

ObsEva Announces Third Quarter 2021 Financial Results and Business Update

-Linzagolix for uterine fibroids: Pending regulatory approval in the US and Europe with commercial planning efforts underway-

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

-Ebopiprant: Global License Agreement completed with Organon -

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

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

GENEVA, Switzerland – November 4, 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 quarter ended September 30, 2021 and provided a business update.

“Recent months have been noteworthy for many reasons, especially the progress made in defining the futures of both the linzagolix and ebopiprant programs,” reported Brian O’Callaghan, CEO of ObsEva. “Regulatory filings for approval of linzagolix in the treatment of uterine fibroids have now been made in both Europe and the US. As a result, commercialization planning is now underway, via our recently announced relationship with Syneos Health to commercialize linzagolix. The future path of ebopiprant was also established with our license agreement with Organon to develop and commercialize ebopiprant. We are looking forward to seeing the advancement of this investigational agent to potentially benefit many patients in the future. As I reflect on my first year with the company, I am incredibly proud of our numerous achievements across all areas of the business, and I am increasingly confident in the team’s ability to continue to grow and redefine ObsEva’s future.”

Anticipated Milestones

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

- **Linzagolix for uterine fibroids:** Committee for Medicinal Products for Human Use (CHMP) marketing approval recommendation (Q4:21)
- **Linzagolix for endometriosis:** Phase 3 EDELWEISS 3 study topline results readout (Q4:21)

Pipeline Update

- **Linzagolix for Uterine Fibroids:** ObsEva is developing linzagolix, an oral GnRH receptor antagonist with the prospect to treat more women due to its 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 only GnRH antagonist in uterine fibroids with a low dose non-ABT option to address the needs of women who cannot or do not want to take hormones. The Company is working closely with the European Medicines Agency (EMA) to achieve marketing approval, with an approval recommendation (positive opinion) from the CHMP projected in Q4:2021. In Q3:2021, the Company also submitted a New Drug Application with the US FDA. Commercial planning efforts are also underway with a recently established relationship with Syneos Health (NASDAQ: SYNH).
- **Linzagolix for Endometriosis:** The EDELWEISS 3 study in the EU is progressing as planned, with randomization of patients completed and primary endpoint data expected in Q4:2021. The ongoing Phase 3 EDELWEISS 3 study (Europe and US) enrolled 486 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 complete the initial six-month treatment period have the option to enter a six-month treatment extension
- **Ebopiprant for Treatment of Preterm Labor:** In Q3:2021, ObsEva granted a license to Organon (NYSE: OGN) for the global development, manufacturing and commercial rights to ebopiprant. Plans for the further development of ebopiprant are yet to be announced.
- **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 income for the quarter ended September 30, 2021 was \$0.8 million, or \$0.01 per share, compared with a net loss of \$24.4 million, or \$0.49 per share, for the quarter ended September 30, 2020. Research and development expenses were \$11.5 million and general and administrative expenses were \$7.0 million for the quarter ended September 30, 2021, compared with \$20.1 million and \$3.5 million, respectively, for the corresponding prior year quarter. Net income for the quarter ended September 30, 2021 included non-cash expenses of \$1.7 million for stock-based compensation, compared with \$1.9 million for stock-based compensation in the corresponding prior year quarter.

As of September 30, 2021, ObsEva had cash and cash equivalents of \$62.9 million, compared with \$31.2 million as of December 31, 2020.

In October 2021, ObsEva entered into a convertible note financing agreement with certain funds and accounts managed by JGB Management, Inc., which is structured to provide up to \$135 million in borrowing capacity, available in nine tranches, subject to certain conditions to funding.

The third 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 third 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 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 of ObsEva SA

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 similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of and commercialization plans for ObsEva's product candidates, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates, and the results of interactions with regulatory authorities. 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, 2020 filed with Securities and Exchange Commission (SEC) on March 5, 2021 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

<i>(In USD '000, except share and per share data) - unaudited</i>	Three-Month Period Ended September 30,		Nine-Month Period Ended September 30,	
	2021	2020	2021	2020
Operating income other than revenue	20,098	3	20,108	11
OPERATING EXPENSES				
Research and development expenses	(11,531)	(20,125)	(41,532)	(52,690)
General and administrative expenses	(7,035)	(3,514)	(15,114)	(9,414)
Total operating expenses	(18,566)	(23,639)	(56,646)	(62,104)
OPERATING INCOME / (LOSS)	1,532	(23,636)	(36,538)	(62,093)
Finance income	128	184	702	292
Finance expense	(822)	(918)	(2,423)	(2,619)
NET INCOME / (LOSS) BEFORE TAX	838	(24,370)	(38,259)	(64,420)
Income tax (expense) / benefit	(19)	(14)	(70)	5
NET INCOME / (LOSS) FOR THE PERIOD	819	(24,384)	(38,329)	(64,415)
Net earnings / (loss) per share				
Basic	0.01	(0.49)	(0.53)	(1.35)
Diluted	0.01	(0.49)	(0.53)	(1.35)
Weighted Average Number of Shares Outstanding	77,971,008	50,086,923	74,152,705	47,848,862

Consolidated Balance Sheets

<i>(In USD '000) - unaudited</i>	September 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	62,884	31,183
Other receivables	3,428	397
Prepaid expenses	5,746	5,388
Total current assets	72,058	36,968
Non-current assets		
Right-of-use assets	730	1,425
Furniture, fixtures and equipment	62	151
Intangible assets	24,503	26,608
Other long-term assets	283	295
Total non-current assets	25,578	28,479
Total assets	97,636	65,447
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Other payables and current liabilities	7,347	10,760
Accrued expenses	10,723	10,248
Current lease liabilities	698	696
Total current liabilities	18,768	21,704
Non-current liabilities		
Non-current lease liabilities	383	952
Non-current borrowings	25,623	25,300
Post-employment obligations	8,116	8,218
Other long-term liabilities	577	919
Total non-current liabilities	34,699	35,389
Shareholders' equity		
Share capital	6,948	4,878
Treasury shares	(630)	(304)
Share premium	424,561	356,822
Reserves	31,014	26,353
Accumulated losses	(417,724)	(379,395)
Total shareholders' equity	44,169	8,354
Total liabilities and shareholders' equity	97,636	65,447

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