Mithra Financial Results for First-Half 2023

- Good progress on strategy to strengthen balance sheet and refocus on innovative R&D
- Revenues EUR 7.0 million, driven by Estelle® and Myring® sales
- U.S. Estelle® (Nextstellis®) H1 dispensed cycles surged 80% over H2 2022
- EU Estelle® (DROVELIS®) revenues hit EUR 1.5 million; launched in new EU and Latam countries
- Financing secured with EUR 20 million private placement in August 2023 and access to EUR 12.5 million loan facility in June 2023
- Positive top-line results from Donesta® Phase 3 program and confirmation of safety profile support application for U.S. marketing authorization by year-end
- Signed binding term sheet for Canadian licensing deal for Donesta® with Searchlight Pharma, worth up to EUR 17.05 million plus royalties
- Cash position EUR 23.7 million at end June 2023

Liege, Belgium, 26 September 2023 – 7:00 CEST – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, today announces its financial results for the six-month period ending on 30 June 2023, prepared in accordance with IFRS. The full interim report is available on the Investors section of the website.

David Solomon, CEO Mithra Women's Health, commented: "*Mithra has made significant progress in the first half of 2023 advancing our business strategy, with the aim of becoming a global leader in women's health. Dispensed cycles of Estelle®, the first contraceptive based on Estetrol (E4) natural estrogen, have surged 80% in the U.S. compared to the previous 6 months period and it has now been launched in Chile, Ecuador and Malta as well as Australia. We reported positive topline efficacy results of the Phase 3 Donesta® program and are now completing the filing of U.S. marketing authorization application, expected in H2 2023.*

"We have significantly reinforced our financial position through several measures, including raising EUR 20 million in a successful private placement equity financing, with potential for up to an additional EUR 45 million in equity; we accessed EUR 12.5 million in loan financing and received EUR 2.5 million in proceeds from an equity investment by Highbridge and Whitebox after amending our loan facility agreement with them. We also signed a binding term sheet for a new Canadian licensing deal for Donesta® with Searchlight Pharma, worth up to EUR 17.05 million plus royalties.

"Mithra's businesses will continue to provide access to capital and afford us opportunities to pursue our ambitious goals. We are now completing the U.S. marketing authorization application for Donesta®. We also are taking steps to continue to invest strongly in Donesta®, along with our commercialization partners, by generating more clinical trial data to support new claims on the Estetrol® risk/benefit profile to further differentiate and expand on its already significant market potential. These examples showcase our efforts, in line with our newly laid out plan to drive for growth."

Financial Highlights (including post-period end)

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

Operational Highlights (including post-period events)

Estetrol (E4) Platform

- **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. Mithra received EUR 55 million in upfront payment and is eligible to receive up to EUR 15 million in additional milestone payments subject to specific regulatory achievements plus tiered double-digit royalties depending on net sales' evolution during the 20-year term contract. Gedeon Richter will be in charge of the supply and the production of the product for all its territories.
- **Announced positive top-line safety results from Donesta® Phase 3 Program in North America** for the treatment of vasomotor symptoms in post-menopausal women. These topline safety results not only confirm Donesta®'s safety profile in the treatment of VMS, but also delineate further E4's unique benefit/risk profile for postmenopausal women. These results will support the filing with U.S. regulatory agency, anticipated by end of H2 2023, for a potential market authorization in 2024, whereas primary safety data are anticipated in H1 2024 for Europe with a potential market authorization in H1 2025.
- **Completed recruitment in paediatric study of Estelle® in adolescent patients** with data expected in H1 2024. The objective of the study is to evaluate the safety, compliance, and pharmacokinetics profile of Estelle® in 100 participants aged 12 to 17 years old, as agreed with regulatory authorities. The study is being conducted in a number of European countries.

- **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). The manufacturing methodology improves robustness and productivity while ensuring a limited environmental footprint through the removal of a metal catalyst in the production process.
- **Signed a binding term sheet 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 is eligible to receive up to €17.05 million in licensing fees and regulatory and sales-related milestone payments, plus tiered double-digit royalties on total Canadian annual net sales. Mithra and Searchlight have a continuing partnership for Nexstellis®, 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.
- **Signed Supply Agreement** with Gedeon Richter 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®.

Novalon complex therapeutics

- **Successful commercial launch of Myring® in the U.S. by Mayne Pharma** (January) under the trademark Haloette®. During H1 2023 Mayne Pharma, entered into an agreement to sell its US retail generics portfolio, including Myring®, to Dr. Reddy's Laboratories SA, which now sells Haloette®. Mayne Pharma kept all its rights to Estelle®.

Tyrosine kinases inhibitors

- **Positive progression in the research collaboration with BCI Pharma**, with the identification of 4 distinct chemical series of selective CSF-1R inhibitors, showing promising profiles in a range of in vitro tests. The most promising compounds were evaluated in a range of in vivo models.
- **Positive data from preclinical studies on CSF-1R inhibitors** for treatment of endometriosis, oncology, and inflammatory disorders, in collaboration with BCI Pharma. The lead CSF-1R inhibitor demonstrated efficacy as a single agent in 3 different preclinical cancer models and the data suggest it may also be synergistic when used in combination with PD-1 inhibitors.

Mithra CDMO

- **Collaboration with VaRi Bioscience to develop an innovative long-acting vaginal ring** to treat vulvovaginal atrophy (VVA). Mithra will be responsible for the development of an innovative long-acting (3 months) estriol (E3)-based vaginal ring to treat VVA in post-menopausal women requiring systemic anti-estrogenic therapy.
- **Mithra is actively exploring several strategic options for the CDMO.** This unique state-of-the-art facility holds unlocked potential for partners and Mithra shareholders' value creation.

