



2023
HALF YEAR RESULTS

mithra
Women's Health

Transforming women's health through innovation

2023 Half Year Results

as on 30 June 2023

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)

Table of contents

I. Interim management report	5
1. Corporate presentation	5
2. Operational Highlights including post-period end	5
3. Financial highlights	6
4. Corporate Governance	8
4.1. Capital and shares	8
4.2. Shareholders & Shareholder structure	10
4.3. Change and/or renewal in the composition of corporate bodies	11
5. Principal risks and uncertainties	12
6. Related party transactions	33
II. Interim condensed consolidated financial statements for the six months ended 30 June 2023	35
1. Interim consolidated statement of profit or loss	35
2. Interim consolidated statement of comprehensive loss	36
3. Interim consolidated statement of financial position	37
4. Interim consolidated statement of changes in equity	38
5. Interim consolidated statement of cash flow	39
6. Notes to interim condensed consolidated financial statements	40
6.1. Significant changes in the current reporting period	40
6.2. Summary of significant accounting policies	40
6.3. Segment and revenue information	42
6.4. Profit and loss information	45
6.5. Intangible assets and goodwill	45
6.6. Property, plant and equipment and right of use assets	46
6.7. Inventories	46
6.8. Contract assets and liabilities	46
6.9. Trade and other receivables	48
6.10. Equity	48
6.11. Financial liabilities	50
6.12. Fair value measurement of financial instruments	51
6.13. Trade and other payables	55
6.14. Deferred tax assets and liabilities	55
6.15. Share-based payments	56
6.16. Contingencies, Commercial Litigations and Commitments	57
6.17. Events after reporting period	58
6.18. Alternative performance measures	59
III. Statement of the responsible persons	62
IV. Statutory auditor's report	64

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's 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 270 collaborators and is headquartered in Liège, Belgium.

2. Operational Highlights including post-period end

Mithra has pursued the achievements of its deliverables in the first six months of 2023 both with regards to its estetrol unique native estrogen pipeline and its Complex Therapeutics business.

- Successful commercial launch of MYRING[®] in the U.S. by Mayne Pharma (January) under the trademark HALOETTE[®].
- Collaboration with VaRi Bioscience for the development of an innovative long-acting vaginal ring indicated for the treatment of vulvovaginal atrophy for menopausal women at our CDMO (February).
- Signed License and Supply Agreement (LSA) with Gedeon Richter for the commercialization of DONESTA[®] in Europe, the CIS countries, Latin America, Australia, and New Zealand (February).
- Positive progression in the research collaboration with BCI Pharma, with the identification of 4 distinct chemical series of selective CSF1R inhibitors and positive data in a range of in vitro and in vivo tests (March).
- Positive top-line safety results from DONESTA[®] Phase 3 Program in North America, which demonstrated meaningful reduction in vasomotor symptoms (VSM) from baseline and compared to placebo (March).
- Appointment of David H Solomon as Chief Executive Officer, effective April 11, 2023.
- Demonstrated proof-of-concept (POC) for a novel manufacturing process of a key estetrol intermediate, in collaboration with the University of Liège's Centre for Integrated Technology and Organic Synthesis (CiTOS) (May).
- Completed recruitment in paediatric study of Estelle in adolescent patients with data expected in H1 2024 (May).
- Changes within Mithra's Board of Directors: appointment of Life Science Strategy Consulting SRL (permanent representative Mr. Christian Homsey) as Chairman and the nominations of Ribono SRL (permanent representative Mr. Sydney Bens) as Independent Director, Inge Beernaert BV (permanent representative Mrs. Inge Beernaert) as Independent Director, and Gaudeto SRL (permanent representative Mr. Jacques Galloy) as Independent Director (May).

- Positive data from preclinical studies on CSF-1R inhibitors for treatment of endometriosis, oncology, and inflammatory disorders, in collaboration with BCI Pharma (June).
- Monetized investment in Mayne Pharma by selling shares, reducing Mithra's stake to 4.96% from 9.93%, in exchange for EUR 10.2 million (June).
- Actively exploring potential options that could maximize the value of the CDMO facility and regain sharper focus on the core business
- Signed License and Supply Agreement (LSA) with Searchlight for the commercialization of DONESTA® in Canada (July).
- Signed Supply Agreement with Gedeon Richter for the production of active pharmaceutical ingredient (API) for ESTELLE® and DONESTA® (August)
- Completed EUR 20 million private placement in equity with U.S. institutional investor; private placement included options with 2 and 5 year terms that could yield additional gross cash proceeds of up to EUR 45 million, if exercised (August).

3. Financial highlights

Key financial figures for the first half of 2023, compared with the first half of 2022, are presented below ¹:

Thousands of Euro (€)	30 June 2023	30 June 2022
Revenue	7,035	11,357
Gross profit	(1,121)	4,516
Research and development expenses	(27,009)	(22,714)
Other net operating expenses	(5,571)	(3,028)
REBITDA	(33,701)	(21,226)
Loss from operations	(40,219)	(27,537)
Net fair value gains/(losses)	(944)	4,332
Financial result	(10,272)	(5,748)
Loss before taxes	(51,435)	(28,952)
NET LOSS FOR THE PERIOD	(50,469)	(31,247)

Thousands of Euro (€)	30 June 2023	30 June 2022
Cash and cash equivalents at beginning of year	28,285	32,872
Net cash (used in)/ provided by operating activities	14,234	(33,204)
Net cash (used in)/ provided by investing activities	2,361	(12,124)
Net cash (used in)/provided by financing activities	(21,129)	41,765
Net increase/(decrease) in cash and cash equivalents	(4,535)	(3,563)
Effects of exchange rate changes on cash and cash equivalents	(37)	(10)
Cash and cash equivalents at end of period	23,714	29,299

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

- Revenues of EUR 7.0 million mainly driven by Myring® for EUR 2.4 million and Estelle product sales of EUR 2.6 million.

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

- Estelle® (Nextstellis®) U.S. product sales volumes (i.e. dispensed cycles) by Mayne Pharma increased by 80% in H1 2023, compared to H2 2022. Estelle H1 revenues were impacted by lower supply sales to Mayne, as Mayne sold trade units from inventory purchased in 2022 during H1 2023. Mayne's promotional initiatives to ramp up Estelle's U.S. sales also led to Mithra predominantly supplying sample units for the U.S. market during H1 2023 at reduced prices. As a result, while U.S. sales volumes by Mayne improved, a similar increase in supply sales volume is not reflected in Mithra's H1 2023 Estelle® sales figures, which also were impacted by lower supply prices. Given the 80% increase in sales volume by Mayne Pharma in H1 2023, compared to H2 2022, the continuing increase in sales volumes in U.S. and Europe, and the generally temporary nature of promotional product pricing, the average Estelle supply price and volume are in good shape to rebound in the future.
- Revenues from Estelle® (Drovelis®) EU product sales achieved EUR 1.5 million in H1 2023, as Gedeon Richter continued to launch the product in new countries: Ecuador and Malta, as well as Chile in August 2023.
- Sales of Novalon complex generic products, including Myring®, Tibelia® and Daphne®, achieved EUR 3.3 million, increased by 36% compared to the same period last year, primarily due to Myring® sales in Europe and Canada, and, as of December 2022, in U.S.
- Cash collection of EUR 50 million Donesta® from EUR 55 million out-licensing fee relating to Europe with Gedeon Richter (EUR 5 million were paid upon signature in H2 2022 and the remaining amount in February 2023). This did not impact H1 2023 revenue as it was already recognized as per IFRS15 in 2022, before the total sum was received.
- Research and development expenses (excluding depreciation) increased by 19% to reach EUR 27.0 million compared to EUR 22.7 million in the first half of 2022. This increase is mainly attributable to Donesta clinical studies and the end of the Phase 3 for the U.S. Mithra is maintaining a focus on innovation as the foundation of future growth while paying close attention to R&D costs.
- REBITDA for the first half of 2023 stands at EUR -33.7 million, compared to EUR -21.2 million for the first half of 2022, mainly due to lower revenues and higher expenses incurred in research and development.
- Below REBITDA, the negative impact of EUR -0.9 million booked in the change in fair value loss related to contingent consideration payable relates to Estelle®, mainly due to the update of both discount rate and timing effect. No payment was done during the period to former owners of Uteron Pharma.
- Financial result decreases mainly due to Highbridge/Whitebox facility to reach EUR 10.3 million for the first half of 2023.
- EUR 23.7 million cash position, on top of which the following facilities are available (subject to conditions):
 - EUR 12.5 million (under Tranche C2) 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 A was for an amount up to EUR 50,000,000.00, the second Tranche B was for an amount up to EUR 25,000,000.00, and the third Tranche C1 and the fourth Tranche C2 are each for an amount up to EUR 12,500,000.00. The first Tranche A has been drawn in August 2022 (following the signing of the Previous Facilities Agreements), the second Tranche B has been drawn in October 2022 and the third Tranche C1 has been drawn in June 2023 (following the signing of the Amended Facilities Agreements).
 - EUR 52.8 million in the framework of LDA capital commitment agreement entered in April 2020 with a maturity date of April 2025.
 - EUR 20 million were received by Mithra when the private placement with Armistice Capital was completed on 24 August 2023. The options granted as part of the placement may provide Mithra up to an additional EUR 22.5 million during the next 18 months, and up to EUR 45 million over a longer five-year term, subject to the exercise of the options by Armistice.

- Equity of EUR -8.7 million, compared to EUR 33.7 million at the end of December 2022. The total comprehensive loss for the period (EUR 49.0 million) was compensated for by the capital increase of Highbridge/Whitebox and by multiple conversions of the Highbridge/Whitebox loans for a total amount of EUR 6.2 million (net of transaction costs). Equity should be improved by the post-closing event on August 24, 2023, which relates to the EUR 20 million in gross proceeds via a private placement placed with Armistice Capital, a professional, qualified institutional investor in the U.S.
- Monetized investment in Mayne Pharma by selling shares and reducing Mithra's stake to 4.96% from 9.93% previously, in exchange for cash proceeds of EUR 10.2 million, which have been received by Mithra.
- Negative financing cash flow which includes, among other items, the repayment of straight loans and other loans/leases for EUR 30.6 million; and the payment of EUR 5.3 million of interests offset by the reception of tranche C1 of Highbridge/WhiteBox for EUR 12.3 million and by the capital increase for EUR 2.5 million.

