for a total amount of EUR 15,000,000.06, the remaining amount committed by GSI under the GSI Financing Agreement to be (potentially) converted into shares, being EUR 84,999,999.94. It is, however, noted that one of the conditions for the Company to be able to make a drawdown under the GSI Financing Agreement is that the lowest daily volume weighted average trading price of the Company's shares during the 10 trading days preceding the date of the Company's drawdown request must not be less than EUR 10.00 per share.

On 24 June 2022, Mithra announced that it had successfully raised an amount of EUR 23.5 million in gross proceeds by means of a private placement of 3,871,491 new Shares at an issue price of EUR 6.07 per share.

On 8 August 2022, the Company and the Lenders (as defined below) entered into the Facilities Agreement (as defined below), pursuant to which, the Lenders agreed to provide, for a period of three years from the date of the Facilities Agreement, a financing by loans convertible into Shares to the Company for a maximum aggregate principal amount of EUR 100,000,000.00, to be drawn in several tranches (subject to the fulfilment of certain conditions), with an outstanding amount at any time not greater than EUR 65,000,000.00 or, subject to the satisfaction of certain conditions, EUR 75,000,000.00, the loans bearing interest in principle at a rate of 7.5% per annum. At the date of this Report, the Company already drawn down the first tranche in the amount of EUR 50,000,000.00. Part of the proceeds of the loan has been used to repurchase outstanding convertible bonds of the Company held by the Lenders for a principal amount of EUR 34.1 million at a discount.

Notwithstanding the above, taking into account its available cash and cash equivalents, Mithra could not have sufficient working capital to meet its present requirements and cover the working capital needs for a period of at least 12 months as of the date of this Report.

Furthermore, over the longer term, should Mithra not be able to enter into one or multiple Donesta[®] license and supply agreement(s) as described above, Mithra's existing capital resources would be insufficient to fund, among other things, the completion of the clinical development of Donesta[®] required to bring it to market in Europe and the United States, as well as its other research and development and general and administrative expenses.

Equity and/or debt financing might not be available when needed or, if available, might not be available on commercially favourable terms, particularly if the difficult market conditions arising from the outbreak of COVID-19 and the conflict in Ukraine persist. If the necessary funds are not available, Mithra may seek funds through collaboration and licensing arrangements, at an earlier stage than originally planned, at terms that are less favourable than those it might otherwise have obtained or at terms which may require it to reduce or relinquish significant rights to its programmes.

Mithra has incurred net losses

Mithra has incurred net losses and negative operating cash flows in each period since 2020. As of 30 June 2022, Mithra has a loss brought forward of EUR 367.9 million. These losses have resulted principally from costs incurred in research and development and general administrative costs. Mithra intends to continue its clinical trial programme for its candidate products (including in particular Donesta[®]), conduct pre-clinical trials in support of clinical development and regulatory compliance activities, which, together with anticipated general and administrative expenses, will result in Mithra incurring further significant expenses for the next several years.

On the other hand, the revenues associated with Mithra's current clinical development activities are not expected to materialise for a significant period of time. Mithra launched its Estelle[®] product during 2021 and launched its Myring[®] product since 2019, with launch in the United States expected in the beginning of 2023. However, other than license revenue, it does not expect to recognise revenue from its Donesta[®] product until 2024. Mithra's revenues from Estelle[®] and Myring[®], which were EUR 13.9 million and EUR 2.5 million in 2021 and EUR 7.7 million and EUR 1.4 million in the six months ended 30 June 2022, respectively, have not been sufficient to compensate for its research and development and general and administrative expenses, which were EUR 85.2 million and EUR 12.5 million in 2021 and EUR 27.5 million and EUR 7.0 million in the six months ended 30 June 2022, respectively, resulting in a loss from operations of EUR 87.9 million and EUR 27.5 million for the year ended 31 December 2021 and the six months ended 30 June 2022, respectively. For that reason, Mithra might continue to incur further losses for the next few years. If the revenues associated with the launch of its future products do not materialise at the level expected by management, Mithra's ability to sustain its operations may be impaired.

- **Risks relating to commercialization**

Mithra's future financial performance will depend on the commercial acceptance of Estelle[®], Donesta[®] and its other products in target markets.

At the date of this report, Estelle[®] is the only estetrol-based product that has been commercialised by Mithra.

Furthermore, Estelle[®] only received regulatory approval from the FDA relatively recently, in 2021. Estelle[®] has been approved in various countries worldwide, mainly in North America and Europe as of the date of this Report and will be rolled out commercially in other countries in the coming years. Estelle[®] and other products launched by Mithra may not gain commercial acceptance in target markets. If Mithra fails to gain and maintain commercial market acceptance of these products in its target jurisdictions, the amount of revenue generated from sales of Estelle[®] and other products in the future could fail to grow as management expects and could even decrease. In addition, Donesta[®] has not yet received marketing approval in any jurisdictions and Mithra's future financial performance will depend on the successful completion of its planned clinical trials on Donesta[®] and its ability to secure strategic partnerships and alliances.

Many factors can influence market acceptance of Mithra's products, including:

- approval from the appropriate regulatory authorities or unavailability of Mithra's products due to regulatory barriers;
- price and reimbursement levels from third party payers;
- successful completion of the clinical development of Donesta[®] and Mithra's other products;
- FDA and other target market regulatory authority approval of Donesta[®] and Mithra's other products;
- macroeconomic conditions in the countries in which Mithra's products are marketed and sold, including the impact of the COVID-19 outbreak or any similar infectious disease outbreak;
- the timing of the launch of Mithra's products in a particular market;
- inclusion in clinical practice guidelines;
- the availability of clinical evidence through trials and registries, including the Donesta[®] Phase 3 clinical trial;
- accurate anticipation of patients', healthcare providers' and payers' needs and emerging technology trends;
- frequency and/or severity of complications or side effects arising from Mithra's products;
- competition, the convenience and ease of use of Mithra's products compared to competing products and other potential advantages and disadvantages over alternative products and services;
- production barriers such as interruptions to the supply of materials or components or Mithra's manufacturing activities being suspended by regulatory authorities;

- the quality of service that Mithra establishes in order to support customers;
- the ability to demonstrate to physicians and other potential stakeholders the benefits and cost-effectiveness of Mithra's products relative to other products available on the market;
- the ability of Mithra to maintain relationships with key opinion leaders in the medical community;
- entrance into additional markets or indications and the scope of the indications approved by regulatory authorities;
- tariffs, trade barriers and other trade protection measures, import or export licensing requirements and any other restrictive actions by the U.S. or other governments;
- the ability of Mithra to hire new sales and marketing personnel and their effectiveness in developing brand equity, monitoring commercial performance and executing its business strategy; and
- the ability of Mithra to secure development and commercial partnerships for the marketing of Donesta[®] and its other products.

These and other factors present obstacles to commercial market acceptance of Mithra's products in target markets. Moreover, once these products gain commercial acceptance, there is a risk that they will subsequently become obsolete, due to the rapid development of technology in the sphere in which Mithra operates and changes to the operations of its suppliers. Failure, or any substantial delay, in gaining significant commercial market acceptance of Mithra's products in target markets, on a timely basis or at all, or the obsolescence of any of these products could limit the revenues Mithra is able to earn from sales of its products.

Mithra's success depends in part on third party payment from government providers, healthcare insurance providers or other public or private sources and it could fail to achieve or maintain reimbursement levels in line with its expectations.

The existence of coverage and adequate reimbursement for Mithra's products by government and/or private payers will be important to market adoption for its products. If Mithra's products do not receive adequate reimbursement, potential users of its products may be unwilling to pay for these products themselves.

In many countries, payment for Mithra's products will be dependent on obtaining a "reimbursement code" for the product. For details of the reimbursement arrangements in the countries in which Mithra has commercialised or plans to commercialise its products, refer to "*Business – Government Regulation – Reimbursement*". Obtaining a reimbursement code can be a lengthy process (months to years) and Mithra may not be able to obtain such a code at satisfactory levels, or at all. Following the grant of a "reimbursement code" payers (e.g. national healthcare systems or health insurance companies) have to agree to provide coverage for the relevant product. Failure to obtain attractive reimbursement may adversely affect Mithra's business, financial condition, results of operations and prospects.

The price that Mithra may receive for, and the marketability of, the products for which Mithra has received or will receive regulatory approval may suffer if government and/or third-party payers fail to provide adequate coverage and reimbursement or if further governmental cost containment or other health reform initiatives are adopted or implemented. From time to time, legislation is enacted that could significantly change the statutory provisions governing the clearance or approval, manufacture, marketing or taxation of Mithra's products. In addition, regulations and guidance are often revised or reinterpreted in ways that may significantly affect Mithra's products. It is impossible to predict whether legislation changes will be enacted, or regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be. Mithra cannot predict what healthcare programmes and regulations will be ultimately implemented at the U.S. federal or state level, or at the E.U. level, or within the implementing legislation of the individual E.U. Member States, or the effect of any future legislation or regulation. However, these types of provisions, as adopted, could materially change the way healthcare is delivered and financed, and may materially impact numerous aspects of Mithra's business. Increasing downward pressure on healthcare pricing and/or any changes that lower reimbursements for Mithra's products could result in product revenues generated from sales of Mithra's products being lower than anticipated. As a result, Mithra could fail to achieve or maintain reimbursement levels sufficient to support a commercial infrastructure or realise an appropriate return on its investment in product development, which could materially and adversely affect Mithra's business, financial condition, results of operations and prospects.

