# ObsEva Announces First Quarter 2022 Financial Results and Provides Corporate Update

*-Linzagolix for uterine fibroids: Received confirmation of positive CHMP opinion for marketing authorization application; United States NDA PDUFA date in Q3:22-*

*-Linzagolix for endometriosis: Reported positive topline results for linzagolix 200 mg with add-back therapy in the Phase 3 EDELWEISS 3 trial-*

*-Linzagolix franchise: Announced licensing agreement with Theramex to support commercialization in Europe, in addition to relationship with Syneos Health to support commercialization in the United States-*

Ad hoc announcement pursuant to Art. 53 LR of the SIX Swiss Exchange

**GENEVA, Switzerland – May 17, 2022 – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN)**, a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today reported financial results for the first quarter ended March 31, 2022 and provided a business update.

"We are eagerly anticipating the approval of linzagolix in Europe, which would mark our first product approval and a major achievement for ObsEva," said Brian O'Callaghan, CEO of ObsEva. "With the potential to be, if approved, the first and only approved GnRH antagonist with flexible dosing options with and without hormonal add-back therapy, we believe linzagolix could transform the standard of care for millions of women living with uterine fibroids. In the United States, the regulatory review process likewise remains on track, setting ObsEva up for multiple potential approvals this year. We are advancing launch preparations in both markets through our commercial agreements with Theramex and Syneos Health to fully realize the significant commercial potential of linzagolix, while continuing to evaluate strategic opportunities in women's health that could further enhance ObsEva's value."

**Anticipated Milestones**

ObsEva anticipates the following key clinical and regulatory objectives in 2022:

- **Linzagolix for uterine fibroids:** Prescription Drug User Fee Act (PDUFA) target action date of September 13, 2022, as set by the U.S. Food and Drug Administration (FDA); European Commission approval expected following confirmation in April of the Committee for Medicinal Products for Human Use (CHMP) positive opinion for the marketing authorization application

(MAA).

- **Linzagolix for endometriosis:** Additional data from the post-treatment follow-up of the Phase 3 EDELWEISS 3 trial as well as data from the long-term treatment in the extension study are expected in mid-2022, and from the post-treatment follow-up of the extension study in early 2023.

**Pipeline Update**

- ***Linzagolix for Uterine Fibroids:*** ObsEva is developing linzagolix, an oral GnRH receptor antagonist with potential best-in-class efficacy, a favorable tolerability profile, and flexible dosing options for the treatment of uterine fibroids. The CHMP of the European Medicines Agency confirmed its positive opinion recommending approval of the linzagolix MAA at the April 2022 CHMP meeting. The European Commission is now reviewing the CHMP recommendation. If approved, linzagolix will be the first and only approved oral GnRH antagonist in uterine fibroids with a dosing option without additional hormonal add-back therapy (ABT) to address the needs of women who cannot or do not want to take hormones. In February 2022, ObsEva announced a strategic licensing agreement with Theramex to support the commercialization and market introduction of linzagolix across global markets outside of the U.S., Canada and Asia, and EU launch preparations are advancing. Theramex's extensive women's health commercial infrastructure includes a dedicated sales force of more than 180 experienced representatives across Europe, Brazil, and Australia, alongside third-party distributors across approximately 60 countries. In the United States, the New Drug Application (NDA) for linzagolix for uterine fibroids has been accepted for review by the FDA, with a PDUFA target action date of September 13, 2022. In October 2021, ObsEva announced a commercial sales agreement with Syneos Health to commercialize linzagolix within the United States. Syneos Health is a fully integrated biopharmaceutical solutions organization with significant experience in women's health launches. ObsEva's agreement with Syneos Health provides access to a dedicated sales force, marketing, medical affairs professionals, and market access in support of the linzagolix launch, if approved.

  At the American College of Obstetricians and Gynecologists (ACOG) Annual Clinical and Scientific Meeting on May 6-8, additional data from the PRIMROSE Phase 3 studies of linzagolix for uterine fibroids was featured in an oral presentation and four posters. The analyses and post-treatment data continue to underscore linzagolix's clinical utility and differentiated profile.

- ***Linzagolix for Endometriosis:*** In January 2022, ObsEva announced positive topline results from the Phase 3 EDELWEISS 3 trial in women with moderate-to-severe endometriosis-associated pain. The 200 mg with hormonal add-back therapy (ABT, estradiol 1mg/norethindrone 0.5mg) dose met the co-primary efficacy objectives, demonstrating reductions in dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) at 3 months. The 75 mg dose without hormonal ABT demonstrated a statistically significant reduction versus placebo in DYS at 3 months. Although the 75 mg dose without hormonal ABT showed improvement in NMPP at 3 months, it did not reach statistical significance versus placebo, and thus did not meet the co-primary efficacy objective. Both doses were generally well-tolerated and results support continued development of linzagolix, including further exploration of dose options without hormonal ABT. Additional efficacy results from the 6-month analysis of the Phase 3 EDELWEISS 3 trial were announced in March 2022, demonstrating rapid onset of treatment effect, positive impact on quality of life, and intentions for surgery. Further data from the post-treatment follow-up of the Phase 3 EDELWEISS 3 trial as well as data from the

long-term treatment in the extension study are expected in mid-2022, and from the post-treatment follow-up of the extension study in early 2023.