4. Corporate Governance

4.1. Capital and shares

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

- On 14 February 2023, the Company announced that the second quarterly interest payment of the loan facility concluded with funds managed by Highbridge Capital Management, LLC ("Highbridge") and funds managed by Whitebox Advisors, LLC ("Whitebox", and together with Highbridge, each a "Lender"), was contributed in kind against the issuance of new shares for an aggregate amount of EUR 721,159.81 through the issuance of 276,120 new shares at an issue price of ca. EUR 2.61 per share.
- On 14th March 2023, the Company announced that following the first and second drawdowns by the Company under the loan facility concluded with funds managed by Highbridge and Whitebox, another portion of the loans was contributed in kind by Highbridge for an aggregate amount of EUR 1,854,570.72 through the issuance of 482,528 new shares at an issue price of ca. EUR 3.84 per share.
- On 12th May 2023, the Company announced that, the third quarterly interests payment of the loan facility concluded with funds managed by Highbridge and Whitebox was paid through contribution in kind for an aggregate amount of EUR 641,289.61 through the issuance of 285,409 new shares at an issue price of EUR 2.25.
- On 26th May 2023, the Company announced that, as a result of a capital increase completed on 25th May 2023 by means of an equity investment in the Company of a total amount of EUR 2.5 million by certain funds managed by Highbridge and Whitebox, the Company's share capital has increased from EUR 41,992,326.28 to EUR 42,824,254.00 and the number of issued and outstanding shares has increased from 57,359,031 to 58,495,395 ordinary shares, through the issuance of a total of 1,136,364 new ordinary shares at an issue price of EUR 2.20 per share.
- On 21st June 2023, the Company announced that it obtained access to a new tranche of the amended loan facility concluded with funds managed by Highbridge and Whitebox for an amount of EUR 12.5 million. The amendments to the loan facility announced by the Company on 25 May 2023 have been formalized as of that date. The amendments include, among others, the access to the aforementioned tranche of EUR 12.5 million, the change of the conversion price of the principal amount of the convertible loans from a floating conversion price to a fixed conversion price (subject to certain customary anti-dilution and takeover protections), and an increase of the interest of the loans.

In order to be able to draw the new tranche, a meeting of the board of directors of the Company has been held to approve the amended conversion features of the loan facility under the authorized capital of the Company for an amount up to EUR 19 million (issue premium excluded, as the case may be). In addition, the Company will convene an extraordinary general shareholders' meeting in order to approve the issuance of additional new shares to cover the amended conversion feature of the loans.

Following the drawdown of the Third Tranche by the Company under the loan facility concluded with funds managed by Highbridge/ Whitebox, a third portion of the commitment fee, representing 25% of the aggregate amount of EUR 2,911,372.65, has been settled through the issuance of 91,663 new shares of the Company at a price per share of EUR 7.9401.

As a reminder, a first portion representing 65% of the commitment fee was already settled in shares at the time of the first drawing and the second portion representing a further 10% of the commitment fee was already settled in shares at the time of the second drawing.

Post period on 21 September 2023, Mithra announced that following the first, second and first part of the third drawdown by the Company under the loan facility concluded with Highbridge/Whitebox, another portion of the loans was contributed in kind by Highbridge against the issuance of new shares for an aggregate amount of EUR 1,157,143.13 through the issuance of 521,339 new shares at an aggregate issue price of ca. EUR 2.22 per share. Following the last contribution in kind, the outstanding principal amount of the loans already drawn is EUR 60,360,161.29.

- Post period, on 28 August 2023, the Company announced that it completed the private placement of 10 million new shares for an amount of EUR 20 million in gross proceeds that it had announced on 24 August 2023 (the "Private Placement"). H.C. Wainwright & Co. acted as the exclusive placement agent for the Private Placement. As a result of the completion of the Private Placement, the share capital of the Company was increased from EUR 42,891,360.13 to EUR 50,212,360.13 and the number of issued and outstanding shares of the Company was increased from 58,587,058 to 68,587,058 ordinary shares, through the issuance of a total of 10,000,000 new shares at an issue price of EUR 2.00 per new share. Under the terms of the Private Placement, the Investor committed to subscribe for 10 million new shares of the Company, of which 7.8 million shares will be admitted to trading and listing on Euronext Brussels immediately upon their issuance, and the remaining 2.2 million shares will be admitted to trading and listing following the approval of a listing prospectus.

In addition, the Investor will receive options, with an 18-month term, to subscribe for an additional 10 million new shares at an exercise price of EUR 2.25 per share. If the options are exercised in full, Mithra would receive additional gross proceeds of EUR 22.5 million, increasing the total gross amount raised from the Private Placement to EUR 42.5 million. Also, as part of the terms of the Private Placement, the Investor will receive additional warrants with a five-year term, to subscribe for 10 million new shares, at an exercise price of EUR 2.25 per share. This warrant plan has not been issued yet by the Company.

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 720,571 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) and the application of adjustments mechanisms.

- 300,000 subscription rights issued on September 7, 2020, giving the right to subscribe for a total number of 313,292 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) and the application of adjustments mechanisms;
- 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).

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 2023 are:

Shareholder	Address	Number of voting rights	% of voting rights ⁴
François Fornieri ¹		10,809,882	18,45 %
NOSHAQ SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,488,257	9,37 %
Marc Coucke ²		2,791,923	4,77 %
Bart Versluys ³		1,641,407	2,80%
Free float		37,855,589	64,61 %

1. François Fornieri, Alychlo NV and Noshag NV jointly hold 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 the latest equity transaction, 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 ⁴
François Fornieri ¹		10,809,882	15.64 %
Armistice		10,000,000	14.47%
NOSHAQ SA	Rue Lambert-Lombard, 3, B-4000 Liège, Belgium	5,488,257	7.94%
Marc Coucke ²		2,791,923	4.04%
Bart Versluys ³		1,641,407	2.38%
Free float		38,376,928	55.53%

1. François Fornieri, Alychlo NV and Noshag NV jointly hold 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 25th May 2023, the Company announced that at its Annual General Meeting, the appointment/renewal of the following Directors for a two-year mandate was approved. The Board of Directors is now made up of 6 members with varied backgrounds spanning both the financial and pharmaceutical sectors, bringing extensive expertise to Mithra covering all aspects of pharmaceutical development. Following these appointment updates the Board will include four independent directors and two non-independent directors, one who is an being executive and the other non-executive.

Until the General Meeting to be held in 2025, 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>
Life Science Strategy Consulting SRL (permanent representative: Mr. Christian Homsy)	Director Chairman	2025	Independent	Nomination and Remuneration Committee
Ribono SRL (permanent representative: Mr. Sydney Bens)	Director	2025	Independent	Risk and Audit Committee
Gaudeto SRL (permanent representative: Mr. Jacques Galloy)	Director	2025	Independent	Risk and Audit Committee (Chair)
Eva Consulting SRL (permanent representative: Mr. Jean-Michel Foidart)	Director	2025	Executive	Risk and Audit Committee
Inge Beernaert BV (permanent representative Mrs. Inge Beernaert)	Director	2025	Independent	Nomination and Remuneration Committee (Chair)
Alius Modi SRL (permanent representative : Mrs. Valérie Gordenne)	Director	2025	Non-executive	Nomination and Remuneration Committee

Following the appointment of Dr David Horn Solomon effective 11 April 2023, the composition of the Company's internal committees has changed leading to a reduced Executive Committee and the creation of a senior leadership meeting. As a result, thereof, only the functions of CEO, Chair of the Scientific Advisory Board, CFO, CCEAO, CSO and COO are included in the Executive Committee; the remaining functions being represented at the senior leadership meeting.

The members of the Executive Committee as of 30 June 2023 are listed in the table below:

<i>Name/ Designation</i>	<i>Function</i>
David Horn Solomon	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 (CCEAO)
GD Lifescience SRL (permanent representative: Mr. Graham Dixon)	Chief Scientific Officer (CSO)

Post period, Xavier Paoli joined the Company on 1st September 2023 as Chief Operating Officer (COO).

5. Principal risks and uncertainties

The Board of Directors considers that the main risk factors summarized in section 1.8 of the Annual Report 2022 which are deemed to be reproduced herein, remain relevant and are completed as far as 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 2022 Annual Report (Financial Risk Management).

The Group has a business structure built on:

- (i) a development portfolio which includes the development of Estetrol-based product candidates in contraception and menopause indications as well as other potential indications such as wound healing, NHIE, and Complex Therapeutics ;
- (i) the CDMO development and manufacturing facility, which will manufacture an important part of its innovative products, but also provides services for customer in terms of development and manufacturing of third parties' products);
- (ii) a commercialized portfolio of our Estetrol-based product Estelle® in the field of oral contraception in several regions, branded generics, in several regions.
- (iii) a diversification of the R&D pipeline through rights' acquisition option relating to a development programs led by the Belgian company BCI Pharma on innovative kinase inhibitors notably indicated for the treatment of female cancers and endometriosis.

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 has transitioned towards a commercial biopharma company in 2023, most focus is on the development portfolio and products' commercial launch.

I. Risks relating to Mithra's 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.

Mithra has incurred net losses and negative operating cash flows in each period since 2020. At end of June 2023, Mithra has a total of EUR 464.8 million accumulated losses on its balance sheet and realized a consolidated net loss of EUR 50.5 million for the 30 June 2023. 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 (expected in H2 2023) as well as on the monitoring of our funding activities and of our cost saving plan.

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 that occurred in the beginning of 2023. However, other than license revenue, it does not expect to recognise revenue from its Donesta[®] product until 2025. Mithra's revenues from Estelle[®] and Myring[®], which were EUR 7.7 million and EUR 1.4 million in the six months ended 30 June 2022 and EUR 1.1 million and EUR 2.4 million in the six months ended 30 June 2023, respectively, have not been sufficient to compensate for its research and development and general and administrative expenses, which were EUR 27.5 million and EUR 7.0 million in the six months ended 30 June 2022 and EUR 32.4 million and EUR 7.2 million in the six months ended 30 June 2023, respectively, resulting in a loss from operations of EUR 26.2 million and EUR 40.2 million for the year ended 31 December 2022 and the six months ended 30 June 2023, respectively. This has been due to a range of factors, including the fact that these products are in the early stages of commercialisation and the relatively long-time scale required for pharmaceuticals companies to realise a return on their research and development investments. For those reasons, 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.

Mithra will require additional funds during and beyond this period in order to meet its operating and capital expenditure needs, such as licensing milestones (Donesta[®] or Estelle[®]), the proceeds of financing/equity transactions, exploration of strategic options to unlock the value of our assets and co-development strategies on some new indications to reduce the amount of R&D expenses supported by Mithra.

