



ObsEva Announces First Quarter 2021 Financial Results and Business Update

-Yselty® for uterine fibroids: US New Drug Application submission planned in Q3:21; European marketing approval recommendation anticipated in Q4:21-

-Yselty® for endometriosis: Readout from Phase 3 EDELWEISS 3 study expected in Q4:21-

-Ebopiprant: Phase 2b dose ranging study planned to initiate in Q4:21 based on positive Phase 2a proof of concept-

-Actively pursuing new indications and partnerships to maximize value of pipeline candidates-

GENEVA, Switzerland and BOSTON, MA – May 6, 2021 – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN) (ObsEva or the Company), a biopharmaceutical company developing and commercializing novel therapies to improve women’s reproductive health, today reported financial results for the quarter ended March 31, 2021 and provided a business update.

“The outset of 2021 was marked with a prioritization of capitalization and commercialization, and we have made significant progress on both fronts,” said Brian O’Callaghan, CEO of ObsEva. “In the first quarter of 2021, we raised over \$60 million in gross equity proceeds, providing the capital needed to continue to advance our pipeline, reach multiple clinical and regulatory milestones, and execute on our well-defined strategic plan. On the commercialization front, we have created significant optionality and momentum with numerous negotiations that have reached an advanced stage. We plan to build on this momentum and select the best potential partners and strategies for each of our programs and look forward to providing additional updates in due course.”

Anticipated Milestones

ObsEva aims to achieve the following key clinical and regulatory objectives in 2021:

- **Yselty for uterine fibroids:** NDA submission (Q3:21); MAA approval recommendation (Q4:21)
- **Yselty for endometriosis:** Phase 3 EDELWEISS 3 primary endpoint readout (Q4:21)
- **Ebopiprant for treatment of preterm labor:** Phase 2b dose ranging study initiation in EU/Asia (Q4:21)

Pipeline Update

Yselty for the treatment of uterine fibroids and endometriosis

- **Yselty for Uterine Fibroids:** ObsEva is developing Yselty, an oral GnRH receptor antagonist with the potential to treat more women due to its potential best-in-class efficacy, a favorable tolerability profile and unique, flexible dosing options for the treatment of uterine fibroids. Following the European Medicine Agency's (EMA) validation of the marketing authorization application (MAA), a major milestone toward making Yselty available in the EU, the Company continues to work closely with the EMA to achieve marketing approval, with an approval recommendation from the Committee for Medicinal Products for Human Use (CHMP) projected in Q4:2021 and formal product approval expected to follow shortly thereafter. The Company is also working to submit a U.S. New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA), projected in Q3:2021, that will include the Week 76 post-treatment follow-up results from the Phase 3 PRIMROSE 1 (US only; n=574) and PRIMROSE 2 (Europe and US; n=535) clinical studies. In addition, the Company recently announced commencement of an observational study (PRIMROSE 3) of bone mineral density in women who completed at least 20 weeks of treatment in either of the PRIMROSE 1 or 2 studies.
- **Yselty for Endometriosis:** The EDELWEISS 3 study in the EU is progressing as planned, with randomization of patients recently completed and primary endpoint data expected in Q4:2021. The ongoing Phase 3 EDELWEISS 3 study (Europe and US) is designed to enroll approximately 450 patients with endometriosis-associated pain, with a co-primary endpoint of response on both dysmenorrhea (menstrual pain) and non-menstrual pelvic pain. The study includes a 75 mg once-daily dose without hormonal ABT (1 mg estradiol / 0.5mg norethindrone acetate), and a 200 mg once-daily dose in combination with hormonal ABT. Subjects who have completed the initial six-month treatment period will have the option to enter a six-month treatment extension.

Ebopiprant for Treatment of Preterm Labor: Preparations are ongoing to initiate a Phase 2b clinical study in Q4:21. The Phase 2b dose ranging study will build on the recently announced PROLONG Phase 2a proof-of-concept study, which demonstrated early clinical efficacy and safety in pregnant women with spontaneous preterm labor. Given ebopiprant is currently the only known product in development for this indication and based on its innovative mechanism of action and positive topline data, the Company plans to discuss with European regulators a possible accelerated registration program based on a Phase 2b/3 adaptive design. In parallel with development of ebopiprant in Europe and Asia, the Company is also actively evaluating the regulatory strategy for ebopiprant development in the United States, where there are currently no FDA-approved tocolytic medications available for treatment of preterm labor.