Governance

- **Appointment of David H Solomon as Chief Executive Officer, effective April 11, 2023.** This follows the temporary 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.

- **Changes within Mithra's Board of Directors:** appointment of Life Science Strategy Consulting SRL (permanent representative: Mr. Christian Homsy) as Chairman and the nominations of Ribono SRL (permanent representative: Mr. Sydney Bens) as Independent Director, Inge Beernaert (permanent representative: Mrs. Inge Beernaert) as Independent Director, and Gaudeto SRL (permanent representative: Mr. Jacques Galloy) as Independent Director. 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.

Strategic priorities and outlook

- **Donesta® U.S. marketing authorization application** -- submission is planned for H2 2023.
- **Donesta® U.S. licensing deal** -- management is in active discussions with potential partners interested in licensing rights for Donesta® in the U.S.
- **Mithra CDMO and Novalon** -- advancing discussions on strategic options.
- **Exploring options to rationalize Mithra's capital structure** to make it compatible with the interests of supporting investors and potential investors.
- **Updating full-year Estelle® revenue guidance to EUR 8.5 million (from EUR 12 million) to reflect inventory and promotional pricing effects in H1 by marketing partners.**

FINANCIAL RESULTS

1. Interim consolidated statement of income statement

(in € thousand)	*30 June 2023*	*30 June 2022*
Revenue	7.035	11.357
Cost of sales	(8.430)	(7.083)
Gross profit	**(1.396)**	**4.275**
Research and development expenses	(32.386)	(27.518)
General and administrative expenses	(7.198)	(7.042)
Selling expenses	(1.194)	(1.185)
Other operating income	1.955	3.933
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)**

2. Interim consolidated statement of financial position

(in € thousand)	*30 June 2023*	*31 December 2022*
ASSETS		
Property, plant and equipment	39.051	40.717
Right-of-use assets	63.259	65.534
Goodwill	5.233	5.233
Other intangible assets	136.537	134.905
Deferred income tax assets	16.009	16.354
Contracts assets	203	2.828
Derivatives financial assets	67	-
Investments in equity securities	11.315	21.437
Other non-current assets	10.144	9.544
Non-current assets	**281.817**	**296.552**
Inventories	49.447	50.312
Contract assets	5.630	44.988
Derivatives financial assets	200	-
Trade and other receivables	13.934	22.277
Cash and cash equivalents	23.714	28.285
Current assets	**92.926**	**145.863**
TOTAL ASSETS	374.744	442.414

(in € thousand)	*30 June 2023*	*31 December 2022*
EQUITY AND LIABILITIES		
Share capital	42.891	41.228
Additional paid-in-capital	413.163	408.647
Other reserves	(20)	(19.934)
Accumulated deficit	(464.763)	(396.254)
Equity attributable to equity holders	**(8.730)**	**33.687**
Subordinated loans	10.124	10.710
Other loans	136.291	127.052
Lease liabilities	34.350	38.253
Refundable government advances	8.592	8.127
Other financial liabilities	75.304	74.210
Derivative financial liabilities	15.601	15.261
Contract liabilities	10.300	-
Provisions	266	266
Deferred tax liabilities	3.574	4.420
Non-current liabilities	**294.402**	**278.298**
Current portion of subordinated loans	919	1.252
Current portion of other loans	19.848	45.980
Current portion of lease liabilities	6.230	5.179
Current portion of refundable government advances	1.499	1.417
Current portion of other financial liabilities	13.558	15.959
Derivative financial liabilities	2.306	2.561
Trade and other payables	44.711	58.082
Current liabilities	**89.071**	**130.430**
TOTAL EQUITY AND LIABILITIES	374.744	442.414

3. Interim consolidated statement of cash flow

(in € thousand)	*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**

Profit and Loss

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 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 Phase 3 in the US.

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

Other operating income (EUR 1.9 million compared to EUR 3.9 million in the first half 2022) are composed of: R&D tax credit for EUR 0.5 million; wage tax reductions for researchers of EUR 0.5 million, and of costs reinvoicing for EUR 0.4 million.

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

The decrease in financial income 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 interest charges linked to the higher financial liabilities during the period, which are higher than first half 2022. 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 mainly resulting from the review of tax impact on temporary differences, partially offset 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).

Alternative performance measures

Mithra has applied some alternative performance measures (APMs) that are not defined by IFRS but that provide helpful additional information to better assess how the business has performed over the period. Mithra uses 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 items 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):

(in € thousand)	*30 June 2023*	*30 June 2022*
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:

(in € thousand)	*30 June 2023*	*30 June 2022*
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)

2023 Half Year Financial Results Webcast

Mithra will host a live webcast on **Tuesday, 26 September 2023 at 14:00 CEST** to announce its 2023 Half Year financial and operating results. The live webcast can be accessed on the Mithra website or by clicking here. A replay of the webcast will be available on the Mithra investor's website shortly after the close of the call.

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About Mithra

Mithra (Euronext: MITRA) is a Belgian biotech company dedicated to transforming Women's Health by offering new choices through innovation, with a particular focus on contraception and menopause. Mithra's goal is to develop products offering better efficacy, safety and convenience, meeting women's needs throughout their life span. Mithra explores the potential of the unique native estrogen estetrol in a wide range of applications in women health and beyond. After having successfully launched the first estetrol-based product in 2021, the contraceptive pill Estelle®, Mithra is now focusing on its second product Donesta®, the next-generation hormone therapy. Mithra also develops and manufactures complex therapeutics in the areas of contraception, menopause and hormone-dependent cancers. It offers partners a complete spectrum of research, development and specialist manufacturing at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra has an approximate headcount of 300 staff members and is headquartered in Liège, Belgium. www.mithra.com

Important information

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. The Company's actual results may differ materially from those predicted by the forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.