Mithra may also experience pricing pressures in connection with the sale of its products. Generally, governments and third-party payers are increasingly exerting downward pressure on pricing and reviewing the cost-effectiveness of medical products, therapies and services. With this global pressure on healthcare costs, payers are attempting to contain costs by, for example, limiting coverage of and the level of reimbursement for new therapies.

If Mithra is unable to obtain or maintain reimbursement for its products in its key markets, this would compromise its ability to commercialise these products on a large scale, which would in turn limit its opportunities to achieve profitability.

The success of Estelle® and Mithra's other products depends on their acceptance and adoption by physicians and all stakeholders involved in market access to its products.

The success of Estelle® and Mithra's other products will require acceptance and adoption by physicians and other stakeholders (healthcare professionals, payers, etc.). Such acceptance will depend on physicians being convinced of the distinctive characteristics, clinical performance, benefits, safety and cost-effectiveness of Estelle® and Mithra's other products. Furthermore, physicians will most likely not adopt Estelle® or Mithra's other products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that these products are an attractive solution for patients.

Even if the safety and efficacy of Mithra's products is established, physicians and other healthcare personnel, may be hesitant to change their medical treatment practices or accept and adopt Mithra's products, including for the following reasons:

- general conservatism about the adoption of new treatment practices;
- history of adverse events;
- lack or perceived lack of long-term evidence supporting additional patient benefits;
- perceived liability risks associated with the use of new products;
- limited or lack of reimbursement and coverage within healthcare payment systems;
- other products competing for physician time and attention;
- the time commitment that may be required for special training;
- insufficient level of commercial attractiveness to physicians;
- the extent of ongoing support required by the clinician; and
- the extent of ongoing involvement of the patient in therapy.

Economic, psychological, ethical and other concerns may also limit general acceptance and adoption of Mithra's products. Lack of acceptance and adoption of Mithra's products by a sufficient number of relevant physicians and other healthcare professionals would substantially reduce Mithra's ability to achieve its sales forecasts and prevent Mithra from achieving or maintaining profitability.

If Mithra's commercial partners are unable to expand their sales, marketing and distribution capabilities for Mithra, Mithra may not be successful in commercialising its products in its targeted markets. Moreover, Mithra will need to invest internally for every product about to be commercialised and from commercialisation onwards in its life cycle management and overall brand equity.

Mithra will need to expand its internal sales and marketing organisation to commercialise its products in markets that it will target directly. There are risks involved with expanding Mithra's own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay launch. In addition, Mithra may experience challenges in recruiting qualified sales and marketing personnel.

Furthermore, Mithra intends to enter into additional licensing agreements to distribute its products in other markets. If Mithra is unable to find suitable partners, loses these partners or if Mithra's partners fail to sell its products in sufficient quantities, on commercially viable terms or in a timely manner, the commercialisation of Mithra's products could be materially harmed, which could prevent Mithra from achieving or maintaining profitability.

Further factors that may inhibit Mithra's efforts to commercialise its products in target markets include the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any of Mithra's future products, and the lack of complementary products to be offered by sales personnel, which may put Mithra at a competitive disadvantage relative to companies with more products.

If Mithra is unable to expand its own sales, marketing and distribution capabilities or enter into arrangements with other third parties to perform these services, Mithra's revenue and profitability may be negatively affected.

- **Risks related to the cost of producing E4**

Mithra is subject to the risk of increasing raw material prices, particularly in relation to solvents used in the synthesis of estetrol.

Prices of certain common raw materials, such as solvents (e.g. THF and DCM) used in the synthesis of estetrol, have been increasing significantly since 2021 in the European Union due to lower availability of their feedstocks. Since it remains unclear when feedstocks will become more readily available, Mithra may continue to experience pricing pressure for these solvents. In addition, palladium is used as a catalyst in the production of estetrol. Palladium prices have doubled over the last several years, with a sharp surge in March 2022. As Russia is a dominant player in the global production of palladium, the war in Ukraine could continue to have a negative effect on the availability of palladium in the global market. Since June and July of 2022, prices have come down to the same level as that which prevailed at the end of 2021 and early 2022 but have remained volatile, leading to significant financial risk for Mithra. Mithra is working on mitigation plan in order to reduce the amounts of these raw materials used in the synthesis of estetrol in order to optimise its manufacturing costs.

Mithra mitigates the risk that raw materials prices could increase to high levels, such as that it experienced in March 2022 for palladium, through mid- and long-term contracts with suppliers, including, among others, setting maximum prices in the renegotiation of contracts. Moreover, Mithra considers new synthesis pathways and internally monitors raw material prices on a continuous basis.

As the world is evolving, the use of raw materials is heavier than in the past, which could lead to a risk of disappearance of raw materials, in particular due to natural disasters which can have an impact on the production of certain raw materials. Furthermore, inflation may generally affect the cost of raw materials in Mithra's supply chain. Inflation has been rampant during the past year due in part to government spending deployed to abate the consequences of the COVID-19 pandemic during 2020 and 2021, as well as to rising energy prices due to the conflict in Ukraine. If Mithra is unable to address the risk of inflation across its supply chain through contractual arrangements, its profitability may be adversely affected

- **Risks relating to the Mithra's dependence on third parties and on key personnel**

Mithra depends on third party suppliers for manufacturing, pharmaceutical ingredients and other raw materials and any disruption of the supply chain or unavailability of third-party services could have a material adverse effect on Mithra.

Mithra relies on third parties across its operations, including in relation to manufacturing, pharmaceutical ingredients and other raw materials. In relation to its CDMO, it has entered into several partnerships, namely in the injectables industry. In addition, it has entered into partnerships for the sourcing of raw materials, including essential active pharmaceutical ingredients such as estetrol. Therefore, Mithra's ability to meet its production targets depends on its sourcing arrangements and its partners' compliance with their own obligations. Mithra was informed by its estetrol sourcing partner that it would have difficulties delivering the contractually defined quantities for the year 2021/2022. In order to mitigate these potential delivery delays, Mithra currently relies on a key estetrol tolling supplier and has signed binding heads of terms in order to secure alternative options for the transformation of estetrol in the future. However, Mithra may not be able to secure such alternative supply.

In addition, third party suppliers may be subject to circumstances which impact their ability to supply, including enforcement action by regulatory authorities, natural disasters (e.g. hurricanes, earthquakes, disease and terrorism), epidemics (e.g. the ongoing COVID-19 outbreak), industrial action (e.g. strikes), financial difficulties including insolvency, among a variety of other internal or external factors. Any such supply disruptions could in turn result in production disruptions for an extended period of time, which could delay production and/or commercialisation of its products and prevent Mithra from achieving or maintaining profitability. Alternative suppliers may be unavailable, may be unwilling to supply and may not have the necessary regulatory approvals.

Any disruptions in manufacturing or in the supply of pharmaceutical ingredients and other raw materials could result in production delays and could compromise Mithra's ability to meet its obligations to its customers and/or strategic partners, which could in turn adversely affect its revenues and cash flows as well as its reputation.

Mithra relies on third parties to conduct its clinical trials, perform data collection and analysis, and provide regulatory advice and other services that are crucial to its business.

Mithra relies, and will rely in the future, on medical institutions, Investigators, contract research organisations ("CROs"), contract laboratories and collaborators to perform data collection and analysis and to carry out Mithra's clinical trials. Mithra's development activities or clinical trials conducted in reliance on third parties may be compromised if the third parties do not devote a sufficient amount of time or effort to Mithra's activities or otherwise fail to successfully carry out their contractual duties or to meet regulatory obligations or expected deadlines. Furthermore, if the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons including the loss of data, this could adversely affect clinical results or require Mithra to repeat the affected trial. In addition, Mithra's third-party

agreements usually contain a clause limiting such third party's liability, such that Mithra may not be able to obtain full compensation for any losses that Mithra may incur in connection with the third party's performance failures.

If the third parties upon which Mithra depends do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, or in the event of a default, bankruptcy or shutdown of, or a dispute with, a third party, Mithra would be required to find a replacement third party or acquire a CRO, to conduct the required activities. Mithra may be unable to enter into a new agreement with another third party on commercially acceptable terms. While Mithra believes that there are alternative sources to provide these services, in the event that Mithra seeks such alternative sources, Mithra may not be able to enter into replacement arrangements without incurring delays or additional costs.

If the third parties upon whom Mithra depends fail to perform to the required standard or if Mithra is required to replace such third parties, this could result in delays in the regulatory approval for Donesta[®] and its other products.

- **Risks relating to intellectual property**

Any inability to fully protect and exploit Mithra's intellectual property may adversely impact Mithra's financial performance and prospects.

