



ObsEva Announces Year End 2021 Financial Results and Provides Corporate Update

-Linzagolix for uterine fibroids: US NDA Q3:22 PDUFA date; Positive CHMP opinion-

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

-Linzagolix franchise: Entered strategic licensing agreement with Theramex for commercialization across global markets outside of the U.S., Canada, and Asia-

-Linzagolix franchise: Entered into commercial sales agreement with Syneos Health to commercialize within the United States-

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

GENEVA, Switzerland – March 10, 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 full year ended December 31, 2021 and provided a business update.

“ObsEva delivered significant business development, clinical, and regulatory achievements in 2021,” said Brian O’Callaghan, CEO of ObsEva. “This positive momentum culminated in a strong finish to the year with FDA acceptance of the NDA for linzagolix for the treatment of uterine fibroids and a positive CHMP opinion in Europe, which together with positive results in the Phase 3 EDELWEISS 3 endometriosis trial position us strongly for the year ahead.”

Mr. O’Callaghan continued: “We look forward to a number of important developments across our late-stage pipeline candidates in 2022, including potential approval of linzagolix in the US and Europe, which would make linzagolix the first and only approved GnRH receptor antagonist in uterine fibroids with a dosing option without additional hormonal add-back therapy to address the needs of women who cannot or do not want to take hormones. With the recent announcement of the Theramex licensing agreement, European commercial preparations are advancing, and we have a strong foundation to realize the commercial potential of the linzagolix program there and in the US. In parallel, we continue to explore new indications, partnerships, and other strategic opportunities that enhance ObsEva’s value and further our mission of bringing to market novel therapies that improve women’s health.”

Anticipated Milestones

ObsEva expects to achieve 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 December 2021 positive Committee for Medicinal Products for Human Use (CHMP) opinion.
- **Linzagolix for endometriosis:** Additional data from the 6-month analysis are expected in 1Q:22. Additional data from the post-treatment follow-up of the Phase 3 EDELWEISS 3 trial are expected in 2Q:22 and from the post-treatment follow-up of the extension study in 4Q:22

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 unique and flexible dosing options for the treatment of uterine fibroids. 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. The CHMP of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of linzagolix in December 2021. ObsEva is working with the EMA toward approval, and is in dialogue with the regulatory agency to address questions on the marketing authorization application (MMA), which is expected to be discussed at the April CHMP plenary meeting. On February 10, 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. In the United States, the New Drug Application (NDA) 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.
- **Linzagolix for Endometriosis:** On January 6, 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 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 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 data from the 6-month analysis are expected in 1Q:22. Additional data from the post-treatment follow-up of the Phase 3 EDELWEISS 3 trial are expected in 2Q:22 and from the post-treatment follow-up of the extension study in 4Q:22
- **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 F2 α (PGF2 α) 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 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 Expansion

- Will Brown was appointed as Chief Financial Officer and member of the company's Executive Committee. Mr. Brown is a Certified Public Accountant with deep experience in capital markets, accounting, and finance.
- Katja Bühler was appointed as Chief Strategy Officer and member of the company's Executive Committee. Ms. Bühler's background spans expertise in corporate strategy, investor relations advisory, financial journalism, and capital markets.

Financial Results for the Year Ended December 31, 2021

- ObsEva had cash and cash equivalents of \$54.7 million at December 31, 2021 compared to \$31.2 million at December 31, 2020. The increase of \$23.5 million is primarily attributable to \$51.7 million of net cash received during 2021 from the utilization of its at-the-market offering program, \$22.1 million in warrant exercise proceeds, a \$25 million upfront payment for the ebopiprant licensing agreement with Organon, offset by \$70.3 million of cash used for operating activities.
- Subsequent to December 31, 2021, the Company received \$8.3 million from its securities purchase agreement with certain funds and accounts managed by JGB Management, Inc. (JGB), a \$5.7 million upfront payment for the licensing agreement with Theramex, \$4.6 million from its at-the-market offering program, and \$2.9 million in other receivable collections.
- In October 2021, ObsEva entered into a securities purchase agreement with JGB, which is structured to provide up to \$135 million in borrowing capacity, available in nine tranches, subject to certain conditions to funding. The Company received \$30 million at closing, which was used to retire the Company's existing debt facility with Oxford Finance LLC, and \$8.3 million in January 2021 in the second tranche under the agreement. In connection with the second tranche, the Company amended the securities purchase agreement and made a cash payment of \$1.25 million in exchange for a waiver by JGB of certain funding conditions for the second tranche.
- Operating income other than revenue was \$20.1 million for the year ended December 31, 2021 compared to \$17,000 in the prior year. The increase year-over-year was due to the recognition of the upfront payment associated with the ebopiprant licensing agreement, net of fees and recognition of the associated intangible asset.