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.

Financial Update

Net loss for the quarter ending March 31, 2021 was \$20.0 million, or \$0.29 per share, compared with a net loss of \$21.9 million, or \$0.48 per share, for the quarter ending March 31, 2020. Research and development expenses were \$15.5 million and general and administrative expenses were \$4.2 million for the quarter ended March 31, 2021, compared with \$17.2 million and \$3.7 million, respectively, for the prior year quarter. The net loss for the quarter ended March 31, 2021 included non-cash expenses of \$2.0 million for stock-based compensation, compared with \$2.7 million for the prior year period.

As of March 31, 2021, ObsEva had cash and cash equivalents of \$68.0 million, compared with \$31.2 million as of December 31, 2020. On March 5, 2021, ObsEva entered into a Sale Agreement with SVB Leerink LLC (SVB Leerink) to offer and sell common shares having an aggregate offering price of up to \$50 million from time to time through an at the market offering under which SVB Leerink will act as sales agent.

The first quarter 2021 financial report will be available in the financial reports section of the Company's website.

To access the financial reports section of the Company's website, please click [\[here\]](#).

To access the first quarter 2021 financial report directly, please click [\[here\]](#).

About ObsEva

ObsEva is a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health. Through strategic in-licensing and disciplined drug development, ObsEva has established a late-stage clinical pipeline with development programs focused on treating endometriosis, uterine fibroids and preterm labor. ObsEva is listed on the Nasdaq Global Select Market and is trading under the ticker symbol "OBSV" and on the SIX Swiss Exchange where it is trading 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 "believe", "expect", "may", "plan", "potential", "will", and other similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the potential therapeutic benefits and the clinical development of ObsEva's product candidates, the potential for new indications for any of ObsEva's product candidates, the timing of enrollment in and data from clinical trials, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA, the timing of and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates, the results of interactions with regulatory authorities and the potential to raise additional funds or enter into strategic partnerships in the future. 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, the impact of the 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, 2020 and other filings ObsEva makes with the U.S. Securities and Exchange Commission. These documents are available on the Investors page of ObsEva's website at <http://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

<i>(in USD '000, except share and per share data) - unaudited</i>	Three-month period ended March 31,	
	2021	2020
Operating income other than revenue	6	4
OPERATING EXPENSES		
Research and development expenses	(15,516)	(17,188)
General and administrative expenses	(4,191)	(3,709)
Total operating expenses	(19,707)	(20,897)
OPERATING LOSS	(19,701)	(20,893)
Finance income	629	60
Finance expense	(911)	(1,011)
NET LOSS BEFORE TAX	(19,983)	(21,844)
Income tax expense	(21)	(19)
NET LOSS FOR THE PERIOD	(20,004)	(21,863)
Net loss per share		
Basic	(0.29)	(0.48)
Diluted	(0.29)	(0.48)
Weighted Average Number of Shares Outstanding	68,574,364	45,725,561

Consolidated Balance Sheets

<i>(in USD '000) - unaudited</i>	March 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	67,998	31,183
Other receivables	364	397
Prepaid expenses	4,607	5,388
Total current assets	72,969	36,968
Non-current assets		
Right-of-use assets	1,271	1,425
Furniture, fixtures and equipment	133	151
Intangible assets	26,608	26,608
Other long-term assets	280	295
Total non-current assets	28,292	28,479
Total assets	101,261	65,447
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Other payables and current liabilities	5,708	10,760
Accrued expenses	10,622	10,248
Current lease liabilities	674	696
Total current liabilities	17,004	21,704
Non-current liabilities		
Non-current lease liabilities	731	952
Non-current borrowings	25,411	25,300
Post-employment obligations	7,790	8,218
Other long-term liabilities	858	919
Total non-current liabilities	34,790	35,389
Shareholders' equity		
Share capital	6,948	4,878
Treasury shares	(938)	(304)
Share premium	414,483	356,822
Reserves	28,373	26,353
Accumulated losses	(399,399)	(379,395)
Total shareholders' equity	49,467	8,354
Total liabilities and shareholders' equity	101,261	65,447

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