ObsEva Announces Third Quarter 2020 Financial Results and Business Update

- **Positive Phase 3 PRIMROSE 1 and 2 trial results of linzagolix for the treatment of heavy menstrual bleeding due to uterine fibroids presented in late breaking session of ASRM Virtual Congress**
- **Linzagolix regulatory submissions planned for Q4:20/H1:21 in Europe/U.S.**
- **Actively discussing commercial partnership to maximize linzagolix best-in-class potential**
- **OBE022 Phase 2 PROLONG trial results on track for Q4:20**

GENEVA, Switzerland and BOSTON, MA – November 5, 2020 – ObsEva SA (NASDAQ: OBSV) (SIX: OBSN), a clinical-stage biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health, today reported financial results for the quarter ended September 30, 2020 and provided a business update.

"The third quarter brought highly important Phase 3 trial results for linzagolix that have allowed us to begin preparing regulatory submissions for the uterine fibroid indication", said Ernest Loumaye, MD, PhD, OB/GYN, CEO and Co-Founder of ObsEva. "We are increasingly optimistic that having the only non-ABT dosing regimen can provide significant commercial differentiation by providing appropriate treatment alternatives for the broadest possible population of women".

Pipeline Update

Linzagolix for the treatment of uterine fibroids and endometriosis

- ***Positive Phase 3 results for PRIMROSE 1 and PRIMROSE 2 trials of linzagolix for the treatment of HMB due to uterine fibroids:*** PRIMROSE 1 is being conducted in approximately 500 women experiencing heavy menstrual bleeding (HMB) due to uterine fibroids. As announced July 6, 2020, the 24-week responder rate was 75.5% for women receiving 200mg linzagolix with add back therapy (ABT) and 56.4% for women receiving 100 mg linzagolix without ABT, vs. 35.0% for placebo ($p<0.001$ and $p=0.003$ respectively). In addition, 52-week data from PRIMROSE 2 demonstrate that continued treatment with linzagolix provides sustained efficacy and is well tolerated. Responder rates of 91.6% and 53.2% were observed in women receiving 200 mg with ABT and 100 mg without ABT, respectively, both of which are similar to the responder rates observed at week 24 of the study. The pooled week 24 data from these two Phase 3 studies support a potentially best-in-class profile, with a responder rate of 84.5% in women receiving linzagolix 200 mg with ABT, and 56.5% in women receiving linzagolix 100 mg without ABT.

- ***Clinical data presentations at ASRM Virtual Congress October 17-21:*** Two late breaking poster presentations detailed Phase 3 PRIMROSE 1 and 2 trial results, with focus on overall efficacy and safety, as well as the potential to treat the significant proportion of women who may have a contraindication to hormonal ABT dosing regimens.
- ***Clinical data presentations at SEUD Digital 2020 Congress November 3-6:*** Two presentations further discuss Phase 3 PRIMROSE 1 and 2 trial results, with a focus on the importance of the potential of an oral GnRH antagonist to alleviate symptoms of HMB due to uterine fibroids through both full as well as partial suppression with and without ABT, respectively. This optionality potentially allows for more women suffering from this condition to be treated effectively.
- ***New patient enrollment ongoing in Phase 3 trials EDELWEISS 2 (U.S.) and EDELWEISS 3 (U.S. and Europe)*****:** Following disruption from the COVID-19 pandemic earlier this year, the EDELWEISS 2 and 3 trials resumed enrollment of new patients in the latter part of the second quarter, and enrollment continued during the third quarter. Each of these trials is designed to assess two once daily oral doses of linzagolix in women with endometriosis-associated pain, including 75mg without ABT and 200mg with ABT.
- ***Linzagolix commercial partnership*****:** ObsEva is engaged in active discussions with several parties for a commercial partnership to maximize the best-in-class potential of linzagolix.

OBE022 to delay childbirth in pregnant women with preterm labor at 24-34 weeks of gestation

- ***Infant and delivery follow-up completing in Phase 2 PROLONG part B:*** Part B is the multicenter, randomized, double-blind, placebo-controlled portion of the PROLONG trial that enrolled up to 120 women with preterm labor at a gestational age between 24 and 34 weeks. Enrollment in Part B was completed earlier this year, and all women have delivered their babies.

