ObsEva Announces Second Quarter 2021 Financial Results and Business Update

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

-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 – August 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 quarter ended June 30, 2021 and provided a business update.

"The outset of 2021 was focused on strengthening the financial position of the company, and we have continued to execute on our strategic plan, which most recently includes the global license to Organon of development, manufacturing and commercial rights to ebopiprant," said Brian O'Callaghan, CEO of ObsEva. "This partnership is an important validation of ObsEva's ability to generate value, and we view Organon as the ideal partner for the development and commercialization of ebopiprant to address the significant unmet need in preterm labor. In parallel, we remain laser focused on advancing linzagolix through the regulatory approval process and preparing for its commercialization. We look forward to providing additional updates in the near future."

Anticipated Milestones

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

- **Linzagolix for uterine fibroids:** U.S. New Drug Application (NDA) submission (Q3:21); Committee for Medicinal Products for Human Use (CHMP) marketing approval recommendation (Q4:21)

- **Linzagolix for endometriosis:** Phase 3 EDELWEISS 3 topline results readout (Q4:21)

Pipeline Update

- ***Linzagolix for Uterine Fibroids:*** ObsEva is developing linzagolix, 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, 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. The Company is also working to submit an NDA, projected in Q3:2021.

- ***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:*** ObsEva recently granted a license to Organon (NYSE:OGN) for the global development, manufacturing and commercial rights to ebopiprant. Plans for the future 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 loss for the quarter ended June 30, 2021 was $19.1 million, or $0.25 per share, compared with a net loss of $18.2 million, or $0.38 per share, for the quarter ended June 30, 2020. Research and development expenses were $14.5 million and general and administrative expenses were $3.9 million for the quarter ended June 30, 2021, compared with $15.4 million and $2.2 million, respectively, for the corresponding prior year quarter. Net loss for the quarter ended June 30, 2021 included non-cash expenses of $0.9 million for stock-based compensation, compared with $1.4 million for stock-based compensation in the corresponding prior year quarter.

As of June 30, 2021, ObsEva had cash and cash equivalents of $58.9 million, compared with $31.2 million as of December 31, 2020.

The second 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 second 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

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 clinical development of and commercialization plans for ObsEva's product candidates, ObsEva's ability to generate value, 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, 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 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 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

(in USD '000, except share and per share data) - unaudited	Three-Month Period Ended June 30, 2021	Three-Month Period Ended June 30, 2020	Six-Month Period Ended June 30, 2021	Six-Month Period Ended June 30, 2020
Operating income other than revenue	**4**	**4**	**10**	**8**
OPERATING EXPENSES				
Research and development expenses	(14,485)	(15,377)	(30,001)	(32,565)
General and administrative expenses	(3,888)	(2,191)	(8,079)	(5,900)
Total operating expenses	**(18,373)**	**(17,568)**	**(38,080)**	**(38,465)**
OPERATING LOSS	**(18,369)**	**(17,564)**	**(38,070)**	**(38,457)**
Finance income	(55)	48	574	108
Finance expense	(690)	(690)	(1,601)	(1,701)
NET LOSS BEFORE TAX	**(19,114)**	**(18,206)**	**(39,097)**	**(40,050)**
Income tax (expense) / benefit	(30)	38	(51)	19
NET LOSS FOR THE PERIOD	**(19,144)**	**(18,168)**	**(39,148)**	**(40,031)**
Net loss per share				
Basic	(0.25)	(0.38)	(0.54)	(0.86)
Diluted	(0.25)	(0.38)	(0.54)	(0.86)
Weighted Average Number of Shares Outstanding	75,809,484	47,709,508	72,211,911	46,717,535

Consolidated Balance Sheets

(in USD '000) - unaudited	June 30, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	58,923	31,183
Other receivables	458	397
Prepaid expenses	8,010	5,388
Total current assets	**67,391**	**36,968**
Non-current assets		
Right-of-use assets	834	1,425
Furniture, fixtures and equipment	65	151
Intangible assets	26,608	26,608
Other long-term assets	284	295
Total non-current assets	**27,791**	**28,479**
Total assets	**95,182**	**65,447**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Other payables and current liabilities	7,515	10,760
Accrued expenses	10,312	10,248
Current lease liabilities	694	696
Total current liabilities	**18,521**	**21,704**
Non-current liabilities		
Non-current lease liabilities	567	952
Non-current borrowings	25,519	25,300
Post-employment obligations	8,074	8,218
Other long-term liabilities	877	919
Total non-current liabilities	**35,037**	**35,389**
Shareholders' equity		
Share capital	6,948	4,878
Treasury shares	(630)	(304)
Share premium	424,567	356,822
Reserves	29,282	26,353
Accumulated losses	(418,543)	(379,395)
Total shareholders' equity	**41,624**	**8,354**
Total liabilities and shareholders' equity	**95,182**	**65,447**

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