On 15 February 2023, Gedeon Richter Plc. ("Richter") and Mithra Pharmaceuticals ("Mithra") announced that they signed a licence agreement for the commercialisation of Donesta[®], a novel product candidate for the treatment of post-menopausal symptoms. Under the terms of the licence agreement, Mithra is eligible to receive EUR 55 million in upfront payment – EUR 5 million was paid upon signature of the binding term sheet in December 2022 and EUR 50 million in February 2023 upon signature of the license agreement

On 8 August 2022, the Company and the Lenders entered into the Previous Facilities Agreement which has been amended and restated in the framework of the entering into of the Amended Facilities Agreements pursuant to which, the Lenders agreed to provide, for a period of three years from the date of the Previous Facilities Agreement, a financing by loans convertible into Shares to the Company for a maximum aggregate principal amount of EUR 100,000,000.00, divided in several tranches (certain drawdowns subject to the fulfilment of certain conditions), with an outstanding amount at any time not greater than EUR 75,000,000.00. The first Tranche A was for an amount up to EUR 50,000,000.00, the second Tranche B was for an amount up to EUR 25,000,000.00, and the third Tranche C1 and the fourth Tranche C2 are each for an amount up to EUR 12,500,000.00. The first Tranche A has been drawn in August 2022 (following the signing of the Previous Facilities Agreements), the second Tranche B has been drawn in October 2022 and the third Tranche C1 has been drawn in June 2023 (following the signing of the Amended Facilities Agreements). The loans under Tranche C2 may be drawn following the satisfaction of certain conditions. If, at any time, the outstanding amount under the loans under Tranche A and Tranche B is less than EUR 20,000,000.00 (e.g., as a result of

conversion of loans into shares of the Company) and the Company does not meet the conditions to draw Tranche C2 of the loan facility, a mechanism is provided to allow the Company to nevertheless draw additional loans in an amount such that the aggregate amount outstanding under the loan is equal to or less than EUR 20,000,000.00. Following the drawdown of the first Tranche A by the Company in the amount of EUR 50,000,000.00, the drawdown of the second Tranche B by the Company in the amount of EUR 25,000,000.00, and the drawdown of the third Tranche C1 by the Company in the amount of EUR 12,500,000.00, a total principal amount of EUR 26,139,838.71 has already been repaid in shares by the Company by contributions in kind by the Lenders of Receivables due to the Lenders by the Company. There remains EUR 32,076,161.29 as principal amount to be repaid for Tranche A, EUR 16,784,000.00 for Tranche B and EUR 12,500,000.00 for Tranche C. The loans carry in principle an interest between 8.00% per year (for Tranche A and Tranche B) and 9.00% per year (Tranche C). The post-closing event private placement of EUR 20 million that occurred with Armistice Capital the 24 August 2023 was supported by "Highbridge/Whitebox", by agreeing to a 45 day restriction on conversions. In consideration of the Lenders' support, the terms of the loan facility will be amended, such that the conversion price for the conversion of outstanding principal amounts for Mithra shares will be EUR 2.25 (subject to certain customary anti-dilution and takeover protections), and the interest rate on the outstanding principal will be adjusted to 13%.

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 Prospectus, five put options have been exercised and settled (two of which were settled in 2022), for a total amount of EUR 22,193,021.00, 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 52,806,979.00.

In an effort to further minimize equity dilution going forward, the Company intends no longer to make drawings under the GSI facility.

Post-closing private placement of EUR 20 million that occurred with Armistice Capital on 24 August 2023 allows Mithra to access an additional total of up to EUR 22.5 million during the next 18 months, or EUR 45 million over the longer term, subject to the exercise of the options

Further, Mithra's management expects entering into another Donesta® license and supply agreement(s) for the US in 2023, which should generate upfront payments, supply revenues and royalties. Mithra's existing capital resources would be sufficient 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.

Management recognizes that material uncertainties exist in the budget due to uncertainties on (i) timing and magnitude of some expected transactions identified here above as well as on (ii) the resolution of a currently ongoing commercial dispute. Still, the management is committed and confident that all potential deviations from the cash flow in the budget can be mitigated with additional financing alternatives, which are currently under investigation.

By managing uncertainty in this way and considering the financing obtained and still available pursuant to the funding initiatives summarised above in addition to expected licensing milestones and potential sale of assets, Mithra is of the opinion that, taking into account its available cash and cash equivalents, it does 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 annual report.

Furthermore, the Company does not believe that the Ukraine war has an impact on the Company's going concern. The Company does not have business direct business relationships with Russia or Ukraine but its products are sold through partners. There is no direct or indirect impact of the conflict on the day-to-day business of the Company. The Company is not specifically impacted by inflation, supply disruption or cyber-attacks due to the current geopolitical conflict. With regards to climate-related matters, the Company is not impacted in a material way by extreme weather conditions.

II. Risks relating to the E4 pipeline

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 organization in place to launch its product candidates on its own. Before the commercialization of Estelle® (outside of Gedeon Richter's territories), 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 organization 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 commercialization of Donesta® as well as its future product candidates 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 commercialize the product through its own sales force. In that event, Mithra might need to invest significant financial and management resources. This would likely lead to an increase in its research and development costs, which were EUR 85.2 million and EUR 64 million end of 2021 and 2022, respectively. 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.

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 reported in March 2023 for the C302 trial (North America) and at the beginning of 2024 for the C301 trial (EU, Russia, Latin America, United States and Canada). Submission is planned in H2 2023 of C302 and in 2024 for the C301.

The timing for the commercialisation of Donesta® remains uncertain in the US, in particular given Mithra's intention to enter into a strategic partnership agreement to achieve this. See " –If Mithra is unable to enter into a partnership or strategic alliance for the further development and commercialisation of Donesta® or its other product candidates, it may incur additional costs, and/or the development of these products might be delayed". See also "Business – Principal activities –Donesta® - An innovative hormone therapy targeting several major menopausal symptoms".

Furthermore, Mithra is currently developing other Estetrol-based products in neuroprotection for the treatment of hypoxic-ischemic encephalopathy ("HIE") in neonates and wound healing. Mithra's Phase I clinical program started in 2022. Mithra's wound healing project is in preclinical development. These products will require substantial technical, preclinical and clinical developments and testing prior to receiving marketing approvals. Their future commercialization and the generation of additional revenues linked to these products, will significantly depend on Mithra's ability to successfully develop, register and commercialize those products.

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.

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 E4-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 product development or non-clinical formulation 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 E4 pipeline. Accordingly, if Mithra is forced to shift its focus to complex therapeutics and injectables and away from E4-based products, management expects that Mithra's revenues and profitability would be severely impacted.

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.

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 another supply agreement with another supplier 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 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".

III. Risks relating to commercialisation

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. This could cause Mithra to fail to generate any meaningful revenue from these products or, once it has begun to generate revenue, in a substantial reduction in such revenue. 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. In particular, if Donesta® is not accepted by physicians and other stakeholders, this would represent a significant setback for Mithra and would limit its revenue growth.

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.

IV. 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 who uses much lower quantities of palladium and therefore being less prone to volatile palladium prices., 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. In order to mitigate these potential delivery delays, Mithra currently relies on a key estetrol tolling supplier and has signed an agreement with another supplier in order to secure alternative options for the transformation of estetrol in the future. Going forward, however, Mithra may not be able to secure such alternative supply accordingly for each territory where the products are commercialised.

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 already 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, trademarks, 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[®] contraceptive pill, Donesta[®] menopausal treatment 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.

In the context of certain financing arrangements with ING Belgium SA/NV and Belfius Bank NV, respectively, as well as in the context of the Facilities Agreements, Mithra has granted security on the businesses of Estetra SRL (Belgium), Novalon SA (Belgium) and Mithra Recherche et Développement SA (Belgium) (and, in the case of the Facilities Agreements, also on the business of the Company). In each case, the pledged businesses include (either expressly or implicitly) all intellectual property rights owned by the relevant pledger, and in some instances separate pledge registrations have been taken with the competent offices in respect of particular items of such intellectual property. If at any time, pursuant to the relevant financing arrangements, the security on the relevant businesses and/or intellectual property rights were to be enforced, the pledged intellectual property rights may be lost to Mithra.

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[®] contraceptive pill, Donesta[®] menopausal treatment 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.

V. Risks relating to global events

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. In addition, the Ukraine conflict has disrupted trade and aggravated inflation for basic goods like energy, wood and metals. Further economic deteriorations could negatively impact Mithra's future revenues and profits. See also "Mithra is subject to the risk of increasing raw material prices, particularly in relation to solvents used in the synthesis of estetrol".

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.

VIII. Legal and regulatory risks

Seeking and obtaining regulatory approval for drugs can be a long, expensive and uncertain process. Strict or changing regulatory regimes, government policies and legislation in any of Mithra's target markets may delay, prohibit or reduce potential sales.

Following completion of the relevant clinical trials, Mithra's products must obtain marketing approval from the European Commission following an opinion from the European Medicines Agency (the "EMA"), from the United States Food and Drug Administration (the "FDA") or other competent regulatory authorities before the products can be commercialised in a given market, and each such approval will need to be periodically renewed. The process of obtaining marketing approvals, both in the United States and in foreign jurisdictions, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Applications for regulatory approval may require extensive pre-clinical, clinical and technical testing, all of which must be undertaken in accordance with the requirements of regulations established by the relevant regulatory agencies.

At the date of this Prospectus, the Estelle® oral contraceptive is the only E4-based product commercialised by Mithra. The Donesta® menopausal program has reached late clinical development stage. Mithra's Phase I clinical programme in neonatal HIE, for which Mithra obtained orphan drug designation in both the United States and the European Union, started in 2022. Mithra's wound healing project is in pre-clinical development. These products will require substantial technical, pre-clinical and clinical developments and testing prior to receiving marketing approvals.

For details of the regulatory regime applicable to Mithra's products in each of the jurisdictions in which Mithra has commercialised or intends to commercialise these products, see "Business Overview— Government Regulation".

In the European Union, Mithra would need to obtain a marketing authorisation from the European Commission or national competent authorities in relevant markets and comply with a body of regulatory requirements including Directive 2001/83/EC on the Community Code relating to Medicines for Human Use. For further detail of these obligations, see "Business Overview – Government Regulation ". In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and implementing regulations.

Ensuring compliance with these regulations is an intensive process requiring substantial human and financial resources. The burden of compliance may become significant relative to revenue from Mithra's products. If Mithra fails to comply with applicable pharmaceutical regulations, it may be forced to withdraw its products from the relevant market. In addition, it may be exposed to administrative, civil and criminal sanctions and lawsuits.

Failure to comply with the applicable requirements at any time pre- or post-approval may result in a delay of approval or administrative or judicial sanctions. These sanctions could include imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, damages claims or criminal prosecution.

The regulations to which Mithra is subject are complex and have tended to become more stringent over time. Mithra may be adversely affected by changes in government marketing approval policy or legislation applying to its product candidates. Varying interpretations of the data obtained from non-clinical and clinical testing could delay, limit, or prevent marketing approval of a product. Any marketing approval Mithra obtains may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Mithra is obliged to comply with regulatory requirements that include obtaining regulatory approval pursuant to the applicable laws and regulations before it can market or sell its products in each market.