Mithra directly holds various families of patents for the Estelle[®] E4/DRSP pill and the menopause product candidate, Donesta[®]. Extensions (from three to five years) of the indication patent end date have been requested (and some have already been granted) for the United States, Canada and some European countries based on the initial marketing authorization for E4/DRSP in those territories. For the Donesta[®] product candidate, several 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. Mithra also holds six families protecting different synthesis pathways for E4, whose main patents expire in 2032. Mithra will also seek to protect market exclusivity once marketing authorisation is granted (where applicable) through market/data exclusivity systems (between three and ten years maximum depending on the territory).

In addition to patents, Mithra relies on a combination of trade secrets, design rights, copyright laws, non-disclosure agreements and other contractual provisions and technical measures that help maintain and develop its competitive position with respect to intellectual property. Mithra may be unable to obtain the patents it applies for or to adequately protect its intellectual property rights or may become subject to a claim of infringement or misappropriation, which it is unable to settle on commercially acceptable terms. Mithra cannot be certain that patents will be issued with respect to Mithra's pending or future patent applications. In addition, Mithra does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or that they will prevent the development of competitive patents or provide meaningful protection against competitors or against competitive technologies.

Mithra's intellectual property rights may also be challenged, invalidated, circumvented or rendered unenforceable. Mithra's competitors or other third parties may successfully challenge and invalidate or render unenforceable Mithra's issued patents, including any patents that may be issued in the future. This could prevent or limit Mithra's ability to stop competitors from marketing products that are identical or substantially equivalent to Estelle[®], Donesta[®] and/or its other products. In addition, competitors may be able to design around Mithra's patents or develop products that provide outcomes that are comparable to Estelle[®], Donesta[®] and/or its other products but that are not covered by its patents. Much of Mithra's value is in its intellectual property, and any challenge to Mithra's intellectual property portfolio (whether successful or not) may impact its value.

Mithra decides on a case-by-case basis the countries in which to seek patent protection. It is not economically feasible or practical to seek patent protection in every country, and it is possible that one or more third parties may develop and market products similar or identical to Estelle[®], Donesta[®] and/or its other products in countries where Mithra has not obtained patent protection. Mithra may not be able to prevent such third-party action, which may limit Mithra's ability to pursue those markets.

Mithra could become subject to intellectual property litigation that could be costly, result in the diversion of management's time and efforts, require Mithra to pay damages, prevent Mithra from marketing Estelle[®], Donesta[®] and/or its other products, and/or reduce the margins for these products.

The pharmaceuticals industry is characterised by rapidly changing products and technologies and there is intense competition to establish intellectual property and proprietary rights covering the use of these new products and the related technologies. This vigorous pursuit of intellectual property and proprietary rights has resulted and will continue to result in extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, and the outcome of such disputes is often uncertain. There may be existing patents of which Mithra is unaware that are inadvertently infringed

by Estelle[®], Donesta[®] and/or its other products. Competitors may have or develop patents and other intellectual property that they assert are infringed by Estelle[®], Donesta[®] and/or its other products.

Any infringement claim against Mithra, even if without merit, may cause Mithra to incur substantial costs, and could place a significant strain on Mithra's financial resources and/or divert the time and efforts of management from the conduct of Mithra's business. In addition, any intellectual property litigation could force Mithra to do one or more of the following: (i) stop selling Estelle[®], Donesta[®] and/or its other products or using technology that contains the allegedly infringing intellectual property; (ii) forfeit the opportunity to license Mithra's technology to others or to collect royalty payments based upon successful protection and assertion of its intellectual property rights against others; (iii) pay substantial damages to the party whose intellectual property rights Mithra may be found to be infringing; or (iv) redesign those products that contain or utilise the allegedly infringing intellectual property. Any of these circumstances may materially and adversely affect Mithra's business, financial condition, results of operations and prospects.

The requirement to obtain licenses to third party intellectual property could also arise in the future. If Mithra needs to license any third-party intellectual property, it could be required to pay lump sums or royalties on its products. In addition, if Mithra is required to obtain licenses to third party intellectual property, it may not be able to obtain such licenses on commercially reasonable terms or at all.

Intellectual property rights do not necessarily address all potential threats to Mithra's competitive advantage.

The degree of protection afforded by Mithra's intellectual property rights is uncertain because intellectual property rights are limited and may not adequately protect Mithra's business or permit it to maintain its competitive advantage or its ability to sell its products. For example:

- others may be able to develop, make and sell products that are similar to or different from that deliver similar benefits to Estelle[®], Donesta[®] and/or its other products without infringing claims of the Mithra patents or other Mithra intellectual property rights;
- pending patent applications may not lead to issued patents;
- issued patents may not provide Mithra with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges;
- Mithra's competitors might conduct research and development activities in countries where Mithra does not have patent rights and sell the resulting competitive products in such countries, or use the information learned from such activities to develop competitive products for sale in major commercial markets;
- Mithra may develop intellectual property that is not patentable; and/or
- the patents of others may dominate the patents of Mithra, thereby preventing their use, or have an adverse effect on Mithra's business.

- **Risks relating to global events**

The outbreak of the coronavirus (COVID-19) or any other infectious disease outbreak or other serious public health concern could result in delays to Mithra's clinical trials and could adversely affect its supply chain and work force, as well as macroeconomic conditions generally, which could have an adverse effect on demand for its products.

Since December 2019 and as of the date of this report, there is an ongoing outbreak of the 2019 coronavirus (COVID-19) which was initially primarily concentrated in China but has affected countries globally. The outbreak resulted in restrictions on non-essential medical procedures and on non-essential travel for Mithra's employees and consultants and has necessitated the introduction of mitigation measures, particularly in relation to enrolment in clinical trials. Enrolment has been affected by the following factors:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of physicians serving Mithra's clinical trial investigators, hospitals serving its clinical trial sites and hospital staff supporting the conduct of its clinical trials;
- limitations on travel that interrupted key clinical 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 products used in Mithra's trials;
- employee absences that have delayed necessary interactions with local regulators, ethics committees and other important agencies and contractors; and
- patients' reluctance to visit hospitals and attend medical check-ups due to COVID-19.

In particular, Mithra's Donesta® Phase III Clinical Program is ongoing, with topline efficacy results having been reported in January and April 2022 and primary safety data anticipated by the end of 2022 for the C302 trial (North-America) and the end of the second half of 2023 for the C301 trial (EU, Russia, Latin America, United States and Canada). While Mithra was able to avoid material delays to its clinical trials through the implementation of a global Safety Management plan, any future delays could result in delays to the approval of Donesta® in the United States and Europe, which is currently expected in the first half of 2024 and the second half of 2024, respectively. The potential resurgence of COVID-19 cases, including as a result of the emergence new variants, may result in further restrictions which could in turn result in further delays to Mithra's clinical trials. Any other global or regional disease may result in similar or greater restrictions and delays to Mithra's clinical trials as compared to COVID-19.

In addition, the outbreak of COVID-19 has already had an adverse effect on supply chains globally and Mithra's supply chain may be similarly affected. While Mithra was able to maintain its production schedule at Mithra CDMO during 2020 and 2021 notwithstanding the impact of COVID-19 restrictions, it may encounter future supply chain issues. Mithra also relies on a relatively small work force and if COVID-19 were to spread across its work force, this could have a disproportionate impact on it compared to other companies with larger work forces and/or greater financial resources. Any supply chain or human resources disruption arising from the COVID-19 outbreak could exacerbate the delays it is already experiencing arising from restrictions on non-essential medical procedures and hospital visits.

Moreover, the COVID-19 outbreak has had a severe impact on global macroeconomic conditions, with the global economy having contracted significantly. While the IMF is forecasting global growth of 3.2% in 2022, this projected growth may be derailed, in particular due to the environment of rising interest rates, as central banks take action to combat inflation arising in part from the deployment of funds for COVID-19 relief by governments during the pandemic. This may have a broader impact on Mithra's business, given the impact any decline in growth might have on the resources of government and/or private payers and their willingness to reimburse costs associated with Mithra's products. There may also be other infectious disease outbreaks or other serious public health issues, any of which could disrupt Mithra's business or adversely affect demand for its products.

If the outbreak of COVID-19 does not abate, this could require Mithra to delay its clinical trials, which could prevent it from achieving the commercialisation of the Donesta® and other products in the expected timeframe, which would in turn delay the timing of expected revenues from these products or prevent Mithra from ever earning revenues from the sale of these products.

The Russian invasion of Ukraine could have a destabilising impact on Mithra's operations, both directly as a result of the conduct of clinical trials and indirectly due to the impact on global macroeconomic conditions.

During 2021, tensions between Russia and Western countries in relation to Ukraine escalated, with Russia's military presence near the Ukrainian border increasing. In January 2022, tensions escalated further when the United States and NATO refused Russia's demand to pledge (among other things) never to admit Ukraine into NATO. On 22 February 2022, President Vladimir Putin recognised the independence of two separatist republics in the Donbass region of Ukraine, Donetsk and Luhansk, and Russian troops moved into the region. On 24 February 2022, Russia launched a full-scale invasion of Ukraine and the conflict remains ongoing. The United States, the United Kingdom and the European Union (among others) imposed sanctions against Russia in response to these events targeting certain Russian banks and individuals. These sanctions included restrictions on such banks' access to the SWIFT international payment system as well as restrictions on reserves of the Russian Central Bank. In addition, Germany announced the freezing of the Nordstream 2 pipeline project, which is being built to transport gas from Russia to the rest of Europe.

