



## Letter to Shareholders and Corporate Update

- Access to EUR15 million under amended deal
- Donesta® U.S. marketing deal is a key near term priority
- CDMO strategic options are being explored
- Donesta® filing rescheduled for H2 2023 - still expecting U.S. approval in H1 2024
- Financial update and guidance provided

**Liege, Belgium, 25 May 2023 – 7:30 CEST** – Mithra (Euronext Brussels: MITRA), a company dedicated to Women's Health, (the "Company" or "Mithra"), today published a Corporate Update and Letter to Shareholders from recently appointed Chief Executive Officer, Dr. David Horn Solomon.

Dear Fellow Shareholders,

I am pleased to have joined Mithra as CEO on April 11th. I was made fully aware of the Company's recent challenges and the many justified concerns of our shareholders. I accepted the role because my analysis revealed strong fundamentals and tremendous potential to create significant value for Mithra shareholders. Because of our current situation, I want to be transparent with regards to our strategy in this critical period and address the most important questions of our shareholders. I will lay out in this letter our most important priorities for the coming year as we work to build solid new foundations for Mithra's future growth.

Three key positive points stood out in my assessment of Mithra: first, our research and development organization's accomplishments show that it is one of the best in the industry; second, Estelle® and Donesta® are not yet fairly valued as highly differentiated innovative therapeutics for women's health; and, third, our underexploited contract development and manufacturing organization (CDMO), holds value that can be unlocked. Given the disappointments the Company has had, and the outsized impact these events have had on our valuation, I am working intensively with Mithra leadership to effect change expeditiously so that the Company can once again be recognized for its achievements and fundamental value.

In order to do this we have three short-term corporate priorities: first, we must provide the financial resources that the Company needs; second, we are in advanced discussions to close a licensing deal for U.S. marketing rights for Donesta®; third, we are actively exploring potential options that would allow us to maximize the value of our CDMO facility and regain sharper focus on the core business.

While our generics business also holds value and could serve to diversify our portfolio of products in the long-run, it is a low margin business that can act as a brake on growth while also taking our focus from our core strength - development of best-in-class innovative novel therapeutics. We will look to re-focus on the areas where we can compete most effectively, and this may mean that we could sell or explore other strategic options for our generic products business.

I am eager to leverage my 30 years of experience in strategic, operational, and innovation-focused leadership to catalyze the exceptional team at Mithra as we work in lockstep to generate shareholder value. In addition, we aim at adding experienced executives with complementary competencies to our senior management and our board of directors over the course of the coming year. My track record has been built on successful product development delivery and high value strategic partnerships, best exemplified by the achievements of Zealand Pharma and Silence Therapeutics. In each of these cases, we have established U.S. operations to pursue our interests in the most important commercial market, and I intend to do the same for Mithra.

As a top priority, I have been working closely with our CFO to secure Mithra's finances in order to empower the Company to pursue our new strategy. I am pleased that after only one month in my role, we are announcing today that we have taken a critical first step by obtaining commitments for EUR 2.5 million in new equity and access to EUR 12.5 million in new funds from drawing under Tranche C while simultaneously improving some of the financial terms of our convertible loan facility from funds managed by Highbridge Capital Management LLC ("Highbridge") and funds managed by Whitebox Advisors LLC ("Whitebox"), who have indicated to me their strong support for Mithra and our new strategy.

While it is an important positive step that enables us to pursue other pressing corporate activities with greater confidence, further step-wise improvements to our financial health are key. We are therefore working to affect a full refinancing of our debt obligations during the second half of this year. In addition to acquiring the requisite financial resources, we want to align shareholder interests such that future increases in our product revenues will benefit all shareholders and motivate new ones to join us, so as to deliver on value creation for patients as well as shareholders.

Collectively, the Mithra leadership understands that our ability to create value for our shareholders is a primary directive that goes hand in hand with developing medicines for women. While most of our attention is focused on immediate priorities, such as the company's finances, negotiating favorable terms for Donesta with a U.S. marketing partner, and exploring strategic options for our CDMO, I am also looking forward and planning for Mithra's growth.