- Research and development expenses were \$53.1 million for the year ended December 31, 2021, compared to \$67.5 million in the prior year period, representing a decrease of \$14.4 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 \$21.5 million for the year ended December 31, 2021 compared to \$12.2 million in the prior year, an increase of \$9.3 million. The increase was attributable to professional fees associated with commercial launch preparation, legal fees, insurance, and additional employee compensation costs.
- Finance expense was \$4.3 million for the year ended December 31, 2021, compared to \$3.9 million for the prior year. The increase was primarily due to higher interest costs related to our borrowings under the convertible note financing agreement with JGB Management, Inc. Finance income remained consistent year over year with \$0.6 million for the year ended December 31, 2021, as compared to \$0.65 million for the prior year period.
- Net loss for the year ended December 31, 2021 was \$58.4 million, or \$0.78 net loss per share, compared to \$83.0 million in the prior year, or \$1.67 net loss per share. The difference in net loss was primarily attributable to the recognition of the upfront payment for the ebopiprant licensing agreement, lower research and development expenses, partially offset by higher general and administrative expenses.

The Annual Report on Form 20-F for Fiscal Year 2021 can be accessed in the [financial reports section](#) of the Company's website, or directly [here](#). ObsEva expects to publish its annual report to shareholders in March 2022.

About ObsEva

ObsEva is a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health and pregnancy. 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 commercialization of linzagolix across global markets, 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, including the anticipated milestones and pipeline updates, the potential for such product candidates to be commercially competitive, the success of the Company's partnerships with third parties, expectations regarding regulatory and development milestones and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates. 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, 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 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 expected to be filed with 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 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)

	Year ended December 31,		
	2021	2020	2019
Operating income other than revenue	20,113	17	16
OPERATING EXPENSES			
Research and development expenses	(53,136)	(67,536)	(88,053)
General and administrative expenses	(21,491)	(12,182)	(19,058)
Total operating expenses	(74,627)	(79,718)	(107,111)
OPERATING LOSS	(54,514)	(79,701)	(107,095)
Finance income	600	648	854
Finance expense	(4,251)	(3,879)	(2,482)
NET LOSS BEFORE TAX	(58,165)	(82,932)	(108,723)
Income tax expense	(212)	(34)	(67)
NET LOSS FOR THE YEAR	(58,377)	(82,966)	(108,790)
Net loss per share			
Basic and diluted	(0.78)	(1.67)	(2.49)
OTHER COMPREHENSIVE INCOME / (LOSS)			
<i>Items that will not be reclassified to profit and loss</i>			
Remeasurements on post-employment benefit plans, net of tax	796	982	(4,694)
TOTAL OTHER COMPREHENSIVE INCOME / (LOSS)	796	982	(4,694)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	(57,581)	(81,984)	(113,484)

Consolidated Balance Sheets

(in USD '000)	December 31,	
	2021	2020
ASSETS		
Current assets		
Cash and cash equivalents	54,734	31,183
Other receivables	3,560	397
Prepaid expenses	5,223	5,388
Total current assets	63,517	36,968
Non-current assets		
Right-of-use assets	625	1,425
Furniture, fixtures and equipment	58	151
Intangible assets	24,503	26,608
Other long-term assets	288	295
Total non-current assets	25,474	28,479
Total assets	88,991	65,447
LIABILITIES AND EQUITY		
Current liabilities		
Other payables and current liabilities	9,038	10,760
Accrued expenses	13,783	10,248
Current lease liabilities	686	696
Total current liabilities	23,507	21,704
Non-current liabilities		
Non-current lease liabilities	240	952
Non-current borrowings	25,733	25,300
Post-employment obligations	6,581	8,218
Other long-term liabilities	591	919
Total non-current liabilities	33,145	35,389
Shareholders' equity		
Share capital	6,489	4,574
Share premium	430,630	356,822
Reserves	32,195	26,353
Accumulated losses	(436,975)	(379,395)
Total shareholders' equity	32,339	8,354
Total liabilities and shareholders' equity	88,991	65,447

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