While Russia and Ukraine represent a relatively small portion of Mithra's revenue (expected to be approximately 1% in 2022), Mithra's management is continuing to monitor the situation. The conflict is expected to result in delays of launches of various products in these countries, including the launch of Estelle® in Russia, which had been planned for the second half of 2022. In addition, approximately 10% of the recruitment sites for Mithra's Donesta® Phase 3 Clinical Program were located in Russia and Mithra was required to activate a mitigation plan in order to replace these sites with other sites in the United States and Europe and to avoid any delay in the submission to the European Medicines Agency (the "EMA"). While this did not result in material delays to the clinical trial, for which topline results were reported in January and in April 2022, if the situation escalates, there may further adverse impacts to Mithra.

Moreover, the conflict could have an adverse impact on global macroeconomic conditions generally, including due to the increase in oil and gas prices resulting from the conflict. This could in turn result in suppressed demand for Mithra's products as well as in higher research and development costs for new products due to an increase in energy prices.

- **Risks relating to complex therapeutics**

Complex therapeutics products must undergo bioequivalence, pharmacodynamic or 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 products will be subject to bioequivalence, pharmacodynamic or other studies (as deemed fit by the relevant regulatory agencies), to demonstrate that the relevant generic product is bioequivalent to the previously approved innovative drug, before they can receive the necessary regulatory approval to enter the market. In 2016, Mithra demonstrated bioequivalence for two complex therapeutics products, Tibelia[®] and Myring[®]. Mithra was involved in the development of Tibelia[®] from the research phase to approval from regulatory authorities. Mithra launched Tibelia[®] in several markets including Canada, where Tibelia[®] is the first tibolone-based hormone treatment to be available. Mithra launched Myring[®] in 2019 in Europe and the rest of the world, with launch in the United States expected in the beginning of 2023. In June 2021, Mithra signed an agreement with SVR Invest BV for the full global licensing and distribution rights for the Zoreline[®] implant. Zoreline[®] is currently under development by Mithra and has not yet received any regulatory approval, which is currently expected in 2025. Any delays in completing studies for complex therapeutics to demonstrate bioequivalence, will delay Mithra's ability to generate revenues from product sales of complex therapeutic products.

In addition, in the event Mithra enters the market too late in the cycle for a particular product, that product will suffer from reduced market share and hence reduced revenues and cash flows compared to management's initial expectations. Management considers that the point of market saturation is the point at which between three and five generic products have been approved.

- **Risks relating to the research and development pipeline**

The strategy chosen by Mithra to diversify its research and development portfolio by triggering an option to purchase related to a development program led by the Belgian company, BCI Pharma, may not deliver the expected benefits.

In November 2021, Mithra acquired the rights relating to two development programs led by the Belgian company, BCI Pharma, on innovative inhibitors of CSF1R kinase. These CSF1R inhibitors are part of a new innovative class of immune-modulatory drugs with established clinical tolerability and proven efficacy. They act on the CSF1 receptor, which is involved in many inflammatory processes and is over-expressed in many pathologies, in particular cancers, neurological disorders and autoimmune diseases. Under the terms of the contract, Mithra has an option to acquire patents covering the CSF1R inhibitor series with an upfront payment of EUR 2.25 million on exercise of the option, following the first results reported by BCI Pharma. Mithra will fund the pre-clinical and clinical development, with a focus on female cancers and endometriosis, while potentially targeting other orphan indications, such as metastatic breast cancer (TNBC). BCI Pharma is expected to initiate clinical development in 2023, with marketing authorisations expected in 2031. This project diversifies Mithra's portfolio in terms of chemistry and indication. It also provides the opportunity to obtain composition of matter intellectual property on the compounds themselves. However, the project might not deliver the benefits expected by management in the cancer or endometriosis indications on which Mithra is focused. While other opportunities exist in therapeutic indications outside of women's health (e.g. pain, inflammatory disease and neurodegenerative disorders), these indications may not be relevant to Mithra's core business. In addition, two distinct chemical series are being proposed to reduce the risk of relying on only one series. If the project does not deliver the expected benefits in the area of cancer and endometriosis, Mithra's revenue potential in connection with the project may not materialise at the expected level or at all and Mithra may not realise what it considers to be an adequate return on its investment.

- **Risks relating to the market in which Mithra operates**

The pharmaceuticals industry is highly competitive and subject to rapid technological changes and if Mithra's current or future competitors develop equally or more effective and/or more economical technologies and products, Mithra's competitive position would be negatively impacted.

The market for pharmaceuticals products is highly competitive. Mithra's competitors in the women's health market include many established pharmaceuticals, biotechnology and chemicals 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 Mithra and could, therefore, adapt more quickly to changes in the marketplace and regulatory environment.

Mithra's competitors may develop new products or adapt existing products for the same patients that Mithra is targeting with Estelle® as well as its other products. Any competitors' products currently in clinical trials or in development or which are developed in the future could have superior clinical results, could be easier to implement clinically, could be more convenient for patients and/or less expensive than Estelle® and Mithra's other products or could reach commercialisation sooner in certain target markets. Competing products may gain faster or broader market acceptance than Mithra's products (if and when marketed) and medical advances or rapid technological development by competitors may result in Mithra's product candidates becoming non-competitive or obsolete before Mithra is able to recover its research and development and commercialisation expenses.

In addition, the commercial availability of any approved competing product could potentially inhibit recruitment and enrolment into Mithra's clinical trials. Mithra may successfully conclude its clinical trials and obtain regulatory approval but may fail to compete against competitors or alternative treatments that may be available or developed for the relevant indication. New products, or modifications of existing products, may emerge which yield clinical results equal to or better than those achieved with Estelle® or Mithra's other products. Emergence of such new products may inhibit Mithra's ability to develop and grow the market for Estelle® and its other products. Furthermore, new entrants into the markets in which Mithra operates could also decide to more aggressively compete on price, requiring Mithra to reduce prices in an effort to maintain market share, which would adversely impact its profitability. There is also a risk that Mithra's competitors have better and more extensive experience in manufacturing and supplying their products, which would provide them with a cost advantage which could in turn impact the profitability of Mithra by requiring it to reduce prices to retain its distribution partners.

6. Related party transactions

On 24 June 2022, 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 2022.

II.

Interim condensed consolidated
financial statements for the six months
ended 30 June 2022

II. Interim condensed consolidated financial statements for the six months ended 30 June 2022

1. Interim consolidated statement of profit or loss

<i>Thousands of Euro (€)</i>		30 June 2022	30 June 2021
	<i>Notes</i>		
Revenue	6.3.2	11,357	12,142
Cost of sales		(7,083)	(8,246)
Gross profit		4,275	3,897
Research and development expenses	6.4	(27,518)	(36,756)
General and administrative expenses	6.4	(7,042)	(5,896)
Selling expenses	6.4	(1,185)	(686)
Other operating income	6.4	3,933	2,908
Loss from operations		(27,537)	(36,534)
Change in the fair value of contingent consideration payable	6.12	4,332	(12,813)
Net fair value gains/(losses) on financial assets at fair value through profit or loss	6.12	-	(6,351)
Financial income	6.4	1,889	1,310
Financial expenses	6.4	(7,638)	(6,090)
Loss before taxes		(28,952)	(60,478)
Income taxes	6.4	(2,295)	5,584
NET LOSS FOR THE PERIOD		(31,247)	(54,894)

Loss per share

Result for the purpose of basic loss per share, being net loss	(31,247)	(54,894)
Weighted average number of shares for the purpose of basic loss per share	45,042,816	43,026,680
Basic loss per share (in Euro)	(0.69)	(1.28)
Diluted loss per share (in Euro)	(0.69)	(1.28)

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

2. Interim consolidated statement of comprehensive loss

<i>Thousands of Euro (€)</i>	<i>Notes</i>	<i>30 June 2022</i>	<i>30 June 2021</i>
Net loss for the period		(31,247)	(54,894)
Other comprehensive income or (loss)		(16,022)	(8,749)
<i>Items that may be reclassified to profit or loss:</i>			
Gains/(losses) on cash flow hedges	6.10.2	(15,906)	(5,949)
Income taxes relating to these items		3,976	1,487
<i>Items that will not be reclassified to profit or loss:</i>			
Changes in the fair value of equity investments at fair value through other comprehensive income or loss	6.10.2	(4,093)	(4,287)
Total comprehensive loss for the period		(47,269)	(63,642)
<i>Attributable to</i>			
Owners of the parent		(47,269)	(63,642)
Non-controlling interests		-	-
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		(47,269)	(63,642)

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

3. Interim consolidated statement of financial position

Thousands of Euro (€)	Notes	30 June 2022	31 December 2021
ASSETS			
Property, plant and equipment	6.6	39,848	38,354
Right-of-use assets	6.6	67,293	69,322
Goodwill	6.5	5,233	5,233
Other intangible assets	6.5	114,880	104,954
Deferred income tax assets	6.14	64,529	63,456
Contracts assets	6.8	2,638	49
Investments in equity securities	6.12	27,805	31,898
Other non-current assets	6.12	8,461	9,263
Non-current assets		330,687	322,528
Inventories	6.7	48,212	43,852
Contract assets	6.8	14,245	12,522
Derivatives financial assets	6.10.2	-	100
Trade and other receivables	6.9	10,058	10,044
Cash and cash equivalents		29,299	32,872
Current assets		101,813	99,389
TOTAL ASSETS		432,500	421,918