Moreover, each regulatory agency may impose its own requirements and may refuse to grant or may require additional data before granting marketing approval even if marketing approval has been granted by other agencies. Changes in regulatory approval policies or enactment of additional regulatory approval requirements may delay or prevent the products from obtaining or renewing marketing approval. Also, post-approval manufacturing and marketing of Mithra's products may show different safety and efficacy profiles to those demonstrated in the data on which approval to test or market said products was based. Such circumstances could lead to the withdrawal or suspension of approval.

Mithra's CDMO as well as the manufacturing facilities of its third-party suppliers are subject to significant regulations and approvals. If Mithra or its third-party manufacturers or suppliers fail to comply with these regulations or maintain these approvals, Mithra could lose the regulatory approvals required to operate the CDMO.

Mithra's CDMO offers a wide range of solutions from early drug development, clinical batches and commercial manufacturing, with expertise in complex polymeric products (such as vaginal rings and implants. Since July 2021, Mithra's CDMO also operates a new manufacturing facility dedicated to fill and finish production of complex liquid injectables and biologicals in vials, pre-filled syringes or cartridges. While currently, Mithra mainly depends on the CDMO in relation to Myring®, going forward it expects to realise additional revenue from products manufactured for third parties. In the first half of 2023, Mithra's CDMO generated revenues amounting to approximately EUR 1 million.

The manufacturing practices of Mithra and its third-party suppliers are subject to ongoing regulation and periodic inspection. Any failure to follow and document the adherence to regulatory requirements by Mithra or its third-party suppliers may lead to delays in production of Mithra's own and third-party products.

Failure to comply with applicable regulations could also result in regulatory authorities taking various actions, including:

- levying fines and other civil penalties;
- imposing consent decrees or injunctions;
- requiring Mithra to suspend or put on hold one or more of Mithra's clinical trials;
- suspending or withdrawing regulatory approvals;
- delaying or refusing to approve pending applications or supplements to approved applications;
- requiring Mithra to suspend manufacturing activities, sales, imports or exports;
- requiring Mithra to communicate with physicians and other customers about concerns related to actual or potential safety, efficacy, and other issues involving Mithra's products;
- mandating product recalls or seizing products;
- imposing operating restrictions; and
- seeking criminal prosecutions.

If Mithra were to lose its regulatory approvals in respect of the CDMO, this could have an adverse effect on its revenue from Myring® as well as a loss of potential revenue from the production of other products. In addition, if fines were to be imposed upon it in relation to violations at the CDMO, this would adversely affect Mithra's profitability.

Mithra is subject to the risk of product liability claims or claims of defectiveness, which could result in uninsured losses for Mithra or recalls of the relevant product.

Mithra is exposed to the risk of potential product liability claims arising from adverse reactions, product failures and malfunctions and product use. Mithra maintains product liability insurance at levels which management believes are in line with market practice. To date, no product liability claim has been initiated against Mithra. However, Mithra may not be able to maintain sufficient insurance coverage on commercially acceptable terms in the future, and its insurance coverage may not provide adequate protection against any product liability claims or claims of product defectiveness. As a consequence, Mithra might have to face liabilities for a claim that may not be covered by its insurance or its liabilities could exceed the limits of its insurance.

Moreover, product failures or safety issues discovered during the clinical trial phase may also lead to the suspension or termination of the relevant trial. In addition, product failures and malfunctions, quality issues may result in a recall of the product, which may relate to a specific manufacturing lot or may impact all products in the field. Recalls may occur at any time during the life cycle of a product once regulatory approval has been obtained for commercial distribution. Recalls of Mithra's products would divert managerial and financial resources, can result in damaged relationships with regulatory authorities such as the FDA, lead to loss of market share to competitors and materially and adversely affect Mithra's business, financial condition, results of operations and prospects. In addition, any product recall may result in irreparable harm to Mithra's reputation. Any product liability claims or other claims of defectiveness or any product recalls could have a financial impact on Mithra (including due to it being required to record a provision in respect of product liability claims to which it becomes subject) or could be detrimental to Mithra's reputation.

Mithra has obtained significant grants and subsidies (mostly in the form of "avances récupérables") and the terms of certain of these agreements may hamper the Company in its flexibility to choose a convenient location for its activities.

Mithra has been awarded several grants and subsidies by governmental or semi-governmental bodies, consisting for the most part of so-called "recoverable advances" ("avances récupérables"), which it needs to reimburse over time. In the year ended 31 December 2021 and in the year ended 31 December 2022, Mithra had refundable government advances of EUR 14.4 million and EUR 9.5 million. For further detail regarding these refundable government advances, please refer note 9.15.2 of the 2022 Annual Report, which is incorporated by reference in this Prospectus. Refundable government advances. Such reimbursements consist of a fixed portion and a variable portion (dependent on net sales of the relevant product). These reimbursements (comprising the combined fixed and variable portions) can amount to up to twice the amounts received, i.e., in the aggregate, an amount of maximum EUR 38 million. While the variable portion of these advances is only due upon commercialisation, the fixed parts will become due in any event. In most cases, there is an exemption to reimburse the advances if the beneficiary of the grant renounces the grant (abandoning the project, thereby avoiding having to pay the fixed repayment amount for a "failed" project) and transfers its rights over the results of the research to the body which has granted the subsidy, thereby avoiding the payment of any amount after such transfer. However, it cannot be excluded that Mithra will be obliged to reimburse grants or subsidies in the future. Some of these grants/subsidies will have to be refunded in the event that the product is successfully commercialised

These subsidies and grants provide that Mithra must maintain its headquarters in the Walloon Region. These provisions affect Mithra's ability to relocate its activities. Furthermore, the ability of any potential foreign acquirer to use the Company's intellectual portfolio built on the basis of these grants and subsidies may be impaired by provisions which would prevent the transfer of such intellectual property outside of Belgium.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about drugs. If Mithra is found to have made false or misleading claims about its products, or otherwise have violated promotion or advertising restrictions, it may become subject to significant fines and/or other liabilities.

Regulations promulgated by the FDA and other regulatory agencies require Mithra to sufficiently substantiate any claims that it make for its products, including claims comparing its products to other companies' products, and must abide by the FDA or a comparable foreign regulatory authority's strict requirements regarding the content of promotion and advertising.

If a relevant governmental authority determines that Mithra's promotional materials violate promotional and advertising requirements, it could request modifications to Mithra's promotional materials or subject Mithra to regulatory or enforcement actions, which may include the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. U.S, E.U. or other applicable governmental authorities might also take action if they consider Mithra's promotional materials to constitute off label promotion, which could result in significant fines or penalties under other statutory provisions, such as laws prohibiting false claims for reimbursement. In that event, Mithra's reputation could be damaged, and adoption of Mithra's products could be impaired. This risk will be heightened as Mithra commercially launches its products in the United States, given the FDA's focus on false or misleading claims and the potential for significant fines. Currently, Estelle® and Myring® are approved for marketing in the United States.

In addition, industry codes particularly in the pharmaceutical sector contain further requirements for pharmaceutical promotion and prohibit companies from engaging in certain promotional activities. Competitors may file complaints with industry associations and courts in which case such instances may enforce violations of such codes and applicable regulations with penalties including fines and publication of decisions. If Mithra becomes subject to such enforcement or court actions its business, financial condition, reputation, stock price and prospects may be materially harmed.

Mithra is subject to healthcare fraud and abuse and other laws applicable to Mithra's business activities. If Mithra is unable to comply with such laws, it could face substantial penalties.

Mithra is subject to various federal and state fraud and abuse laws. Such laws include the federal and state anti-kickback statutes, physician payment transparency laws and false claims laws. These laws may impact, among other things, Mithra's and its partners' proposed sales and marketing activities and require it to implement additional internal systems for tracking certain marketing expenditures and to report to governmental authorities. In addition, Mithra may be subject to patient privacy and security regulations by both the federal government and the states in which Mithra conducts its business. The laws that may affect Mithra's ability to operate include, inter alia:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly or wilfully soliciting, receiving, offering or paying any remuneration, overtly or covertly, directly or indirectly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order, arrange for, or recommendation of, any good, facility, item or services for which payment may be made, in whole or in part, under a federal healthcare program;
- federal false claims laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from or approval by a governmental payer program that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which established new federal crimes for, among other things, knowingly and wilfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, wilfully obstructing a criminal investigation of a healthcare offense, concealing a material fact, or making materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- an increasing number of state transparency laws that require manufacturers to provide reports to state governments on pricing and marketing information; and
- a federal law known as the Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals, and medical supplies to report annually to the Centres for Medicare & Medicaid Services information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Mithra is also subject to European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and transfers of value to healthcare providers, organisations and/or patient organisations.

If Mithra's operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to it, it may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of Mithra's operations, the exclusion from participation in government healthcare programmes and individual imprisonment. In particular, the Anti-Kickback Statute provides for both criminal and civil penalties for violations. The criminal penalties include fines of up to US\$25,000 per violation and five years' imprisonment. In addition, the Office of the Inspector General for the Department of Health and Human Services can pursue civil penalties of up to US\$50,000 per violation plus three times the amount of any government overpayment. Penalties for Anti-Kickback Statute violations also frequently include a period of debarment or exclusion from participation in Medicare, Medicaid, and all other federal plans and programmes that provide health benefits, which could impact reimbursement for Mithra's products, as applicable, if it were deemed to have violated the statute. Violations of the other statutes referred to above can result in similar sanctions to the Anti-Kickback Statute.

Mithra faces risks related to environmental matters and animal testing activities

Mithra's CDMO is subject to a broad range of environmental laws and requirements, including those governing discharges to the air and water, remediation of contamination associated with the release of any hazardous substances at Mithra's manufacturing facility and offsite disposal locations and occupational safety and health. Mithra is also subject to strict laws and requirements governing the handling or disposal of solid and hazardous substances and wastes. Mithra has made, and will continue to make, expenditures to comply with such laws and requirements. Future events, such as changes in existing laws and regulations, or the enforcement thereof, or the discovery of contamination at Mithra's manufacturing facility, may give rise to additional compliance or remediation costs that could have a material adverse effect on Mithra's business, financial condition, results of operations and prospectus. Such laws and requirements are constantly changing, are different in every jurisdiction and can impose substantial fines and sanctions for violations. As a manufacturer, Mithra is exposed to some risk of claims with respect to environmental matters, and material costs or liabilities may be incurred in connection with any such claims.

In addition, Mithra has been required to use animals to test certain of its products, and may be required to use animals to test future products. In particular, it is conducting animal testing in relation to its Zoreline® product. Testing on animals can be vital for the development of a product. If applicable regulations were to ban this practice, or if, due to pressure from animal welfare groups, Mithra is no longer able to source animals to perform such tests, it would be difficult and, in some cases, impossible to develop products in certain jurisdictions under the applicable marketing authorisations. In addition, negative publicity regarding Mithra's use, or the industry's use, of animal subjects could harm Mithra's reputation.

