RNS Number : 4529E
Ovoca Bio PLC
30 June 2023

Ovoca Bio plc

("Ovoca" or the "Company")

Publication of 2022 Annual Report

Dublin, Ireland, June 30, 2023 - Ovoca Bio, a biopharmaceutical company with a focus on women's health, announces the publication of its Annual Report and Financial Statements for the year ended 31 December 2022. The Annual Report and Financial Statements can be viewed online at the following link:

http://www.rns-pdf.londonstockexchange.com/rns/4529E_1-2023-6-29.pdf

2022 Highlights

During the reporting period, Ovoca dedicated its efforts to the ongoing clinical and regulatory development of our lead product Orenetide (BP-101), with notable highlights including the following:

- Continuing enrolment into the Phase II dose ranging study assessing Orenetide being conducted in Australia and New Zealand. All participants were successfully recruited by July 2022 and data collection completed in December 2022. The results of the study are currently being finalised and are currently expected to be available by August 2023.
- Further investment in developing a manufacturing process in Europe to support the planned development of Orenetide for global markets.
- Ovoca's subsidiary, IVIX, obtained Marketing Authorization for Orenetide in Russia under the trade name "Desirix" in late February 2022. Subsequently, all necessary permissions for commencing commercial sales were obtained in mid-2022. However, Ovoca encountered challenges in establishing a commercial partnership for sales of Orenetide in Russia due to the Russia-Ukraine conflict and from the subsequent international sanctions imposed on the Russian economy and financial system.
- Maintenance of a sustainable financial position.

Letter from the CEO

As CEO of Ovoca, I would like to begin my review of the Company's activities in 2022 by once again acknowledging the tragic ongoing events in Ukraine and Russia and reiterating the Board's hope for a peaceful resolution to the conflict as soon as possible. Despite challenges for the Company and its operations arising as a result, I am proud of the way all the team here at Ovoca continued to focus on advancing key areas for the development of Orenetide during the last financial year.

During 2022, we continued to progress our ongoing Phase II dose ranging study being undertaken in Australia and New Zealand. The recruitment of participants into the study finished in July 2022, with all required study data collection activities then completed in December. The study results are currently expected to be delivered in August 2023.

This Phase II study is being conducted in Australia and New Zealand to investigate our lead product candidate Orenetide, a novel treatment for premenopausal women with hypoactive sexual desire disorder ("HSDD"). This double-blind placebo-controlled study enrolled 453 participants. The objectives of the study are to evaluate the effect of three different doses of Orenetide versus a placebo on a number of clinically relevant and validated endpoints being assessed between a four-week baseline period and after four weeks of daily dosing, and then again after a further eight weeks of no-treatment follow-up. The drug supplied for this study has been outsourced to well-established manufacturers in Switzerland and the UK.

Ovoca has also undertaken strategic investment and collaboration with one of the leading European peptide manufacturers to develop an enhanced manufacturing process for Orenetide, aiming to improve its production process. The first key objective is to deliver sufficient material to support the upcoming long-term toxicological assessments, as required by the US Food and Drug Association and regulatory authorities in Europe and, from a strategic perspective, to secure our future clinical development and commercialization plans for Orenetide internationally.

The tragic events in Ukraine and the subsequent international sanctions imposed on the Russian economy and financial system completely changed the paradigm of the Company's operations in Russia during the course of 2022. Russian Marketing Authorisation was granted for Orenetide in February 2022 under trade name of "Desirix", and all requisite permissions to start commercial sales were collected in mid-2022. However, following the developments arising as a result of the conflict in Ukraine, the Company found itself unable to adequately finance any activities related to the manufacturing, marketing or sale of Orenetide in Russia due to the disruption of financial transactions between EU and Russia. This led to substantial difficulties in securing a licensing agreement with Russian commercial partners and resulted in an inability to generate sales of Desirix in Russia.

As announced by the Company in March 2023, a strategic decision to sell certain Russian assets related to its clinical development product Orenetide, namely the Russian patents for Orenetide, the results of completed scientific development of Orenetide in Russia, together with the right to own a Russian Marketing Authorization for Orenetide in Russia was taken and approved by Company Board in March 2023.

Following completion of the disposal, Company is in the process of ceasing its operations in Russia and will continue to focus on progressing the development of Orenetide in the major international markets.

Despite the difficulties that have arisen, these events have not affected Ovoca's global operations due to our international team and the Company's presence in Ireland, UK, Australia, as well as Russia. Our subsidiaries in Russia accounted for only 10% of the Group's cashflow in 2021, with a decreasing role throughout 2022, and the Company has no affiliation nor receives any funding from the Russian state, and is not currently subject to EU, US or other international sanctions or restrictions. No member of the Board, management or any of the Company's substantial shareholders are on the list of sanctioned individuals.

The Company continued to manage its resources carefully throughout 2022 and management has remained vigilant to the potential impact of the ongoing conflict in Ukraine. Expenditure increased during the year, principally due to costs associated with the ongoing Phase II study being conducted in Australia and New Zealand. As a result, the total comprehensive loss for the full year in 2022 was €5.8 million (US$7.1 million) and the Company retained cash and liquid investments at fair value of €3.7 million (US$4.0 million) as at 31 December 2022. During 2022, the Company also disposed of its remaining holdings of ordinary shares of Polymetal International plc.

Finally, we were pleased to welcome Kristina Zakurdaeva to the Board as a new Non-Executive Director in January 2022 and the Company's management and Board governance remained stable throughout 2022.

I would like to conclude by thanking our employees and partners for their support and contributions to the Group over the past year, in what have been challenging circumstance. We look forward to receiving the results from the Phase II trials for Orenetide and updating the market on these in due course and I continue to believe Ovoca is well positioned to achieve our vision of becoming a leader in the research and development of, and commercial partner of choice for, novel medicines in areas of high unmet need that affect women.

Annual Report

The Annual Report and Financial Statements will shortly be posted to shareholders and are also available online at the Company's website, www.ovocabio.com.

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About Ovoca Bio
Ovoca Bio is a European-based biopharmaceutical company with a focus on women's health. The Company is currently developing a novel treatment for women with hypoactive sexual desire disorder (HSDD), a condition characterized by a distressing lack or loss of sexual desire affecting an estimated ~4 million premenopausal women in the US alone.

The Company's lead product, Orenetide (earlier - BP-101), a novel synthetic peptide administered through a nasal spray, is clinically validated, with earlier conducted regional Phase II and Phase III studies demonstrating statistically significant improvement in a number of key efficacy outcomes, including an increase in female sexual desire and reduction of symptoms of distress associated with HSDD.

Ovoca Bio is seeking to develop the drug for major global markets - in particular the United States and Europe.

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