Thousands of Euro (€)	Notes	30 June 2022	31 December 2021
EQUITY AND LIABILITIES			
Share capital	6.10.1	37,031	32,250
Additional paid-in-capital	6.10.1	385,058	340,769
Other reserves	6.10.2	(18,083)	(2,545)
Accumulated deficit		(367,881)	(336,633)
Equity attributable to equity holders		36,125	33,840
Subordinated loans	6.11	11,043	11,629
Other loans	6.11	114,535	113,608
Lease liabilities	6.11	40,016	42,353
Refundable government advances	6.11	11,572	12,769
Other financial liabilities	6.11, 6.12	75,413	102,675
Derivative financial liabilities	6.10.2	10,859	2,897
Provisions	6.16	266	266
Deferred tax liabilities	6.14	5,268	6,089
Non-current liabilities		268,973	292,285
Current portion of subordinated loans	6.11	940	1,314
Current portion of other loans	6.11	47,376	45,253
Current portion of lease liabilities	6.11	6,184	6,561
Current portion of refundable government advances	6.11	1,745	1,617
Current portion of other financial liabilities	6.11, 6.12	38,759	15,829
Derivative financial liabilities	6.10.2	4,822	1,886
Trade and other payables	6.13	27,576	23,331
Current liabilities		127,402	95,792
TOTAL EQUITY AND LIABILITIES		432,500	421,918

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

4. Interim consolidated statement of changes in equity

<i>Thousands of Euro (€)</i>	<i>Share capital</i>	<i>Additional paid-in-capital</i>	<i>Other reserves</i>	<i>Accumulated deficit</i>	<i>Total equity</i>
Balance 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 at 30 June 2021	32,020	335,286	5,426	(274,652)	98,080
Balance at 1 January 2022	32,250	340,769	(2,545)	(336,633)	33,840
Net loss for the period				(31,247)	(31,247)
Losses on cash flow hedges			(11,929)		(11,929)
Changes in the fair value of equity investments at fair value through other comprehensive income or loss			(4,093)		(4,093)
Total comprehensive loss for the period	-	-	(16,022)	(31,247)	(47,269)
LDA capital increases of 14 February 2022 and 30 June 2022, net of transaction costs	781	11,118			11,899
Exercises of a Call Option from Goldman Sachs of 21 March 2022, 19 April 2022 and 31 May 2022, net of transaction costs	1,166	12,650			13,816
Capital increase of 24 June 2022, net of transaction costs	2,834	20,520			23,355
Share-based payments expense			485		485
Balance at 30 June 2022	37,031	385,058	(18,083)	(367,881)	36,125

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

5. Interim consolidated statement of cash flow

<i>Thousands of Euro (€)</i>	<i>Notes</i>	<i>30 June 2022</i>	<i>30 June 2021</i>
CASH FLOWS FROM OPERATING ACTIVITIES			
Result from operations		(27,537)	(36,534)
<i>Adjustments for:</i>			
Depreciation, amortization and impairment charges	6.5, 6.6	5,828	4,637
R&D tax credit		(1,007)	(889)
Share-based payments	6.15	485	485
Grant income		(125)	(339)
Gain on derecognition of contingent consideration payable		-	(366)
Write-down of account receivables and inventories		816	657
Subtotal		(21,541)	(32,349)
Increase/(decrease) in trade and other payables	6.13	721	(7,884)
(Increase)/decrease in trade and other receivables	6.9	1,634	(6,617)
(Increase)/decrease in inventories	6.7	(5,099)	(4,697)
(Increase)/decrease in contract assets and liabilities	6.8	(3,916)	20,676
Realized foreign exchange gains/(losses)	6.10.2	(5,003)	(677)
Net cash (used in)/ provided by operating activities		(33,204)	(31,548)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payment for acquisition of tangible fixed assets	6.6	(3,585)	(5,298)
Proceeds from disposal of tangible fixed assets		170	-
Payment for acquisition of intangible fixed assets	6.5	(8,708)	(5,117)
Other financial liabilities payments	6.11, 6.12	-	(33,500)
Net cash (used in)/ provided by investing activities		(12,124)	(43,915)
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of subordinated loans and other loans	6.11	(1,592)	(5,213)
Repayment of refundable government advances	6.11	-	(717)
Proceeds from subordinated loans and other loans	6.11	2,425	4,300
Lease payments	6.11	(3,129)	(4,732)
Interests paid	6.4	(4,815)	(4,490)
Proceeds from issuance of shares (net of issue costs)	6.10.1	35,204	3,501
Proceeds from drawing requests under flexible equity financing (net of issue costs)	6.10.1	13,672	-
Net cash (used in)/provided by financing activities		41,765	(7,352)
Net increase/(decrease) in cash and cash equivalents		(3,563)	(82,815)
Cash and cash equivalents at beginning of year		32,872	138,675
Effects of exchange rate changes on cash and cash equivalents		(10)	(30)
Cash and cash equivalents at end of period		29,299	55,830

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

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:

- In February, Mithra has entered into a flexible equity financing agreement with Goldman Sachs International, pursuant to which the Company can at its sole discretion require GSI (subject to certain conditions) to provide funding to the Company for an aggregate amount of up to EUR 100,000,000 in return for issuing GSI with call options over the Company's ordinary shares. The arrangement has been entered into for a term of approximately 2 years. The maximum amount that can be drawn on each subsequent occasion will be EUR 5 million or, if certain conditions are satisfied, up to EUR 7.5 million.

Note : For more details about the operations during this period, please refer to 6.10. Equity

- In April, LDA Capital Limited extended its capital commitment agreement with for a period of two additional years, as well as the increase of the commitment amount by EUR 25 million. With this extension and the additional EUR 25 million, the Company can now rely on funds of up to approximately EUR 53.8 million, available until April 2025. Mithra issued two Put Option Notice, on December 2021 and on 13 May 2022, which have been followed by the issuance of 442,191 new shares in February for a total amount of EUR 8,061,142 and of 625,000 new shares for a total amount of EUR 4,133,933 end of June 2022.

Note : For more details about the operations during this period, please refer to 6.10. Equity

- Mithra completed the private placement of 3,871,491 new shares for an aggregate amount of EUR 23.5 million that it had announced on 21 June 2022. As a result of the completion of the Private Placement, the share capital of the Company was increased from EUR 33,739,072.34 to EUR 36,573,390.90 and the number of issued and outstanding shares of the Company was increased from 46,085,634 to 49,957,125 ordinary shares, through the issuance of a total of 3,871,491 new shares at an issue price of EUR 6.07 per new share.

Note : For more details about the operations during this period, please refer to 6.10. Equity

- In February, the commercial launch of Mithra's vaginal contraceptive ring Myring[®] under the brand name Haloette[®] in Canada has occurred.

Note : For more details about the operations during this period, please refer to 6.3 Segment and revenue information

- In the first semester of 2022, Mithra collected one Estelle[®] out-licensing milestones with Gedeon Richter (EUR 1 million), without impact on revenue as already recognized as per IFRS15 previously and recognized EUR 4.0 million out-licensing revenue in the context of the license and supply with Gedeon Richter following the submission of the regulatory file in Latin America for Estelle[®].

Note : For more details about the operations during this period, please refer to 6.3 Segment and revenue information and to 6.8 Contract assets.

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 2022 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 2021. 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 21 September 2022.

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 2021 and are consistent with those of the previous corresponding interim reporting period.

The new standards and interpretations effective for the first time for periods beginning on (or after) 1 January 2022 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 2021.

6.2.4. Going concern

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

End of June 2022, Mithra has a total of EUR 367.9 million accumulated losses on its balance sheet and realized a consolidated net loss of EUR 31.2 million for the 30 June 2022. Based on going concern accounting principles, the Board is to justify the going concern during twelve months following the issuance of the report. Based on their assessment, the Management and Board of directors consider it appropriate to prepare the financial statements on a going concern basis. Indeed, the assessment is based on following assumptions such as expected R&D clinical results and a commercial deal for Donesta (foreseen in H2 2022) as well as on the monitoring of our funding activities.

In consideration of those above-mentioned assumptions, the Board of directors has analyzed the financial statements and accounting policies and, made the assessment that the current cash position of EUR 29.3 million at 30 June 2022, plus the access to various financing facilities and the ongoing licensing discussions around the Donesta's asset will allow the Group to keep up with operating expenses and capital expenditure requirements at least until September 2023.

We remind that the Company extended the LDA Capital Limited capital commitment agreement for a period of two additional years together with an additional commitment amount of EUR 25 million; and post period secured a convertible loan facilities agreement with funds managed by Highbridge Capital Management LLC and Whitebox Advisers LLC for a three years term in an amount of up to EUR 100 million to be drawn in three tranches.

6.2.5. 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, 2022.