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 2026. 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 2024, 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. While first preclinical results confirm the broad potential of innovative and proprietary inhibitors of CSF1R to treat different pathologies, including endometriosis, cancer and inflammatory disorders, if the project does not deliver the expected benefits in those areas, 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

IX. 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

During the period under review, there were no new decisions or transactions in execution of a decision falling within the competence of the Board of Directors and involving a party related to the Company within the meaning of the international accounting standards adopted in accordance with Regulation (EC) 1606/2002.

Consequently, the Board of Directors did not have to apply the procedure laid down in paragraphs 3, 4 and 4/1 of Article 7:97 of the Company Code, and therefore did not have to disclose any conflict of interest in this respect.

II.

Interim condensed consolidated
financial statements for the six
months ended 30 June 2023

II. Interim condensed consolidated financial statements for the six months ended 30 June 2023

1. Interim consolidated statement of profit or loss

<i>Thousands of Euro (€)</i>		<i>30 June 2023</i>	<i>30 June 2022</i>
	<i>Notes</i>		
Revenue	6.3.2	7,035	11,357
Cost of sales		(8,430)	(7,083)
Gross profit		(1,396)	4,275
Research and development expenses	6.4	(32,386)	(27,518)
General and administrative expenses	6.4	(7,198)	(7,042)
Selling expenses	6.4	(1,194)	(1,185)
Other operating income	6.4	1,955	3,933
Loss from operations		(40,219)	(27,537)
Change in the fair value of contingent consideration payable	6.12	(944)	4,332
Financial income	6.4	741	1,889
Financial expenses	6.4	(11,013)	(7,638)
Loss before taxes		(51,435)	(28,952)
Income taxes	6.4	966	(2,295)
NET LOSS FOR THE PERIOD		(50,469)	(31,247)

Loss per share

Result for the purpose of basic loss per share, being net loss	(50,469)	(31,247)
Weighted average number of shares for the purpose of basic loss per share	57,096,900	45,042,816
Basic loss per share (in Euro)	(0.88)	(0.69)
Diluted loss per share (in Euro)	(0.88)	(0.69)

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 2023</i>	<i>30 June 2022</i>
Net loss for the period		(50,469)	(31,247)
Other comprehensive income or (loss)		1,508	(16,022)
<i>Items that may be reclassified to profit or loss:</i>			
Gains/(losses) on cash flow hedges	6.10.2	1,895	(15,906)
Income taxes relating to these items		(474)	3,976
<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	86	(4,093)
Total comprehensive loss for the period		(48,961)	(47,269)
<i>Attributable to</i>			
Owners of the parent		(48,961)	(47,269)
Non-controlling interests		-	-
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		(48,961)	(47,269)

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

3. Interim consolidated statement of financial position

Thousands of Euro (€)	Notes	30 June 2023	31 December 2022
ASSETS			
Property, plant and equipment	6.6	39,051	40,717
Right-of-use assets	6.6	63,259	65,534
Goodwill	6.5	5,233	5,233
Other intangible assets	6.5	136,537	134,905
Deferred income tax assets	6.14	16,009	16,354
Contracts assets	6.8	203	2,828
Derivatives financial assets		67	-
Investments in equity securities	6.12	11,315	21,437
Other non-current assets	6.12	10,144	9,544
Non-current assets		281,817	296,552
Inventories	6.7	49,447	50,312
Contract assets	6.8	5,630	44,988
Derivatives financial assets		200	-
Trade and other receivables	6.9	13,934	22,277
Cash and cash equivalents		23,714	28,285
Current assets		92,926	145,863
TOTAL ASSETS		374,744	442,414

Thousands of Euro (€)	Notes	30 June 2023	31 December 2022
EQUITY AND LIABILITIES			
Share capital	6.10.1	42,891	41,228
Additional paid-in-capital	6.10.1	413,163	408,647
Other reserves	6.10.2	(20)	(19,934)
Accumulated deficit		(464,763)	(396,254)
Equity attributable to equity holders		(8,730)	33,687
Subordinated loans	6.11	10,124	10,710
Other loans	6.11	136,291	127,052
Lease liabilities	6.11	34,350	38,253
Refundable government advances	6.11	8,592	8,127
Other financial liabilities	6.11, 6.12	75,304	74,210
Derivative financial liabilities	6.12.2	15,601	15,261
Contract liabilities	6.8	10,300	-
Provisions	6.16	266	266
Deferred tax liabilities	6.14	3,574	4,420
Non-current liabilities		294,402	278,298
Current portion of subordinated loans	6.11	919	1,252
Current portion of other loans	6.11	19,848	45,980
Current portion of lease liabilities	6.11	6,230	5,179
Current portion of refundable government advances	6.11	1,499	1,417
Current portion of other financial liabilities	6.11, 6.12	13,558	15,959
Derivative financial liabilities	6.12.2	2,306	2,561
Trade and other payables	6.13	44,711	58,082
Current liabilities		89,071	130,430
TOTAL EQUITY AND LIABILITIES		374,744	442,414

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 2022	32,250	340,769	(2,545)	(336,633)	33,840
Net loss for the period	-	-	-	(31,247)	(31,247)
Gains/(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
Balance at 1 January 2023	41,228	408,647	(19,934)	(396,254)	33,687
Net loss for the period	-	-	-	(50,469)	(50,469)
Gains/(losses) on cash flow hedges	-	-	1,421	-	1,421
Changes in the fair value of equity investments at fair value through other comprehensive income or loss	-	-	86	-	86
Total comprehensive loss for the period	-	-	1,508	(50,469)	(48,961)
Investments in equity securities derecognition	-	-	18,041	(18,041)	-
Multiple conversions of the Highbridge/Whitebox loans including accrued interest, net of transaction costs	831	2,848	-	-	3,679
Highbridge/Whitebox capital increase of 25 May 2023	832	1,668	-	-	2,500
Share-based payments expense	-	-	365	-	365
Balance at 30 June 2023	42,891	413,163	(20)	(464,763)	(8,730)

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

5. Interim consolidated statement of cash flow

Thousands of Euro (€)	Notes	30 June 2023	30 June 2022
CASH FLOWS FROM OPERATING ACTIVITIES			
Result from operations		(40,219)	(27,537)
<i>Adjustments for:</i>			
Depreciation, amortization and impairment charges	6.5, 6.6	6,154	5,828
R&D tax credit		(581)	(1,007)
Share-based payments	6.15	(621)	485
Grant income		(304)	(125)
Write-down of account receivables, contract assets and inventories		(1,810)	816
Subtotal		(35,894)	(21,541)
Increase/(decrease) in trade and other payables	6.13	(11,712)	721
(Increase)/decrease in trade and other receivables	6.9	8,322	1,634
(Increase)/decrease in inventories	6.7	1,189	(5,099)
(Increase)/decrease in contract assets and liabilities	6.8	53,769	(3,916)
Realized foreign exchange gains/(losses)	6.10.2	47	(5,003)
Net cash (used in)/ provided by operating activities		14,234	(33,204)
CASH FLOWS FROM INVESTING ACTIVITIES			
Payment for acquisition of tangible fixed assets	6.6	(302)	(3,585)
Proceeds from disposal of tangible fixed assets		-	170
Payment for acquisition of intangible fixed assets	6.5	(5,296)	(8,708)
Other financial liabilities payments	6.11, 6.12	(2,250)	-
Proceeds from disposals of investment in equity securities	6.12	10,208	-
Net cash (used in)/ provided by investing activities		2,361	(12,124)
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of subordinated loans and other loans	6.11	(27,585)	(1,592)
Proceeds from subordinated loans and other loans	6.11	12,341	2,425
Proceeds from refundable government advances and other grants		186	-
Lease payments	6.11	(3,026)	(3,129)
Interests paid	6.4	(5,275)	(4,815)
Other financial expenses		(270)	-
Proceeds from issuance of shares (net of issue costs)	6.10.1	2,500	35,204
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		(21,129)	41,765
Net increase/(decrease) in cash and cash equivalents		(4,535)	(3,563)
Cash and cash equivalents at beginning of year		28,285	32,872
Effects of exchange rate changes on cash and cash equivalents		(37)	(10)
Cash and cash equivalents at end of period		23,714	29,299

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 January, Mayne Pharma Group Limited and Mithra announced the launch of HALOETTE® (etonogestrel and ethinyl estradiol) a vaginal hormonal contraceptive ring into the US market. To be noted that later in February, Dr Reddy's bought US generic products portfolio of Mayne Pharma and is becoming now the main US partner for Mithra for Myring®.

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

- Mithra, appoints Dr. David H Solomon as Chief Executive Officer starting on 11 April 2023. This follows the assignment of Mr. Leon Van Rompay and an extensive, global search process for a successor. Dr. David H Solomon brings over 30 years of experience of strong strategic, operational, and innovation-minded leadership to Mithra. He has a proven track record of successful R&D pipeline delivery, strategic business development and deal making across multiple leading roles in the life sciences, biotechnology and pharmaceutical industries in the US and Europe.
- End of May, Mithra and Mithra's General Meeting of Shareholders approved the appointment and renewal of its Board of Directors for a two-year mandate. The Board of Directors is now made up of 6 members with varied backgrounds spanning both the financial and pharmaceutical sectors, bringing extensive expertise to Mithra covering all aspects of pharmaceutical development.
- In June, Mithra announced the sale of 4,221,815 shares in Mayne Pharma Group Limited at a price of A\$3.86 per share, in line with Mayne Pharma's last close (ie 0% discount).

Note : For more details about the operations during this period, please refer to 6.12 Fair value measurement of financial instruments and 6.10. Equity

- In June, the amendments to the loan facility and access to the new tranche of EUR 12.5 million come in addition to other measures to improve the Company's financial health that were announced earlier by the Company, such as the EUR 2.5 million equity raising by the Company through the issuance of 1,136,364 new shares to the Lenders that was completed on 25 May 2023.

Note : For more details about the operations during this period, please refer to 6.10. Equity and to 6.11 Financial liabilities.

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 2023 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 2022. 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 2023.

The condensed consolidated interim financial information has been reviewed, not audited, by the statutory auditor. Please refer to the issued report included at the end of these interim financial statements, section IV.

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 2022 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 2023 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, please refer to the issued report included at the end of these interim financial statements, section IV.

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 2022.

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.

At end of June 2023, Mithra has a total of EUR 464.8 million accumulated losses on its balance sheet and realized a consolidated net loss of EUR 50.5 million. 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 2023) as well as on the monitoring of our funding activities and of our cost savings plan.

Moreover, Mithra's management expects entering into another Donesta® license and supply agreement(s) for the US during the second half of 2023, which should generate upfront payments, supply revenues and royalties. Based on the internal budget and cash forecast, Mithra's existing capital resources would be sufficient 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.