In the medium term, we will look to maximize sales of Estelle® and Donesta® by continuing to develop them in new indications and also conducting studies to produce data (in support of our partners' marketing efforts) demonstrating their unique points of differentiation compared to other products on the market. Longer term, we will look to continue to source and develop new products for women's health, potentially through in-licensing or acquisitions.

Our ambition is to become a global leader in women's health. Therefore, Mithra will work to replenish its pipeline through organic growth as well as partnering. We will work with international investors and stakeholders to introduce our ambition and rebuild our business and are establishing a US representation office.

### **Financial Update**

Today we announced that we have successfully reached an agreement to update the terms of our loan facility agreement with Highbridge and Whitebox, a first step to put Mithra back on secure financial footing.

Following successful negotiation with key debt providers, Highbridge and Whitebox, Mithra will receive access to EUR 12.5 million of Tranche C. Furthermore, existing convertible loans that had a floating conversion price have been successfully renegotiated to new fix conversion price of EUR 2.75 (a premium of 25% over the price for the new equity round to be subscribed for by Highbridge and Whitebox, subject to customary anti-dilution and takeover protections). The loan interest coupon will be adjusted in line with current market conditions from 7.5% to 8.0% for Tranche A and B, and 9% for newly drawn Tranche C. Access to EUR 12.5 million of Tranche C and the other amendments to the convertible loan facility with Highbridge and Whitebox are subject to conditions and subject to

finalizing additional contractual agreements. In an effort to further minimize equity dilution going forward, the Company intends no longer to make drawings under the GSI facility. As an evidence of strong support for Mithra's long-term growth, Highbridge and Whitebox have elected to subscribe for EUR 2.5 million of new shares to be issued by the Company at an issue price of EUR 2.20, a 14% discount to the arithmetic mean of the five trailing daily VWAPs, a favourable market rate. The capital increase is expected to be completed later today.

At the end of April, Mithra's unaudited cash position was about EUR 26 million on a proforma basis. At the same time, our projected 2023 research and development spend is approximately EUR 60 million. It goes without saying that the cash level must be taken into account during negotiations; now, thanks to this new capital, as well as access to additional cash via the amended loan facility, I believe we can leverage our improved financial strength with confidence to negotiate U.S. marketing rights to Donesta<sup>®</sup> as well consider options for our CDMO facility. Furthermore, we can also work in good faith to achieve another mutually acceptable amendment: one that will align the Uteron Sellers with Mithra's long-term growth and success.

Considering our current financial status, the amendment demonstrates Highbridge and Whitebox are strongly supportive of our strategy and committed to support Mithra's long-term growth.

### **Estelle<sup>®</sup>**

Our first marketed product Estelle<sup>®</sup> composed of 15 mg Estetrol (E4) and 3 mg Drospirenone (DRSP), is the first and only contraceptive pill containing Estetrol, a native estrogen. Estetrol shows a specific mode of action compared to other estrogens. Estetrol has also a beneficial impact on the cardiovascular system, brain, bone and endometrium; unlike other estrogens, it has a limited impact on the liver and breast tissue. This unique mode of action results in an improved benefit/risk profile compared to other estrogens.

Because of its unique mode of action and safety profile, we believe Estetrol represents a major breakthrough in women's health starting with contraception and potentially for menopause. While it is only just beginning to generate significant value for shareholders, we believe that our marketing partners in U.S. and Europe (Mayne Pharma and Gedeon Richter, respectively), will be able to further optimize commercial exploitation of these assets.

Estelle<sup>®</sup> was recently commercialized in the US, Canada and Europe. It is the first new estrogen introduced in the US in more than 50 years.

### **Donesta<sup>®</sup>**

A US licensing deal for Donesta<sup>®</sup> (estetrol-based hormone therapy), should provide a significant short-term upfront cash payment and long-term revenues from milestones and royalties on sales for Mithra. I believe this is the most important short and medium-term source of revenue for the Company and am working, together with our team, to establish a deal that properly reflects the potential value generated by Mithra's exceptional research and development team.