- ***Ebopiprant for Treatment of Preterm Labor:*** In July 2021, ObsEva granted a license to Organon (NYSE:OGN) for the global development, manufacturing and commercial rights to ebopiprant. Ebopiprant is an investigational, orally active, selective prostaglandin F2α (PGF2α) receptor antagonist being evaluated as a potential treatment for preterm labor by reducing inflammation and uterine contractions. ObsEva previously conducted clinical development through an ex-US Phase 2a clinical trial, where reduced deliveries in singleton pregnancies 48 hours after the start of dosing were observed. Under the terms of the agreement, ObsEva is entitled to receive tiered double-digit royalties on commercial sales as well as up to $500 million in upfront and milestone payments, including up to $90 million in development and regulatory milestones. ObsEva is working closely with Organon to discuss with the FDA the submission of an Investigational New Drug Application for ebopiprant anticipated in 2022 to enable clinical development in the United States.

- ***Nolasiban for In Vitro Fertilization:*** ObsEva is also advancing nolasiban, an oral oxytocin receptor antagonist, to improve live birth rates in women undergoing *in vitro* fertilization. ObsEva has partnered with Yuyuan BioScience Technology for the development and commercialization of nolasiban in China.

**Leadership Transition**

- Dr. Brandi Howard was appointed as Chief Clinical Officer and member of the company's Executive Committee. Dr. Howard brings to ObsEva more than 20 years of expertise in women's health, with increasing responsibilities in medical affairs strategy and leadership, as well as leading large clinical development programs. Dr. Howard succeeds Dr. Elizabeth Garner, who departed ObsEva on May 6, 2022 to pursue a new opportunity. To help ensure a smooth transition, Dr. Garner has agreed to provide advisory consulting services to ObsEva on an as needed basis.

**Financial Results for the First Quarter Ended March 31, 2022**

- ObsEva had cash and cash equivalents of $57.6 million at March 31, 2022 compared to $54.7 million at December 31, 2021. The increase of $2.8 million is primarily attributable to $5.7 million of net cash received during the first quarter 2022 from the utilization of its at-the-market offering program, $8.3 million in proceeds from the Company's securities purchase agreement with certain funds and accounts managed by JGB Management, Inc. (JGB), a $5.7 million upfront payment in connection with the Company's licensing agreement with Theramex, offset by cash used for operating activities.
- Operating income other than revenue was $2.2 million for the quarter ended March 31, 2022 compared to $6,000 in the prior year period. The increase was due to the partial recognition of the upfront payment associated with the Company's licensing agreement with Theramex, net of fees and recognition of the associated intangible asset.
- Research and development expenses were $5.6 million for the quarter ended March 31, 2022, compared to $15.5 million in the prior year period, representing a decrease of $9.9 million. The decrease was primarily due to decreased costs related to the development of linzagolix due to the timing of clinical trial activities.
- General and administrative expenses were $7.2 million for the quarter ended March 31, 2022 compared to $4.2 million in the prior year period, an increase of $3.0 million. The

increase was attributable to professional fees associated with commercial launch preparation, insurance, and additional employee compensation costs; partially offset by lower legal fees.

- Finance result, net was $1.1 million for the quarter ended March 31, 2022, compared to $0.3 million for the prior year period. The increased expense was primarily due to higher interest costs related to ObsEva's borrowings under its securities purchase agreement with JGB.
- Net loss for the quarter ended March 31, 2022 was $11.8 million, or $0.14 net loss per share, compared to $20.0 million in the prior year period, or $0.29 net loss per share. The difference in net loss was primarily attributable to the recognition of the upfront payment in connection with the Company's licensing agreement with Theramex and lower research and development expenses, offset by higher general and administrative expenses.

The first quarter 2022 financial statements can be accessed in the financial reports section of the Company's website, or directly here.

**Webcast and Conference Call**

ObsEva will host a conference call and webcast today at 8:00 a.m. Eastern time, 2:00 p.m. Central European Time. Individuals may participate via telephone by dialing (877) 300-8521 (domestic) or +1 (412) 317-6026 (international) and using conference ID 10166576. The webcast can be accessed live here and will also be accessible under "Events Calendar" in the investors section of ObsEva's website. The webcast will be archived on the company's website for at least 30 days after the conference call.