Management recognizes that material uncertainties exist in the budget due to uncertainties on (i) timing and magnitude of some expected transactions identified here above as well as on (ii) the resolution of a currently ongoing commercial dispute. Still, the management is committed and confident that all potential deviations from the cash flow in the budget can be mitigated with additional financing alternatives, which are currently under investigation.

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 23.7

million at 30 June 2023, strengthened by post-closing event described below 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 2024.

We remind that the Company still has access to EUR 12.5 million (under Tranche C2) 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, to EUR 52.8 million in the framework of LDA capital commitment agreement entered in April 2020 with a maturity in April 2025. Also post-closing private placement of EUR 20 million that occurred with Armistice Capital the 24th August 2023 permits to Mithra to get access to additional total of up to EUR 22.5 million during the next 18 months, or EUR 45 million over the longer term, subject to the exercise of the options.

The Company does not believe that COVID-19 or the Ukraine war has an impact on the Company's going concern.

The Company does not have business relationships with Russia or Ukraine. There is no direct or indirect impact of the conflict on the day-to-day business of the Company. The Company is not specifically impacted by inflation, supply disruption or cyber-attacks due to the current geopolitical conflict. With regards to climate-related matters, the Company is not impacted in a material way by extreme weather conditions.

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, 2023.

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 2023 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

<i>Thousands of Euro (€)</i>	<i>30 June 2023</i>	<i>30 June 2022</i>
Product sales	5,926	6,172
Out-licensing	157	4,207
Others	952	978
Total revenue	7,035	11,357

Group revenue amounts to EUR 7.0 million for the six months period ended 30 June 2023.

Product sales (EUR 5.9 million) are lower than in the comparative period of the previous year :

- Sales from generic products in our portfolio (including Myring[®], Tibelia[®] and Daphne[®]), at EUR 3.3 million, increased by 36% compared to the same period last year. The majority concerns Myring[®] sales in Europe, Canada and since December 2022, in U.S..
- Estelle[®] H1 revenues (EUR 2.6 million) were impacted by lower supply sales to Mayne, as Mayne sold trade units from inventory purchased in 2022 during H1 2023. Mayne's promotional initiatives to ramp up Estelle's U.S. sales also led to Mithra predominantly supplying sample units for the U.S. market during H1 2023 at reduced prices. As a result, while U.S. sales volumes by Mayne improved, a similar increase in supply sales volume is not reflected in Mithra's H1 2023 Estelle[®] sales figures, which also were impacted by lower supply prices. Revenues from Estelle[®] (Drovelis[®]) EU product sales achieved EUR 1.5 million in H1 2023, as Gedeon Richter continued to launch the product in new countries: Ecuador and Malta, as well as Chile in August 2023.

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 2023 and 2022, as well as the basis on which revenue is recognized:

Thousands of Euro (€)

30 June 2023

	Product sales	Out-licensing	Others
Primary Geographic Markets			
Belgium	462	-	176
Europe	3,168	10	775
Outside Europe	2,296	147	-
Total	5,926	157	952
Product type			
Generics	3,309	140	-
E4 Contraception	2,617	17	-
E4 Menopause	-	-	-
Others	-	-	952
Total	5,926	157	952
Timing of transfer of goods and services			
At a point in time	5,926	157	-
Over time	-	-	952
Total	5,926	157	952

	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	-
Over time	-	-	978
Total	6,172	4,207	978

6.4. Profit and loss information

The Group reported a net loss of EUR 50.5 million for the first half 2023, compared to a net loss of EUR 31.2 million for the first half 2022.

Revenues stand at EUR 7.0 million mainly driven by Myring® for EUR 2.4 million and Estelle® product sales of EUR 2.6 million.

- Sales from generic products in our portfolio (including Myring®, Tibelia® and Daphne®), at EUR 3.3 million, increased by 36% compared to the same period last year. The majority concerns Myring® sales in Europe, Canada and since December 2022, in U.S..
- Estelle H1 revenues were impacted by lower supply sales to Mayne, as Mayne sold trade units from inventory purchased in 2022 during H1 2023. Mayne's promotional initiatives to ramp up Estelle's U.S. sales also led to Mithra predominantly supplying sample units for the U.S. market during H1 2023 at reduced prices. As a result, while U.S. sales volumes by Mayne improved, a similar increase in supply sales volume is not reflected in Mithra's H1 2023 Estelle® sales figures, which also were impacted by lower supply prices. Revenues from Estelle® (Drovelis®) EU product sales achieved EUR 1.5 million in H1 2023, as Gedeon Richter continued to launch the product in new countries: Ecuador and Malta, as well as Chile in August 2023.

Research and development expenses (including depreciation) increased by 17.7% to reach EUR 32.3 million compared to EUR 27.5 million in the first half of 2022. This increase is mainly attributable to Donesta clinical studies and the end of the Phase 3 for the US.

General and administrative expenses and selling expenses are relatively stable regarding the same period in 2022.

Other operating income (EUR 1.9 million, compared to EUR 3.9 million in first half 2022) are composed of R&D tax credit for EUR 0.5 million, of EUR 0.5 million of wage tax reductions for researchers and of costs re invoicing for EUR 0.4 million which strongly decreased compared to 2022.

The negative impact about EUR -0.9 million of change in fair value related to contingent consideration payable for Estelle® is mainly the consequence of the updated of both discount rate and timing effect.

Financial income decrease is explained by the impact of the remeasurement of refundable government advances measured at amortized cost, due to the review of revenue forecasts.

Increase of financial expenses is mostly driven by the interest charges, higher than in first half 2022, linked to the higher financial liabilities during the period. The financial expenses contain interests and commitment fees paid in kind to Highbridge and Whitebox lenders for a total amount of EUR 2.8 million.

The group recorded a tax income of EUR 1 million for the six months that mainly results of the review of tax impact on temporary differences, partially compensated by the recognition of tax losses carried forward. 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 historical 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, and now relating to post approval safety study).

The increase in intangible assets during the first semester of 2023 (for EUR 1.6 million) is explained by capitalization of development costs related to the project "E4 synthesis" (EUR 0.5 million) and the post-approval complementary studies for Estelle[®] (EUR 2.7 million), partially compensated with amortization (EUR 1.7 million).

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

During the period, the Group recorded EUR 0.3 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 (capitalized until 2022). In order to finance these machines, the Group entered into several leases. Right-of-use assets additions amount to EUR 0.2 million.

Depreciations for property plant and equipment and right of use assets respectively amount to EUR 2.0 million and EUR 2.4 million.

6.7. Inventories

Thousands of Euro (€)	30 June 2023	31 December 2022
Raw materials & consumables	48,273	49,180
Semi-finished goods	1,051	1,300
Finished goods	285	316
Total at cost	49,608	50,797
Cumulated amounts written off at the beginning of the period	(484)	(72)
Reversal of write-down of inventories credited to expense in the period	331	72
Addition of write-down of inventories debited to expense in the period	(8)	(484)
Cumulated amounts written off at the end of the period	(161)	(484)
Total net carrying amount	49,447	50,312

Inventories are relatively flat. The slight decrease is mainly explained by the commercial launch of Myring[®] in the USA.

6.8. Contract assets and liabilities

Contract assets arise when the Group recognises revenue in excess of the amount billed to the customer and the right to payment is contingent on conditions other than simply the passage of time, such as the completion of a related performance obligation.

Contract liabilities represent the obligation to transfer goods or services to a customer for which the Group has received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before the Group transfers goods or services to the customer, a contract liability is recognised when the payment is made, or the payment is due (whichever is earlier).

Regarding out-licensing revenue, 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.

Regarding product sales revenue, sales-based royalties received in connection with the license of IP, also called variable supply prices, represent a form of variable consideration as the payments are contingent on the occurrence of future events which is customer's subsequent sales. Variable supply prices payments are estimated and included in the transaction price based when the order is made available to the customer (Ex Works sales), the Group's performance obligation is fully fulfilled. Variable income can therefore be recognized at the same time as fixed income if it is considered highly probable.

An analysis has been conducted in order to determine whether the single performance obligation was satisfied as at 30 June 2023.

The tables below present the roll forward of the related contract assets and liabilities :

<i>Thousands of Euro (€)</i>	<i>Contracts assets</i>
Balance at 1 January 2023	47,816
Revenue billed during the period already recognised in previous years	(41,116)
Revenue recognized during the period	621
Impairment of contract assets	(1,487)
Balance at 30 June 2023	5,834

<i>Thousands of Euro (€)</i>	<i>Contract liabilities</i>
Balance at 1 January 2023	-
Amount billed during the period not recognised as revenue	10,300
Balance at 30 June 2023	10,300

Regarding out-licensing revenue, following signature of the binding term sheet in December 2022 with Gedeon Richter for the commercialization of Donesta[®], out-licensing revenue for a total amount of EUR 44.7 million was booked, out of which EUR 5 million was paid in December. In this context, in February 2023, Gedeon Richter and Mithra signed a licence agreement. Under the terms of this licence agreement, Mithra collected in cash an additional EUR 50 million as upfront payment. This amount was accounted partially in deduction of contract asset (EUR 39.7 million) and partially in addition to contract liabilities (EUR 10.3 million). Indeed, according to our IFRS 15 accounting policies, this amount of EUR 10.3 million, paid by Gedeon Richter was not recognized as revenue (will be the case, as soon as the Group will achieve the performance obligations).

As a result of submitting regulatory file in Latin America for Estelle[®], previously unbilled revenue was invoiced, leading to a cash collection about EUR 0.5 million in the context of the license and supply agreement of Estelle[®] in Latin America with Gedeon Richter.

In the framework of "variable supply price", EUR 0.9 million already recognized in previous years were billed during the period. Revenue recognized during the period amounts to EUR 0.6 million on Estelle[®] products that were delivered in 2023 and on which royalties will be due by our partners in the next quarters according to their own sales of Estelle[®] in their markets. An unexpected impairment of contract assets of EUR 1.5 million is impacting the gross profit (cost of sales). It is attributed to a reduction in the variable supply price recognized for Estelle[®] sold by Mayne during the first half of 2023. Indeed, Mayne recently communicated to Mithra that the Estelle net sales price upon which the supply price is calculated – was lower than expected based on previous Mayne's reporting. This implies the impairment of the related contract assets to account for the lower net sales price. This sales price could improve in the future periods.

As at 30 June 2023, the balance of contract assets considers:

- Unbilled milestones revenue for EUR 3.0 million, which relates to Gedeon Richter for Estelle® in Latin America.
- Unbilled “variable supply price” for EUR 2.8 million related to Estelle® products already delivered by Mithra to our partners.

As at 30 June 2023, the balance of contract liabilities considers EUR 10.3 million billed milestone to Gedeon Richter for Donesta licence agreement.