The symptoms of menopause represent a significant unmet need that is increasingly recognized as requiring treatment by the medical profession and incidence of menopause is growing with our aging population. While symptoms such as hot flashes, night sweats, mood changes, sleep disturbances, joint aches and cognitive difficulties damage the quality of life for millions of women, the adverse effect on women has recently had an estimated societal cost assigned to it, further justifying therapeutic intervention. A newly published [Mayo Clinic study](#) estimated \$1.8 billion in lost work time per year and \$26.6 billion annually when medical expenses are added, in the US alone. Furthermore, data suggest that proper management during pre-menopause and menopause can reduce incidence of dementia and other long-term causes of mortality. Donesta<sup>®</sup> can play an important role in improving not only women's quality and quantity of life but also reduce medical costs and improve productivity.

We have a pre-NDA meeting with the FDA in the near term to support the filing of our new drug application (NDA) for Donesta®, which has been slightly delayed; we now plan to file it in H2 2023 instead of H1 2023 due to regulatory enquiries, as previously communicated. The expected timing of the marketing authorization for the US remains unchanged at the moment. In Europe, where Donesta® was recently licensed (in key territories) to Gedeon, we are reiterating our guidance on filing and working closely with our partner to support the marketing authorization (MAA) filing, planned for 2024.

### **CDMO**

Executing on a strategy to unlock the value of our world-class CDMO facility in Flémalle, is critical to returning the Company to financial health. This state-of-art building holds tremendous capacity and untold potential. In light of the new Company strategies, an in-house manufacturing and development facility is not a strategic asset for the Company, and therefore is currently underutilized, offering untapped potential. Considering strategic options is helping us to realize the full value of the CDMO and leveraging the team's expertise and versatile capabilities.

Europe, and much of the rest of the developed world, is struggling to maintain secure, sustainable drug supplies, with ongoing and varied challenges in supply chains. As such, we are exploring potential strategic solutions for the CDMO that may ultimately benefit multiple parties, including the Flémalle region, Mithra employees and shareholders.

### **Revenue projection**

Our product sales are still ramping up but I can share that we are currently projecting total product revenues for Estelle® of about EUR 12 million in 2023 to more than double in 2024 and again in 2025 as they grow to up to approximately EUR 130 million by 2029.

Mithra could be cash flow positive in 2026 or, counting possible milestone revenues, potentially even 2025. We currently expect Mithra's combined revenues from global sales of Estelle®, Donesta® and MyRing® to grow to approximately EUR 300 million by 2029.

### **Conclusion**

In conclusion, I believe my priorities as CEO are clear: secure the Company's finances; secure a U.S. marketing partner for Donesta®; find the best solution for our CDMO; maximize product revenues and, finally, empower our accomplished R&D organization to identify and bring to market new and exciting products for women's health.

To achieve these goals, we must restore Mithra's financial health, execute on impactful partnerships and focus our internal team's efforts on delivering the best value from our existing and future pipeline of innovative products, especially Donesta®. Simply put, Mithra can and will navigate through the current situation and ultimately deliver on its promise of becoming a global leader in women's health.

I wish to thank you, our shareholders, for your support during this difficult transition period in the Company's history, especially in light of the troubling geopolitical and volatile market conditions. I believe communication is an essential part of any successful relationship, especially during difficult periods. I look forward to continuing with increased transparency and regular communications to providing updates on our progress to you, our shareholders.

With best regards,

David Horn Solomon  
Chief Executive Officer

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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<sup>®</sup>, Mithra is now focusing on its second product Donesta<sup>®</sup>, the next-generation hormone therapy. Mithra also offers partners a complete spectrum of solutions from early drug development, clinical batches and commercial manufacturing of complex polymeric products (vaginal ring, implants) and complex liquid injectables and biologicals (vials, pre-filled syringes or cartridges) at its technological platform Mithra CDMO. Active in more than 100 countries around the world, Mithra is headquartered in Liège, Belgium. [www.mithra.com](http://www.mithra.com) ESTELLE<sup>®</sup> DONESTA<sup>®</sup>, LYDISILKA are registered trademarks of Mithra Pharmaceuticals or one of its affiliate.*

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