**About ObsEva**

ObsEva is a biopharmaceutical company developing and commercializing novel therapies to improve women's health. Through strategic in-licensing and disciplined drug development, ObsEva has established a late-stage clinical pipeline with development programs focused on new therapies for the treatment of uterine fibroids, endometriosis, and preterm labor. ObsEva is listed on the Nasdaq Global Select Market and is traded under the ticker symbol "OBSV" and on the SIX Swiss Exchange where it is traded under the ticker symbol "OBSN". For more information, please visit www.ObsEva.com.

**Cautionary Note Regarding Forward-Looking Statements**

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "anticipate", "believe", "continue", "could", "estimate", "expect", "intend", "may", "might", "ongoing", "objective", "plan", "potential", "predict", "should", "will", "would", or the negative of these and similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the potential approval of linzagolix by regulatory authorities, including the European Commission and the FDA, and the timing of such approval and subsequent transition of ObsEva to a commercial-stage company, the timing or results of interactions with regulatory authorities, the commercialization of linzagolix across global markets, expected timing of the European Commission's decision and the FDA target action date for linzagolix, clinical development of ObsEva's product candidates, including the timing, advancement of, and potential therapeutic benefits of such product candidates, regulatory and development milestones, including the anticipated milestones and pipeline updates, the potential for such product candidates to be commercially competitive and the success of the Company's partnerships with third parties. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the

conduct of clinical trials and clinical development, including the risk that the results of earlier clinical trials may not be predictive of the results of later stage clinical trials, related interactions with regulators, including interactions with the European Medicines Agency during the marketing authorization application process and with the FDA during the NDA process for linzagolix, ObsEva's reliance on third parties over which it may not always have full control, and the capabilities of such third parties, the impact of the ongoing novel coronavirus outbreak and other geopolitical events, and other risks and uncertainties that are described in the Risk Factors section of ObsEva's Annual Report on Form 20-F for the year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on March 10, 2022, and other filings ObsEva makes with the SEC. These documents are available on the Investors page of ObsEva's website at www.ObsEva.com. Any forward-looking statements speak only as of the date of this press release and are based on information available to ObsEva as of the date of this release, and, except as required by law, ObsEva assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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## Consolidated Statements of Comprehensive Loss

| (in USD '000, except per share data) | Three-month period ended March 31, 2022 | 2021 |
|---|---|---|
| **Operating income other than revenue** | **2,237** | **6** |
| **OPERATING EXPENSES** | | |
| Research and development expenses | (5,608) | (15,516) |
| General and administrative expenses | (7,233) | (4,191) |
| **Total operating expenses** | **(12,841)** | **(19,707)** |
| **OPERATING LOSS** | **(10,604)** | **(19,701)** |
| Finance income | 1,933 | 629 |
| Finance expense | (3,077) | (911) |
| **NET LOSS BEFORE TAX** | **(11,748)** | **(19,983)** |
| Income tax expense | (53) | (21) |
| **NET LOSS FOR THE PERIOD** | **(11,801)** | **(20,004)** |
| **Net loss per share** | | |
| Basic | (0.14) | (0.29) |
| Diluted | (0.14) | (0.29) |
| **TOTAL OTHER COMPREHENSIVE INCOME / (LOSS)** | — | — |
| **TOTAL COMPREHENSIVE LOSS FOR THE PERIOD** | **(11,801)** | **(20,004)** |

## Consolidated Balance Sheets

| (in USD '000) | March 31, 2022 | December 31, 2021 |
|---|---|---|
| **ASSETS** | | |
| **Current assets** | | |
| Cash and cash equivalents | 57,553 | 54,734 |
| Other receivables | 953 | 3,560 |
| Prepaid expenses | 5,756 | 5,223 |
| **Total current assets** | **64,262** | **63,517** |
| **Non-current assets** | | |
| Right-of-use assets | 521 | 625 |
| Furniture, fixtures and equipment | 63 | 58 |
| Intangible assets | 23,903 | 24,503 |
| Other long-term assets | 395 | 288 |
| **Total non-current assets** | **24,882** | **25,474** |
| **Total assets** | **89,144** | **88,991** |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| **Current liabilities** | | |
| Other payables and current liabilities | 4,734 | 9,038 |
| Accrued expenses | 15,421 | 13,783 |
| Current lease liabilities | 624 | 686 |
| **Total current liabilities** | **20,779** | **23,507** |
| **Non-current liabilities** | | |
| Non-current lease liabilities | 119 | 240 |
| Non-current borrowings | 33,134 | 25,733 |
| Post-employment obligations | 6,563 | 6,581 |
| Other long-term liabilities | 584 | 591 |
| **Total non-current liabilities** | **40,400** | **33,145** |
| **Shareholders' equity** | | |
| Share capital | 6,812 | 6,489 |
| Share premium | 436,694 | 430,630 |
| Reserves | 33,236 | 32,195 |
| Accumulated losses | (448,777) | (436,975) |
| **Total shareholders' equity** | **27,965** | **32,339** |
| **Total liabilities and shareholders' equity** | **89,144** | **88,991** |

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