6.9. Trade and other receivables

Trade and other receivables decreased compared to previous closing mainly impacted by :

- Myring® commercialization in the U.S. at the end of the year 2022 (EUR 1.6 million license milestone and first deliveries invoiced end of December for EUR 1.5 million, paid in the meantime);
- EUR 2.9 million dividend from Mayne Pharma formally approved in 2022 and collected in February 2023;
- At the opposite, prepayments increased by EUR 1.5 million

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 2,272,084 new shares for a total amount of EUR 6,179,464 (net of transaction costs).

As of 30 June 2023, following the completion of the above-mentioned capital increases, the Company’s capital consisted of a recognized amount of EUR 42,891,360 with 58,587,058 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 2023 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 2022	56,314,974	41,228	408,647	449,875
Interests on Highbridge/Whitebox loans paid in kind on 13 February 2023	276,120	202	519	721
Conversions of the Highbridge/Whitebox loans dated 13 March 2023, including accrued interest, net of transaction costs	482,528	353	1,247	1,600
Interests on Highbridge/Whitebox loans paid in kind on 11 May 2023	285,409	209	432	641
Highbridge/Whitebox capital increase of 25 May 2023	1,136,364	832	1,669	2,500
Commitment fees on Highbridge/Whitebox loans paid in kind on 21 June 2023	91,663	67	650	717
Balance at 30 June 2023	58,587,058	42,891	413,163	456,054

The amounts mentioned above are presented net of transaction costs.

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</i>	<i>Cash flow hedge reserve</i>	<i>Total other reserves</i>
Balance at 1 January 2022	16,779	(16,370)	(2,954)	(2,545)
Gains/(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)
Balance at 1 January 2023	17,688	(26,831)	(10,791)	(19,934)
Gains/(losses) on cash flow hedges	-	-	1,421	1,421
Changes in the fair value of equity investments at fair value through other comprehensive income or loss	-	86	-	86
Total comprehensive loss for the period	17,688	(26,745)	(9,370)	1,508
Investments in equity securities derecognition	-	18,041	-	18,041
Share-based payments expense	365	-	-	365
Balance at 30 June 2023	18,053	(8,704)	(9,370)	(20)

▪ 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 2022 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.

In June 2023, Mithra sold 4,221,815 Mayne shares. Following the equity securities derecognition, EUR 18 million of accumulated change in fair value was transferred from other reserves to accumulated deficit. Mithra continues to hold 4,221,816 shares in Mayne Pharma. In this context, as at 30 June 2023, the other reserves contain the cumulative changes in fair value of financial assets through other comprehensive income or loss for EUR 8.7 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 30 June 2023, the cash flow hedge reserve contains the cumulative changes in fair value of hedge instruments (net of tax) for EUR 5.2 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	50,960	-1.160
1-2 years	76,000	-1.173
2-5 years	40,000	-1.269
As at 30 June 2023	166,960	-1.191

6.11. Financial liabilities

An overview of the financial liabilities is shown below.

Thousands of Euro (€)	30 June 2023			31 December 2022		
	Total	Current	Non-Current	Total	Current	Non-Current
Subordinated loans	11,043	919	10,124	11,962	1,252	10,710
Other loans	156,139	19,848	136,291	173,032	45,980	127,052
<i>Bank loans</i>	19,634	16,164	3,470	46,301	42,296	4,005
<i>Convertible bond</i>	85,538	3,684	81,854	84,593	3,684	80,909
<i>Convertible loans</i>	50,967	-	50,967	42,138	-	42,138
Lease liabilities	40,580	6,230	34,350	43,432	5,179	38,253
Refundable government advances	10,091	1,499	8,592	9,544	1,417	8,127
Derivatives financial liabilities - Convertible loans	9,310	-	9,310	7,597	-	7,597
Sub-total liabilities arising from financing activities	227,163	28,496	198,667	245,566	53,828	191,738
Other financial liabilities	88,862	13,558	75,304	90,169	15,959	74,210
Derivatives financial liabilities - Hedge	8,597	2,306	6,291	10,225	2,561	7,664
Total financial liabilities	324,623	44,360	280,262	345,960	72,348	273,612

Here is the roll forward of liabilities arising from financing activities:

Thousands of Euro (€)	31 December 2022	Cash flow		Non-cash changes			30 June 2023
		Inflow	Outflow	Additions	Amortized costs adjustments	Conversions to equity	
Subordinated loans	11,962	-	(919)	-	-	-	11,043
Other loans	173,032	10,245	(28,598)	-	2,877	(1,417)	156,139
<i>Bank loans</i>	46,301	-	(26,666)	-	-	-	19,635
<i>Convertible bond</i>	84,593	-	(1,932)	-	2,877	-	85,538
<i>Convertible loans</i>	42,138	10,245	-	-	-	(1,417)	50,967
Lease liabilities	43,432	-	(3,026)	174	-	-	40,579
Refundable government advances	9,544	-	-	-	547	-	10,091
Derivatives financial liabilities - Convertible loans	7,597	1,896	-	-	-	(183)	9,310
Total	245,566	12,140	(32,543)	174	3,424	(1,600)	227,169

During the first semester of 2023, straight loans have been repaid at maturity for an amount of EUR 26.0 million.

The Group obtained access to a new tranche of the amended loan facility concluded with funds managed by Highbridge Capital Management, LLC (“Highbridge”) and funds managed by Whitebox Advisors, LLC (“Convertible loans” in the above table) for an amount of EUR 12.5 million. Cash inflows, net of transaction costs, are presented under the lines Other loans and Derivative financial liabilities (see the note 6.12.2). During the period, a portion of these convertible loans was contributed in kind for an aggregate amount of EUR 1.6 million (see the note 6.10 Equity).

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

6.12. Fair value measurement of financial instruments

The following table presents the Company's financial assets and financial liabilities measured and recognised or unrecognised at fair value at 30 June 2023 :

<i>Thousands of Euro (€)</i>	<i>Balanc e at 30 June 2023</i>	<i>Recognised fair value measurements</i>	<i>Fair value measuremen t hierarchy</i>	<i>Unrecognised fair value measurements</i>
Financial assets				
Financial assets at fair value through other comprehensive income				
Investments in equity securities	11,315	11,315	Level 1	-
Financial assets at amortised cost				
Other non-current assets	10,144	-	-	10,144
Contracts assets	5,834	-	-	5,834
Trade and other receivables	13,934	-	-	13,934
Cash and cash equivalents	23,714	-	-	23,714
Financial liabilities				
Financial liabilities at fair value through profit and loss				
Derivatives financial liabilities - Convertible loans	9,310	9,310	Level 2	-
Other financial liabilities - Estelle ®	82,612	82,612	Level 3	-
Financial liabilities at fair value through other comprehensive				
Derivatives financial liabilities - Hedge	8,597	8,597	Level 2	-
Liabilities at amortised cost				
Subordinated loans	11,043	-	-	11,043
Other loans - convertible bond	85,538	-	-	85,538
Other loans - others	19,634	-	-	19,634
Lease liabilities	40,580	-	-	40,580
Refundable government advances	10,091	-	-	10,091
Contract liabilities	10,300	-	-	10,300
Trade and other payables	44,711	-	-	44,711
Other financial liabilities - Zoreline ®	6,250	-	-	6,250

The following table presents the Company's financial assets and financial liabilities measured and recognised or unrecognised at fair value at 31 December 2022 :

<i>Thousands of Euro (€)</i>	<i>Balance at 31 December 2022</i>	<i>Recognised fair value measurements</i>	<i>Fair value measurement hierarchy</i>	<i>Unrecognised fair value measurements</i>
Financial assets				
Financial assets at fair value through other comprehensive				
Investments in equity securities	21,437	21,437	Level 1	-
Financial assets at amortised cost				
Other non-current assets	9,544	-	-	9,544
Contracts assets	47,816	-	-	47,816
Trade and other receivables	22,277	-	-	22,277
Cash and cash equivalents	28,285	-	-	28,285
Financial liabilities				
Financial liabilities at fair value through profit and loss				
Derivatives financial liabilities - Convertible loans	7,597	7,597	Level 2	-
Other financial liabilities - Estelle ®	81,669	81,669	Level 3	-
Financial liabilities at fair value through other comprehensive				
Derivatives financial liabilities - Hedge	10,225	10,225	Level 2	-
Liabilities at amortised cost				
Subordinated loans	11,962	-	-	11,962
Other loans - convertible bond	84,593	-	-	84,593
Other loans - others	46,301	-	-	46,301
Lease liabilities	43,432	-	-	43,432
Refundable government advances	9,544	-	-	9,544
Trade and other payables	58,082	-	-	58,082
Other financial liabilities - Zoreline ®	8,500	-	-	8,500

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 2023, 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 recognised or disclosed at fair value</i>
Investments in equity securities	Level 1	11,315
Assets recognised or disclosed at fair value		11,315

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.

In June 2023, Mithra sold 4,221,815 Mayne shares at a price of A\$3.86 per share. Mithra continues to hold 4,221,816 shares in Mayne Pharma.

<i>Thousands of Euro (€)</i>	<i>Investments in equity securities</i>
Balance at 1 January 2023	21,437
Sale of shares	(10,208)
Fair value loss through other comprehensive income	86
Balance at 30 June 2023	11,315

▪ 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 recognised or disclosed at fair value</i>
Other financial liabilities - Estelle ®	Level 3	82,612
Derivatives financial liabilities - Convertible loans	Level 2	9,310
Derivatives financial liabilities - Hedge	Level 2	8,597
Liabilities recognised or disclosed at fair value		100,519

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 2023	81,669
Payments related to Estelle ®	-
Fair value loss through profit or loss	944
Balance at 30 June 2023	82,612

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 2023 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	25%	75%	64,782
Alternative 2	45%	55%	82,612
Alternative 3	75%	25%	108,849
Alternative 4	100%	0%	125,095

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).

The increase of fair value for the contingent consideration for Estelle® (EUR 82.6 million in June 2023, compared to EUR 81.7 million in December 2022) is explained by the update of timing compensated with an increase in discount rate (WACC 14.10% compared to 13.78% end of 2022).

No payment occurred during the period.

December 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	25%	75%	63,479
Alternative 2	50%	50%	81,669
Alternative 3	75%	25%	101,688
Alternative 4	100%	0%	118,047

Derivatives financial liabilities - Convertible loans

The convertible loans meet the definition of a hybrid financial instrument with two components, one host liability and one derivative financial liability, given that those two elements are not closely related.

The derivative financial liability is recognized at fair value through profit or loss.

