



## ObsEva Announces Year End 2020 Financial Results and Business Update

*-Yselty® for uterine fibroids: US New Drug Application filing planned in Q2:21; European marketing approval 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 – March 5, 2021 – 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 year ended December 31, 2020 and provided a business update.

"2020 was a critical year for ObsEva as it marked the beginning of our transformation from a clinical stage company to one preparing for regulatory approvals and commercialization," said Brian O'Callaghan, CEO of ObsEva. "The clinical and regulatory achievements of 2020 provide a solid foundation upon which to prepare Yselty® for market launch in uterine fibroids and further its development for endometriosis."

"Our accomplishments also provide the impetus for advancing ebopiprant for treatment of preterm labor into a Phase 2b dose ranging study later this year," continued Mr. O'Callaghan. "Given the potential for expedited approval for this program, we are already beginning planning for its regulatory submission and commercialization. And though we have recently extended our cash runway into Q2 2022, we remain focused on securing further sources of long-term funding as well as suitable commercialization partners. Given the very positive outlook for ObsEva, our entire team is excited about the coming year and what the long-term future holds."

### **Anticipated Milestones**

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

- **Yselty® for uterine fibroids:** NDA submission (Q2:21); MAA approval (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

- **Yselyt<sup>®</sup> for Uterine Fibroids:** ObsEva is developing Yselyt<sup>®</sup>, an oral GnRH receptor antagonist with the potential to treat more women thanks 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) recent validation of the marketing authorization application (MAA), a major milestone toward making Yselyt<sup>®</sup> available in the E.U., the Company will continue to work closely with the EMA to achieve marketing approval, projected in Q4:2021. Meanwhile, the Company is also working to submit a U.S. New Drug Application (NDA), projected in Q2:2021, 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.
- **Yselyt<sup>®</sup> for Endometriosis:** The EDELWEISS 3 trial in the EU is progressing as planned, with primary endpoint data expected in Q4:2021. The ongoing Phase 3 EDELWEISS 3 study (Europe and US) was 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, and a 200 mg once-daily dose in combination with hormonal ABT (1 mg E2 / 0.5mg NETA). Subjects who completed the initial six-month treatment period will have the option to enter a six-month treatment extension.
- **Ebopiprant for Treatment of Preterm Labor:** A key objective for 2021 will be to initiate a Phase 2b clinical study, which will build on the recently announced positive topline data from the PROLONG Phase 2a proof-of-concept study by initiating a late-stage clinical development program. Based on the unmet need, ebopiprant's innovative mechanism of action and positive topline data regarding early clinical efficacy and safety in pregnant women with spontaneous preterm labor, and with no other known compound under development for this indication, the Company plans to discuss with European regulators a possible accelerated registration program based on a Phase 2b/3 adaptively designed trial.
- **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

Cash Position: As of December 31, 2020, ObsEva had cash and cash equivalents of \$31.2 million, compared with \$69.4 million as of December 31, 2019. In January and February 2021, ObsEva received additional net proceeds of \$55.6 million from equity issuances via its At-The-Market (ATM) program and exercises of warrants that were issued in connection with ObsEva's underwritten equity offering completed in September 2020. ObsEva believes its available cash and cash equivalents are sufficient to fund its planned operations (not including commercialization) into Q2:2022. The Company is actively exploring potential sources of non-dilutive or hybrid funding, including strategic partnerships and structured financing related to its further proposed development and commercialization efforts.

Net Loss: For the year ending December 31, 2020 was \$83.0 million, or \$1.67 per share, compared with a net loss of \$108.8 million, or \$2.49 per share, for the year ending December 31, 2019. Research and development expenses were \$67.5 million and general and administrative expenses were \$12.2 million for the full year 2020, compared with \$88.1 million and \$19.1 million, respectively, for the full year 2019. The net loss for 2020 included non-cash expenses of \$6.5 million for stock-based compensation, compared with \$11.9 million for 2019.

The full year 2020 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 full year 2020 financial report directly, please click [\[here\]](#).

## **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 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](http://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 SEC. 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 December 31,		Twelve-Month Period Ended December 31,	
	2020	2019	2020	2019
<b>Operating income other than revenue</b>	<b>6</b>	<b>5</b>	<b>17</b>	<b>16</b>
<b>OPERATING EXPENSES</b>				
Research and development expenses	(14,846)	(17,539)	(67,536)	(88,053)
General and administrative expenses	(2,768)	(2,751)	(12,182)	(19,058)
<b>Total operating expenses</b>	<b>(17,614)</b>	<b>(20,290)</b>	<b>(79,718)</b>	<b>(107,111)</b>
<b>OPERATING LOSS</b>	<b>(17,608)</b>	<b>(20,285)</b>	<b>(79,701)</b>	<b>(107,095)</b>
Finance income	356	429	648	854
Finance expense	(1,260)	(874)	(3,879)	(2,482)
<b>NET LOSS BEFORE TAX</b>	<b>(18,512)</b>	<b>(20,730)</b>	<b>(82,932)</b>	<b>(108,723)</b>
Income tax expense	(39)	(16)	(34)	(67)
<b>NET LOSS FOR THE PERIOD</b>	<b>(18,551)</b>	<b>(20,746)</b>	<b>(82,966)</b>	<b>(108,790)</b>
<b>Net loss per share</b>				
<b>Basic</b>	<b>(0.32)</b>	<b>(0.48)</b>	<b>(1.67)</b>	<b>(2.49)</b>
<b>Diluted</b>	<b>(0.32)</b>	<b>(0.48)</b>	<b>(1.67)</b>	<b>(2.49)</b>
Weighted Average Number of Shares Outstanding	55,692,358	43,869,187	49,820,451	43,674,746
Other Comprehensive Income/(loss)				
Remeasurements on post-retirement benefit plans	982	(4,694)	982	(4,694)
<b>TOTAL COMPREHENSIVE LOSS FOR THE PERIOD</b>	<b>(17,569)</b>	<b>(25,442)</b>	<b>(81,984)</b>	<b>(113,484)</b>

## Consolidated Balance Sheets

(in USD '000)	December 31, 2020	December 31, 2019
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	31,183	69,370
Other receivables	397	1,044
Prepaid expenses	5,388	4,359
<b>Total current assets</b>	<b>36,968</b>	<b>74,773</b>
<b>Non-current assets</b>		
Right-of-use assets	1,425	2,042
Furniture, fixtures and equipment	151	245
Intangible assets	26,608	26,608
Other long-term assets	295	275
<b>Total non-current assets</b>	<b>28,479</b>	<b>29,170</b>
<b>Total assets</b>	<b>65,447</b>	<b>103,943</b>
<b>LIABILITIES AND EQUITY</b>		
<b>Current liabilities</b>		
Other payables and current liabilities	10,760	8,432
Accrued expenses	10,248	10,418
Current lease liabilities	696	618
<b>Total current liabilities</b>	<b>21,704</b>	<b>19,468</b>
<b>Non-current liabilities</b>		
Non-current lease liabilities	952	1,541
Non-current borrowings	25,300	24,917
Post-employment obligations	8,218	7,946
Other long-term liabilities	919	1,116
<b>Total non-current liabilities</b>	<b>35,389</b>	<b>35,520</b>
<b>Shareholders' equity</b>		
Share capital	4,574	3,499
Share premium	356,822	320,955
Reserves	26,353	21,912
Accumulated losses	(379,395)	(297,411)
<b>Total shareholders' equity</b>	<b>8,354</b>	<b>48,955</b>
<b>Total liabilities and shareholders' equity</b>	<b>65,447</b>	<b>103,943</b>

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