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 2022 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, 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 2022	30 June 2021
Product sales	6,172	8,185
Out-licensing	4,207	3,957
Others	978	-
Total revenue	11,357	12,142

Group revenue amounts to EUR 11.4 million for the six months period ended 30 June 2022.

Approximately 68% of the Group's revenue was derived from Estelle® (52% for the same period in the previous year). During the period, the Group accounted for EUR 3.7 million Estelle® product sales and EUR 4.0 million out-licensing revenue in the context of the license and supply agreement of Estelle® in Latin America with Gedeon Richter :

- Estelle® product sales are lower than previous year due to the safety stock built by our partners for last year's commercial launch.
- Regarding the EUR 4.0 million out-licensing, the performance obligation of the Company was considered as achieved and the revenue considered as highly probable following the submission of the regulatory file in Latin America for Estelle®. (We refer to note 6.8 Contract assets).

Sales from generic products in our portfolio, at EUR 2.4 million, increased by 30% compared to last year. The majority of it concerns Myring® sales in Europe and Canada.

Product sales include variable considerations. (We refer to note 6.8 Contract assets).

Finally, during the period, Mithra CDMO rendered several R&D services to third parties (EUR 1 million revenue).

▪ Disaggregation of revenue

The tables below show the segment information for the reportable segments for the half-year ended 30 June 2022 and 2021, as well as the basis on which revenue is recognized:

Thousands of Euro (€)

30 June 2022

	Product sales	Out-licensing	Others
Primary Geographic Markets			
Europe	2,225	112	978
Outside Europe	3,947	4,095	-
Total	6,172	4,207	978
Product type			
Generics	2,437	207	-
E4 Contraception	3,735	4,000	-
E4 Menopause	-	-	-
Total	6,172	4,207	-
Timing of transfer of goods and services			
At a point in time	6,172	4,207	978
Over time	-	-	-
Total	6,172	4,207	978

Thousands of Euro (€)

30 June 2021

	Product sales	Out-licensing	Others
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	-

6.4. Profit and loss information

The Group reported a net loss of EUR 31.2 million for the first half 2022, compared to a net loss of EUR 54.9 million for the first half 2021.

Group revenue was about EUR 11.4 million in the first half 2022. Approximately 68% of it was derived from Estelle® (52% for the same period in the previous year). During the period, the Group accounted for EUR 3.7 million Estelle® product sales, which are lower than previous year due to the safety stock built by our partners for last year's commercial launch, and EUR 4.0 million out-licensing revenue in the context of the license and supply agreement of Estelle® in Latin America with Gedeon Richter. Mithra CDMO rendered several R&D services to third parties (EUR 1 million revenue).

Sales from generic products in our portfolio, at EUR 2.4 million, increased by 30% compared to last year. The majority of it concerns Myring® sales in Europe and Canada.

Research and development expenses decreased by 25% to reach EUR 27.5 million compared to EUR 36.8 million in first half 2021. This decrease is attributable to a timing effect as these expenses should accelerate in the second half of 2022. First half 2021 was still impacted by Covid study, for which no further clinical development is conducted since second half of 2021. This decrease is partially offset by the increase in amortization of other intangible assets (intellectual property rights and internally generated research and development expenses for this project are considered as available for use since the reception of Estelle® Marketing authorization in May 2021).

General and administrative expenses and selling expenses increased by 25%, mainly explained by an increase in insurance costs and salaries indexation.

Other operating expenses (EUR 3.9 million, compared to EUR 2.9 million in first half 2021) are composed of R&D tax credit for EUR 1.0 million and costs re invoicing for EUR 2.2 million.

The positive impact about EUR 4.3 million of change in fair value gain related to contingent consideration payable Estelle® is mainly the consequence of conservative review of management estimate, namely the updated discount rate (the WACC is 1,5% higher than for previous closing).

Financial income increase is explained by the positive impact of the remeasurement of refundable government advances measured at amortized cost (EUR 1.4 million), following the review of revenue forecasts (slower ramp-up on Estelle® product sales).

Increase of financial expenses is mostly driven by the interest charges, higher than in first half 2021, linked to the higher financial liabilities during the period.

The group recorded a tax loss of EUR 2.3 million for the six months that mainly results of the review of tax impact on temporary differences on contingent consideration payable Estelle® (IFRS liability decreases), partially compensated by the recognition of tax losses carried forward in several entities. The latter are limited compared to previous periods in the view of the tax forecasts and the accumulated losses already recorded on the balance sheet (to be set off 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).

Other intangible assets consist mainly of a portfolio of acquired product rights, market access fees and development costs. This section primarily includes the intellectual property rights acquired for Estelle®, Zoreline®, Myring® and the Donesta® asset deal, as well as development costs in the framework of E4 activity (the project "E4 synthesis" and the project Estelle® with the development costs which occurred after the application for market authorization).

The increase in intangible assets during the first semester of 2022 (for EUR 13.6 million) is explained by capitalization of development costs related to the project "E4 synthesis" (EUR 9.7 million) and the post-approval complementary studies for Estelle® (EUR 1.5 million), partially compensated with amortization (EUR 1.5 million).

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

During the period, the Group recorded EUR 3.6 million of additions to tangible fixed assets which were mainly related to machinery and equipment of the production facility for the manufacturing of pharmaceuticals products (Mithra CDMO) and their directly attributable costs for EUR 3.2 million. In order to finance these machines, the Group entered into several leases. Right-of-use assets additions amount to EUR 0.5 million.

6.7. Inventories

Thousands of Euro (€)	30 June 2022	31 December 2021
Raw materials & consumables	42,941	38,887
Semi-finished goods	5,242	4,960
Finished goods	29	5
Total	48,212	43,852
Write-down / write-back of inventories during the period	(739)	(72)

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

6.8. Contract assets

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 2022.

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

Thousands of Euro (€)	Contracts assets
Balance at 1 January 2022	12,571
Revenue billed during the period already recognised in previous years	(1,294)
Revenue recognized during the period	5,209
Currency translation differences	396
Balance at 30 June 2022	16,883

As a result of submitting regulatory file in Latin America for Estelle®, previously unbilled revenue was invoiced, leading to a cash collection about EUR 1.0 million and a revenue recognition about EUR 4.0 million out-licensing revenue in the context of the license and supply agreement of Estelle® in Latin America with Gedeon Richter.

In the framework of “variable supply price”, revenue recognized during the period amounts to EUR 1.2 million on Estelle® products that were delivered in 2022 and on which royalties will be due by our partners in the next quarters according to their own sales of Estelle® on their markets. At the opposite, EUR 0.3 million already recognized in previous years were billed during the period.

As at 30 June 2022, the balance of contract assets considers:

- Unbilled milestones revenue for EUR 12.1 million, among which EUR 7.6 million relates to Mayne Pharma for Myring® (out of which EUR 6 million were invoiced in August 2022 following market approval in USA), EUR 4 million relates to Gedeon Richter for Estelle® in Latin America and EUR 0.5 million relates to performance obligation achieved in the framework of Mayne Pharma agreement for Estelle®.
- Unbilled “variable supply price” for EUR 4.8 million related to Estelle® products already delivered by Mithra to our partners.

6.9. Trade and other receivables

Trade and other receivables are steady compared to previous closing.

6.10. Equity

6.10.1. Share capital and additional paid-in capital

During the period under review, several capital increases took place with the issuance of 6,530,866 new shares for a total amount of EUR 48,875,834 (net of transaction costs).

As of June 30, 2022, following the completion of the above-mentioned capital increases, the Company's capital consisted of a recognized amount of EUR 37,031,083 with 50,582,125 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 2022 is as follows:

<i>Thousands of Euro (€)</i>	<i>Number of shares</i>	<i>Share capital</i>	<i>Additional paid-in-capital</i>	<i>Total</i>
Balance at 31 December 2021	44,051,259	32,250	340,769	373,020
LDA capital increase of 14 February 2022, net of transaction costs	442,191	324	7,406	7,730
Exercise of a Call Option from Goldman Sachs of 21 March 2022, net of transaction costs	377,198	276	4,132	4,408
Exercise of a Call Option from Goldman Sachs of 19 April 2022, net of transaction costs	489,686	358	4,050	4,408
Exercise of a Call Option from Goldman Sachs of 31 May 2022, net of transaction costs	725,300	531	4,469	5,000
Capital increase of 24 June 2022, net of transaction costs	3,871,491	2,834	20,520	23,355
LDA capital increase of 30 June 2022, net of transaction costs	625,000	458	3,712	4,169
Balance at 30 June 2022	50,582,125	37,031	385,058	422,090

The amounts mentioned above are presented net of transaction costs, namely:

- In the framework of LDA Capital, the costs of the extension of the Capital Commitment Agreement agreed in April 2022 are imputed on the first completion of capital increase following this agreement (the LDA capital increase of 30 June 2022).
- In the context of Goldman Sachs flexible equity funding, potential future drawings are subject to conditions. Therefore, the costs of transaction (incurred consequently to the agreement and first drawing request exercised on 4 February 2022 for EUR 10 million) are presented in deduction of the first two effective exercises of call option from Goldman Sachs (two contributions in kind for EUR 5 million dated 21 March 2022 and 19 April 2022).