The convertible loans are presented under Derivatives financial liabilities as follows:

<i>Thousands of Euro (€)</i>	<i>Derivatives financial liabilities - Convertible loans</i>
Balance at 1 January 2023	7,597
Initial recognition	1,896
Conversions to equity	(183)
Balance at 30 June 2023	9,310

The fair value of the conversion feature was determined using the Option Prepayment Amount rate. Under the facility, in case of early prepayment or conversion, the early prepayment or conversion include a compensatory amount representing a percentage of the relevant amount calculated on the basis of a "Black Scholes" digressive option pricing model. The Option Prepayment Amount represents a form of compensation for the loss of option value represented by the exercise of the conversion mechanism in advance of the maturity date of the loan facility. The earlier the conversion, the greater the Option Prepayment Amount. This contractually agreed rate is considered as the most appropriate rate to measure the derived financial liability at any time.

The initial fair value for the new tranche drawn in June 2023 (EUR 12.5 million) is calculated using the rate of 15.17% : EUR 1.9 million.

During the period, a portion of these convertible loans was contributed in kind for an aggregate amount of EUR 0.2 million related to derivative financial instrument (see the note 6.10 Equity).

Derivatives financial liabilities - Hedge

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>Derivatives financial liabilities - Hedge</i>
Balance at 1 January 2023	10,225
Fair value gain through other comprehensive income	(1,627)
Balance at 30 June 2023	8,597

6.13. Trade and other payables

Trade and other payables decrease is namely due to the open amount of Trade accounts payable. As a reminder, this section contains, among others, trade payables against E4 manufacturer with whom Mithra is in current dispute. Please refer to the note 6.16 Contingencies, Commercial Litigations and Commitments.

6.14. Deferred tax assets and liabilities

<i>Thousands of Euro (€)</i>	<i>Balance at 30 June 2023</i>	<i>Balance at 31 December 2022</i>
Deferred tax asset to be recovered after more than 12 months	16,009	16,354
Deferred tax assets	16,009	16,354

Deferred tax assets and liabilities are rather stable (globally EUR 0.5 million increase on the balance sheet compared to previous closing). Variances are 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 a limited recognition of tax losses carried forward for the period.

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).

6.15. Share-based payments

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

	30 June 2023		31 December 2022	
	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	24.3	2,710,900
Granted	-	-	-	-
Forfeited	-	-	-	-
Exercised	-	-	-	-
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 365k has been recognized at the consolidated statement of income.

No new warrant plan was issued during the first half of 2023.

6.16. Contingencies, Commercial Litigations and 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.

Conditional payments

For more details on contingent consideration payments, reference is made to section 6.12.2.

The contingent considerations relating to the asset deal Donesta® are not accounted for based on accounting policy 9.2.6.

As the acquisition of Donesta® qualified as an asset deal – because the definition of a business as defined in IFRS 3 was not met – the transaction was measured initially at cost. Subsequently the intangible assets will be measured at their cost less any accumulated amortisation and any accumulated impairment losses. The transaction price further contains several instalments which, since the date of acquisition, are considered as a contingent price based on future performance, hence this measurement is more an attribute of fair value measurement throughout the life of the asset than being representative of the cost model upon initial recognition of the asset. Hence, the contingent payments are disclosed as a contingent liability for an amount of EUR 12,000k, with any liability being re-measured at the end of each reporting period as an adjustment to the cost of intangible assets to the extent that it relates to future reporting periods.

Seqens commercial litigation

Since end of 2022, Mithra is involved in a commercial litigation with its Estetrol supplier, SEQENS and more particularly, with one of the SEQENS' affiliates, which is PCAS. The payments requested during the legal proceedings are formally disputed and part of a broader complex factual situation. As far as it may be necessary, some amounts have been provisioned taken into account all facts known as of today, knowing that the commercial litigation is ongoing without resolution expected before the end of the year. Mithra takes appropriate measures to protect its interests and those of its stakeholders. To mitigate its risks, Mithra has initiated the process of selecting new Estetrol suppliers in a diversification perspective. In such a way, Mithra is taking all necessary measures to secure the continuity of Estetrol's deliveries in the medium and long term.

Collaborative research and development arrangements

In September 2019, Mithra contracted with ICON Plc to manage the pivotal Phase III trial of Donesta® to demonstrate the long-term efficacy and safety of Estetrol in the relief of vasomotor symptoms in postmenopausal and hysterectomized women in the US. The expenses needed to conclude the study are currently forecasted at approximately EUR 1 million.

On 6 November 2019, the Company also entered into a contract with ICON Plc for a similar study in Europe and the rest of the world. The expenses needed to conclude the study are currently forecasted at approximately EUR 12 million.

In December 2022, Mithra contracted with ZEG Berlin to manage the PASS study Estelle® requested by the EMA, which approved the PASS study protocol. This study is conducted to demonstrate that the product has a similar impact as the second-generation pills on VTE (Venous thromboembolism) incidence, which is of high interest for Mithra. The expenses needed to complete the study are currently forecasted at approximately EUR 40 million until 2028.

Others

Straights loans with ING Belgium SA/NV and Belfius Bank NV as well as convertible loans are secured on the businesses of Estetra SRL (Belgium), Novalon SA (Belgium) and Mithra RD SA (Belgium) (and, in the case of the Facilities Agreements, also on the business of the Company), including any existing and future intellectual property rights that are part of those businesses. More specifically about the nature of the guarantees, Straight loans ING & BELFIUS are secured with pledges on receivables, receivable pledge mandates, mortgage mandates in respect of the office building owned by the Group.

Regarding commitments and pledges towards financial institutions and banks, please refer to section 9.3. Financial Risk Management – Liquidity Risk of the annual report 2022.

6.17. Events after reporting period

In July 2023, Mithra signed a License and Supply Agreement (LSA) with Searchlight for the commercialization of DONESTA® in Canada. Searchlight is a private Canadian-specialty pharmaceutical company and has repeatedly ranked among the top-growth companies in Canada, with one of the largest portfolios of women's health products and associated sales team in the Canadian market. Mithra and Searchlight have a continuing partnership for NEXTSTELLIS®, a combined oral contraceptive product based on Estetrol and HALOETTE®, a vaginal contraceptive ring in Canada. NEXTSTELLIS® was launched in Canada in Q3 2021, while HALOETTE® was launched in Q1 2022.

In August 2023, Gedeon Richter and Mithra signed a supply agreement for the production of active pharmaceutical ingredient (API) for the combined oral contraceptive Estelle® and Donesta®. The agreement specifies that Gedeon Richter will manufacture and supply the Estetrol (E4) native estrogen for Mithra's Estelle® and Donesta®.

In August 2023, Mithra raised EUR 20 million in gross proceeds via a private placement of 10 million new ordinary shares at an issue price of EUR 2.00 per share, representing a 17% discount to the closing share price on 23 August 2023. This private placement has been placed with Armistice Capital, a professional, qualified institutional investor in the U.S. Under the terms of the deal, Armistice has committed to subscribe for 10 million new shares of Mithra, of which 7.8 million shares will be admitted to trading and listing on Euronext Brussels immediately upon their issuance, and the remaining 2.2 million shares will be admitted to trading and listing following the approval of a listing prospectus. In addition, the Armistice will receive options, with an 18-month term, to subscribe for an additional 10 million new shares at an exercise price of EUR 2.25 per share. If the options are exercised in full, Mithra would receive additional gross proceeds of EUR 22.5 million, increasing the total gross amount raised from the Private Placement to EUR 42.5 million. Also, as part of the terms, Armistice will receive additional options, with a five-year term, to subscribe for 10 million new shares, at an exercise price of EUR 2.25 per share. If the additional options are exercised in full, Mithra would receive another EUR 22.5 million, bringing the total cash gross proceeds from the private placement to EUR 65 million.

Funds managed by Highbridge Capital Management, LLC ("Highbridge") and funds managed by Whitebox Advisors, LLC ("Whitebox"), which provided a convertible loan facility to Mithra, also supported the deal by agreeing to a 45 day restriction on conversions. In consideration of their support, the terms of the loan facility were amended, such that the conversion price for the conversion of outstanding principal amounts for Mithra shares will be EUR 2.25 (subject to certain customary anti-dilution and takeover protections), and the interest rate on the outstanding principal will be adjusted to 13%.

In the press release of 21 September 2023, Mithra announced that following the first, second and first part of the third drawdown by the Company under the loan facility concluded with Highbridge/Whitebox, another portion of the loans was contributed in kind by Highbridge against the issuance of new shares for an aggregate amount of EUR 1,157,143.13 through the issuance of 521,339 new shares at an aggregate issue price of ca. EUR 2.22 per share. Following the last contribution in kind, the outstanding principal amount of the loans already drawn is EUR 60,360,161.29.

There has been no other subsequent event which occurred between the end of the six-month period ended on June 30, 2023 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 2023</i>	<i>30 June 2022</i>
Revenue	7,035	11,357
Cost of sales	(8,156)	(6,842)
Gross profit	(1,121)	4,516
Research and development expenses	(27,009)	(22,714)
General and administrative expenses	(6,365)	(5,818)
Selling expenses	(1,160)	(1,143)
Other operating income	1,955	3,933
REBITDA	(33,701)	(21,226)
Share-based payments expenses	(365)	(485)
EBITDA	(34,066)	(21,711)
Depreciations	(6,153)	(5,826)
Loss from operations	(40,219)	(27,537)
Change in the fair value of contingent consideration payable	(944)	4,332
Financial income	741	1,889
Financial expenses	(11,013)	(7,638)
Loss before taxes	(51,435)	(28,952)
Income taxes	966	(2,295)
NET LOSS FOR THE PERIOD	(50,469)	(31,247)

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 2023</i>	<i>30 June 2022</i>
Loss from operations	(40,219)	(27,537)
Depreciations	6,153	5,826
Share-based payments	365	485
REBITDA	(33,701)	(21,226)
Share-based payments	(365)	(485)
EBITDA	(34,066)	(21,711)

III.
Statement of the responsible
persons

III. Statement of the responsible persons

The CEO and the CFO of Mithra declare that, to their knowledge:

- The condensed consolidated 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.



David H Solomon, Managing Director



Christophe Maréchal, CFO
CMM&C SPRL, represented by

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 2023

Introduction

We have reviewed the accompanying interim condensed consolidated statement of financial position of MITHRA PHARMACEUTICALS SA as of 30 June 2023 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 condensed 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 condensed 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.

Material uncertainty related to going concern

We draw attention to Note 6.2.4 of the interim condensed consolidated financial statements which describes the events and conditions indicating that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

Battice, September 25, 2023



BDO Réviseurs d'Entreprises SRL
Statutory auditor

Represented by Christophe Pelzer*

*Acting for a company

For all additional information,
please address to:

Investor Relations

investorrelations@mithra.com

Press

press@mithra.com

+32 4 349 28 22

www.mithra.com

Contact

Rue Saint Georges, 5
4000 Liège Belgium
+32 (0)4 349 28 22
info@mithra.com

mithra
Women's Health