6.10.2. Other reserves

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

<i>Thousands of Euro (€)</i>	<i>Share-based payment reserve</i>	<i>Financial assets at FVOCI and foreign currency translation reserves</i>	<i>Cash flow hedge reserve</i>	<i>Total other reserves</i>
Balance 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	-	(4,287)	(4,462)	(8,749)
Share-based payments expense	485			485
Balance at 30 June 2021	16,199	(14,149)	3,376	5,426
Balance at 1 January 2022	16,779	(16,370)	(2,954)	(2,545)
Losses on cash flow hedges			(11,929)	(11,929)
Changes in the fair value of equity investments at fair value through other comprehensive income or loss		(4,093)		(4,093)
Total comprehensive loss for the period	16,779	(20,463)	(14,884)	(16,022)
Share-based payments expense	485			485
Balance at 30 June 2022	17,264	(20,463)	(14,884)	(18,083)

▪ 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 2021 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, 2022, the other reserves contain the cumulative changes in fair value of financial assets through other comprehensive income or loss (Mayne shares) for EUR 20.5 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, as well as realized foreign exchange gains or losses, are 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, 2022, the cash flow hedge reserve contains the cumulative changes in fair value of hedge instruments (net of tax) for EUR 10.7 million and the cumulative realized foreign exchange losses for EUR 4.2 million. The latter is the result of the swap of transactions to align the settlement with underlying sales related milestones.

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

<i>Time to maturity</i>	<i>Hedged Amounts (kUSD)</i>	<i>Average Hedge Rate</i>
< 1 year	50,000	1.180
1-2 years	50,960	1.160
2-5 years	116,000	1.205
As at 30 June 2022	216,960	1.188

6.11. Financial liabilities

An overview of the financial liabilities is shown below.

Thousands of Euro (€)	30 June 2022			31 December 2021		
	Total	Current	Non-Current	Total	Current	Non-Current
Subordinated loans	11,983	940	11,043	12,943	1,314	11,629
Other loans	161,911	47,376	114,535	158,861	45,253	113,608
<i>Bank loans</i>	46,944	42,310	4,634	45,150	40,187	4,963
<i>Convertible bond</i>	114,968	5,066	109,901	113,711	5,066	108,645
Lease liabilities	46,200	6,184	40,016	48,914	6,561	42,353
Refundable government advances	13,317	1,745	11,572	14,386	1,617	12,769
Sub-total liabilities arising from financing activities	233,411	56,244	177,167	235,105	54,746	180,359
Other financial liabilities	114,172	38,759	75,413	118,504	15,829	102,675
Derivative financial liabilities	15,682	4,822	10,859	4,783	1,886	2,897
Total financial liabilities	363,264	99,826	263,439	358,392	72,461	285,931

In February, Mithra has entered into a flexible equity financing agreement with Goldman Sachs International. The amount drawn during the period (EUR 15 million before costs) was subsequently contributed to equity. Please refer to the section 6.10 Equity.

EUR 2 million additional were drawn on existing credit facilities in first half 2022.

The evolution of other financial liabilities and derivatives financial liabilities are explained in the section 6.12 Fair value measurement of financial instruments.

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

Thousands of Euro (€)	31 December 2021	Cash flow		Non-cash changes			30 June 2022
		Inflow	Outflow	Exercise of call option	Additions	Amortized costs adjustments	
Subordinated loans	12,943	-	(961)	-	-	-	11,983
Other loans	158,861	16,097	(3,288)	(13,672)	-	3,913	161,911
<i>Bank loans</i>	45,150	2,425	(632)	-	-	-	46,944
<i>Convertible bond</i>	113,711	-	(2,656)	-	-	3,913	114,967
<i>Flexible equity financing</i>	-	13,672	-	(13,672)	-	-	-
Lease liabilities	48,914	-	(3,129)	-	416	-	46,200
Refundable government advances	14,386	-	-	-	-	(1,069)	13,317
Total	235,105	16,097	(7,378)	(13,672)	416	2,844	233,412

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.

Post period (please refer to section 6.17), the Company announced that is has entered into a senior secured convertible facilities agreement with funds managed by Highbridge Capital Management LLC and fund managed by Whitebox Advisers LLC for a three years term in an amount of up to EUR 100 million. At the date of this Report, the Company already drawn down the first tranche in the amount of EUR 50 million. Part of the proceeds of the loan been used to repurchase outstanding convertible bonds of the Company held by the Lenders for a principal amount of EUR 34.1 million at a discount.

Straight loans ING & BELFIUS are secured with pledges on receivables, receivable pledge mandates, mortgage mandates in respect of the office building owned by the Company and by a mandate to pledge on 50% of Estetra's shares in Mayne Pharma.

6.12. Fair value measurement of financial instruments

The following table presents the Company's financial assets and financial liabilities measured and recognised or unrecognised at fair value at 30 June 2022 :

Thousands of Euro (€)	Balance at 30 June 2022	Recognised fair value measurements	Fair value measurement hierarchy	Unrecognised fair value measurements
Financial assets				
Financial assets at fair value through other comprehensive income				
Investments in equity securities	27,805	27,805	Level 1	-
Financial assets at amortised cost				
Other non-current assets	8,461	-	-	8,461
Contracts assets	16,883	-	-	16,883
Trade and other receivables	10,058	-	-	10,058
Cash and cash equivalents	29,299	-	-	29,299
Financial liabilities				
Financial liabilities at fair value through profit and loss				
Other financial liabilities - Estelle ©	105,672	105,672	Level 3	-
Financial liabilities at fair value through other comprehensive income				
Derivative financial liabilities	15,682	15,682	Level 2	-
Liabilities at amortised cost				
Subordinated loans	11,983	-	-	11,983
Other loans - convertible bond	114,968	-	-	114,968
Other loans - others	46,944	-	-	46,944
Lease liabilities	46,200	-	-	46,200
Refundable government advances	13,317	-	-	13,317
Trade and other payables	27,576	-	-	27,576
Other financial liabilities - Zoreline ©	8,500	-	-	8,500

The following table presents the Company's financial assets and financial liabilities measured and recognised or unrecognised at fair value at 31 December 2021 :

Thousands of Euro (€)	Balance at 31 December 2021	Recognised fair value measurements	Fair value measurement hierarchy	Unrecognised fair value measurements
Financial assets				
Financial assets at fair value through other comprehensive income				
Investments in equity securities	31,898	31,898	Level 1	-
Derivatives financial assets	100	100	Level 2	-
Financial assets at amortised cost				
Other non-current assets	9,263	-	-	9,263
Contracts assets	12,571	-	-	12,571
Trade and other receivables	10,044	-	-	10,044
Cash and cash equivalents	32,872	-	-	32,872
Financial liabilities				
Financial liabilities at fair value through profit and loss				
Other financial liabilities - Estelle ©	110,004	110,004	Level 3	-
Financial liabilities at fair value through other comprehensive income				
Derivative financial liabilities	4,783	4,783	Level 2	-
Liabilities at amortised cost				
Subordinated loans	12,943	-	-	12,943
Other loans - convertible bond	113,711	-	-	113,711
Other loans - others	45,150	-	-	45,150
Lease liabilities	48,914	-	-	48,914
Refundable government advances	14,386	-	-	14,386

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:

As per 30 June 2022, there is one category of financial assets at fair value: Investments in equity securities.

<i>Thousands of Euro (€)</i>	<i>Fair value measurement hierarchy</i>	<i>Assets recognized or disclosed at fair value</i>
Investments in equity securities	Level 1	27,805
Assets recognised or disclosed at fair value		27,805

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 recognise 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 decrease in Mayne's share price and the increase in AUD / EUR conversion rate as of June 30, 2022.

<i>Thousands of Euro (€)</i>	<i>Investments in equity securities</i>
Balance at 1 January 2022	31,898
Fair value loss through other comprehensive income	(4,093)
Balance at 30 June 2022	27,805

▪ **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.

<i>Thousands of Euro (€)</i>	<i>Fair value measurement hierarchy</i>	<i>Liabilities recognized or disclosed at fair value</i>
Other financial liabilities - Estelle ®	Level 3	105,672
Derivative financial liabilities	Level 2	15,682
Liabilities recognised or disclosed at fair value		121,353

Other financial liabilities – Estelle®

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

<i>Thousands of Euro (€)</i>	<i>Other financial liabilities - Estelle ®</i>
Balance at 1 January 2022	110,004
Payments related to Estelle ®	-
Fair value gain through profit or loss	(4,332)
Balance at 30 June 2022	105,672

As a reminder, as at June 30, 2022, 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 three 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 2022 assumptions for Estelle®:

<i>Contingent considerations relating to Estelle®</i>	<i>Total cash-out until 2028</i>	<i>Partial cash-out until 2028</i>	<i>Net Present Value</i>
Alternative 1	50%	50%	85,500
Alternative 2	67%	33%	105,672
Alternative 3	75%	25%	110,159
Alternative 4	100%	0%	125,293

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 decrease of fair value for the contingent consideration for Estelle® of EUR 4.3 million is mainly the consequence of the updated discount rate.

The WACC used in June 2022 is 12.84%, compared to 11.34% for 2021 year-end closing. At stable WACC, the contingent liability would have been EUR 109.9 million, approximatively the same level of debt as per 31 December 2021.

December 2021 assumptions for Estelle®:

<i>Contingent considerations relating to Estelle®</i>	<i>Total cash-out until 2028</i>	<i>Partial cash-out until 2028</i>	<i>Net Present Value</i>
Alternative 1	50%	50%	98,542
Alternative 2	67%	33%	110,004
Alternative 3	75%	25%	116,888
Alternative 4	100%	0%	132,927

Derivatives financial liabilities

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.

<i>Thousands of Euro (€)</i>	<i>Derivative financial liabilities</i>
Balance at 1 January 2022	4,783
Fair value loss through other comprehensive income	10,899
Balance at 30 June 2022	15,682

6.13. Trade and other payables

Trade and other payables increased by EUR 4.2 million, which is mainly the result of invoice and payment timing.

6.14. Deferred tax assets and liabilities

<i>Thousands of Euro (€)</i>	<i>Balance at 30 June 2022</i>	<i>Balance at 31 December 2021</i>
Deferred tax asset to be recovered after more than 12 months	64,529	63,456
Deferred tax assets	64,529	63,456

Increase of deferred tax assets is the result of temporary difference changes (arising from the difference between the fair value of assets acquired at the acquisition date and their tax base) and the recognition of tax losses carried forward of the period in several subsidiaries of the Group. The latter are limited compared to previous periods in the view of the tax forecasts and the accumulated losses already recorded on the balance sheet.

Management is convinced that subsidiaries of the Group located in Belgium will generate sufficient profits in the future in order to be able to recover the fiscal losses carried forward recorded on the balance sheet (to be set off against future taxable income).

The total amount of statutory historical tax losses available was exceeding EUR 365 million as per end of June 2022 (EUR 300 million as per 2021 year-end), knowing that about 52% of these losses are valued within the deferred tax assets (60% as per 2021 year-end), we are considering a balance of 48% as non-recoverable in the future.

6.15. Share-based payments

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

	30 June 2022		31 December 2021	
	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	24.3	2,710,900	18.8	2,701,520
Granted	-	-	19.0	10,000
Forfeited	-	-	-	-
Exercised	-	-	5,646.0	(620)
Expired	-	-	-	-
Outstanding and granted as of reporting date	24.3	2,710,900	24.3	2,710,900

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	799,387	342,595	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 Grant 1)	Plan 2020 (Mgmt Grant 2)
Number of warrants granted	87,695	690,000	300,000	316,000	10,000
Exercise price per warrant	EUR 16,54	EUR 27	EUR 27	EUR 17,87	EUR 18,96
Expected dividend yield	-	-	-	-	-
Expected stock price volatility	37.50%	37.50%	37.50%	37.50%	37,50%
Risk-free interest rate	0.36%	0.36%	0.36%	0.36%	0,36%
Expected duration	5 years	3 years	3 years	10 years	10 years
Fair value at grant date	EUR 479k	EUR 1581k	EUR 608k	EUR 2552k	EUR 87k

During the period, a charge of EUR 485k has been recognized at the consolidated statement of income (same amount as per half year 2021).

No new warrant plan were issued during the first semester of 2022.

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 2022, Mithra announced a change in its Board of Directors' Chairmanship. Following the resignation with immediate effect of Mr. Ajit Shetty for personal reasons nonrelated to the Company, the Board of Directors approved, on the proposal of the outgoing Chairman and the recommendation of the Nomination and Remuneration Committee, the appointment of Mr. Christian Moretti as Chairman, as well as that of Mr. Erik Van Den Eynden as Vice-Chairman. These functions will be exercised until the next Company's Shareholders Meeting in May 2023 called to deliberate on the renewal of the Board at the end of the members' terms of office.

In July, Mayne Pharma and Mithra were pleased to announce the launch of NEXTSTELLIS[®] in Australia. NEXTSTELLIS[®] will compete in the Australian combined (estrogen plus progestin) oral contraceptive market which is valued at A\$ 60 million (circa EUR 40 million). Combined oral contraceptives continue to be the most common method of contraception with nearly 1 million Australian women using them.

In July, Mithra's U.S. commercial partner, Mayne Pharma, has entered into a new strategic collaboration with GoodRx (Nasdaq: GDRX), a leading consumer-focused digital healthcare platform in the U.S. The collaborative initiative will deliver an enhanced direct-to-consumer (DTC) program aimed at building awareness of NEXTSTELLIS[®] oral contraceptive availability in the United States.

In August, NEXTSTELLIS[®] has been nominated for the 2022 Prix Galien USA Award for Best Pharmaceutical Agent. After France and Belgium, the contraceptive developed by Mithra is selected for the third time by the Galien Prize, the most prestigious award of the pharmaceutical research and innovation.

In August, Mayne Pharma and Mithra announced that the US Food and Drug Administration (FDA) has granted approval of the Abbreviated New Drug Application (ANDA) for HALOETTE[®] vaginal hormonal contraceptive ring. Mayne Pharma anticipates the commercial launch of HALOETTE[®] ring by early calendar year 2023.

In August, Mithra entered into a senior secured convertible facilities agreement with funds managed by Highbridge Capital Management, LLC and funds managed by Whitebox Advisors LLC, for a three-year term, in an amount of up to EUR 100 million to be drawn down in three different tranches, while tranches 2 and 3 for a total of 50 million are subject to certain conditions to be fulfilled by Mithra. This facility is subject to an annual interest rate of 7.5% and to a global commitment fee of 2.9 million EUR. At the date of this Report, the Company already drawn down the first tranche in the amount of EUR 50,000,000.00. Part of the proceeds of the loan has been used to repurchase outstanding convertible bonds of the Company held by the Lenders for a principal amount of EUR 34.1 million at a discount. Following the first drawdown by the Company and the several conversions of a portion of the loans from Highbridge and Whitebox, the outstanding principal amount of the loans already drawn is EUR 37,089,161.29. The Company's obligations under the loans will be guaranteed by certain subsidiaries of the Company and will be secured by a business pledge including particularly all intellectual property, data, contracts and assets related to E4 such as Estelle[®] and Donesta[®] as well as other assets related to E4, and a pledge on the shares in certain subsidiaries of the Company and on 50% of Estetra's shares in Mayne Pharma.

Also, pursuant to the loan facility and a separate conversion agreement entered into between the Company and the Lenders, the loans plus accrued interest and an option prepayment amount will be convertible into new shares of the Company, either at the option of the respective Lenders or (subject to certain conditions) at the option of the Company, in each case at a discount of 10% to a relevant volume weighted average trading price of the Company's shares prior to conversion. The Company may also voluntarily prepay the loans in whole or in part at any time for cash at par plus an option prepayment amount. The interest on the loans and the option prepayment amount are payable in cash or, at the Company's option, in kind in Company shares at a discount of 10% to a relevant volume weighted average trading price of the Company's shares prior to the settlement in shares.

There has been no other subsequent event which occurred between the end of the six-month period ended on June 30, 2022 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 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 (loss from operations) from the consolidated statement of profit or loss prepared in accordance with IFRS. The Group considers share-based payments as non-recurring item above EBITDA.

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

Financial Highlights (management figures) are presented as follows in the first part of this report (with a condensed view):

<i>Thousands of Euro (€)</i>	<i>30 June 2022</i>	<i>30 June 2021</i>
Revenue	11,357	12,142
Cost of sales	(6,842)	(8,246)
Gross profit	4,516	3,897
Research and development expenses	(22,714)	(32,880)
General and administrative expenses	(5,818)	(4,733)
Selling expenses	(1,143)	(604)
Other operating income	3,933	2,908
REBITDA	(21,226)	(31,412)
Share-based payments expenses	(485)	(485)
EBITDA	(21,711)	(31,897)
Depreciations	(5,826)	(4,637)
Loss from operations	(27,537)	(36,534)
Change in the fair value of contingent consideration payable	4,332	(12,813)
Net fair value gains/(losses) on financial assets at fair value through profit or loss	-	(6,351)
Financial income	1,889	1,310
Financial expenses	(7,638)	(6,090)
Loss before taxes	(28,952)	(60,478)
Income taxes	(2,295)	5,584
NET LOSS FOR THE PERIOD	(31,247)	(54,894)

Please refer to the table below for the reconciliation to loss from operations as presented within consolidated statement of profit or loss:

<i>Thousands of Euro (€)</i>	<i>30 June 2022</i>	<i>30 June 2021</i>
Loss from operations	(27,537)	(36,534)
Depreciations	5,826	4,637
Share-based payments	485	485
REBITDA	(21,226)	(31,412)
Share-based payments	(485)	(485)
EBITDA	(21,711)	(31,897)

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



Selva Luxembourg SA, represented by
Christian Moretti, Chairman



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



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 2022

Introduction

We have reviewed the accompanying interim consolidated statement of financial position of MITHRA PHARMACEUTICALS SA as of 30 June 2022 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.

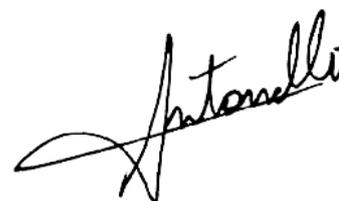
Scope of review

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 22, 2022



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

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