Nolasiban for improving pregnancy and live birth in women undergoing embryo transfer (ET) following in-vitro fertilization (IVF)

- ***Nolasiban partnership with YuYuan BioScience Technology (YuYuan) for development and commercialization in China:*** On July 1, 2020, ObsEva and YuYuan announced a pre-IND meeting request to the Chinese National Medical Products Administration (NMPA) to enable a Phase 1 and Phase 2 proof of concept study in China.
- ***Clinical data presented at ASRM Virtual Congress October 17-21*****:** Poster number # P-482: "The Effect of the Oral Oxytocin Antagonist, Nolasiban, On Pregnancy Rates in Women Undergoing Embryo Transfer Following IVF", presented results supporting the further evaluation of higher doses and/or alternate regimens of nolasiban.

Financial Update

- ***Equity offering raised gross proceeds of $20 million.*** An underwritten equity offering and concurrent private placement were completed in September, bringing ObsEva's cash and cash equivalents at September 30, 2020 to $50.6 million. The exercise of warrants issued in the equity offering and concurrent private placement could provide additional capital over the 15-month term of the securities.

Anticipated Milestones

ObsEva expects to achieve the following clinical and regulatory milestones in 2020-21:

Fourth Quarter 2020

- **Linzagolix**: Submit a Marketing Authorization Application (MAA) in Europe through a centralized procedure for the uterine fibroid indication.
- **OBE022:** Report final safety and efficacy results from the PROLONG trial encompassing maternal and neonatal follow-up.
- **Nolasiban:** YuYuan to submit an IND in China to initiate clinical development.

First Half 2021

- **Linzagolix:** Complete safety follow-up, and submit a New Drug Application (NDA) to the U.S. Food and Drug Administration for the uterine fibroid indication.
- **OBE022:** Pending positive Phase 2a results, seek regulatory feedback on development program requirements and proceed to Phase 2b for the treatment of pre-term labor.

Third Quarter 2020 Financial Results

Net loss for the quarter ending September 30, 2020 was $24.4 million, or $0.49 per share, compared with a net loss of $27.6 million, or $0.63 per share, for the quarter ending September 30, 2019. Research and development expenses were $20.1 million and general and administrative expenses were $3.5 million for the quarter, compared with $21.9 million and $4.9 million, respectively, for the prior year quarter. The net loss for the quarter included non-cash expenses of $1.9 million for stock-based compensation, compared with $3.0 million a year ago.

As of September 30, 2020, ObsEva had cash and cash equivalents of $50.6 million, compared with $69.4 million as of December 31, 2019.

The third quarter 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 third quarter 2020 financial report directly, please click [here].

About ObsEva

ObsEva is a clinical-stage biopharmaceutical company focused on the clinical development and commercialization of novel therapeutics for serious conditions that compromise a 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, preterm labor, and improving IVF outcomes. 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 similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of ObsEva's product candidates, the timing of enrollment in and data from clinical trials, including the impact of the COVID-19 pandemic on such trials, ObsEva's plan to submit its MAA in Europe and NDA in the U.S., and YuYuan's submission of an IND application in China, the results of interactions with regulatory authorities and ObsEva's ability to enter into a future commercial partnership for linzagolix. 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 effects of the COVID-19 pandemic, any benefits from the joint collaboration with YuYuan or any future commercial partnership for linzagolix may not be fully realized or may take longer to realize than expected 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, 2019, 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 September 30 2020	2019	Nine-Month Period Ended September 30 2020	2019
Operating income other than revenue	**3**	**5**	**11**	**11**
OPERATING EXPENSES				
Research and development expenses	(20,125)	(21,935)	(52,690)	(70,513)
General and administrative expenses	(3,514)	(4,865)	(9,414)	(16,306)
Total operating expenses	**(23,639)**	**(26,800)**	**(62,104)**	**(86,819)**
OPERATING LOSS	**(23,636)**	**(26,795)**	**(62,093)**	**(86,808)**
Finance income	184	219	292	425
Finance expense	(918)	(1,021)	(2,619)	(1,608)
NET LOSS BEFORE TAX	**(24,370)**	**(27,597)**	**(64,420)**	**(87,991)**
Income tax (expense) / benefit	(14)	(10)	5	(51)
NET LOSS FOR THE PERIOD	**(24,384)**	**(27,607)**	**(64,415)**	**(88,042)**
Net loss per share				
Basic	**(0.49)**	**(0.63)**	**(1.35)**	**(2.01)**
Diluted	**(0.49)**	**(0.63)**	**(1.35)**	**(2.01)**
Weighted Average Number of Shares Outstanding	50,086,923	43,739,938	47,848,862	43,693,245
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD	**(24,384)**	**(27,607)**	**(64,415)**	**(88,042)**

Consolidated Balance Sheets

(in USD '000)	September 30, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	50,597	69,370
Other receivables	516	1,044
Prepaid expenses	5,183	4,359
Total current assets	**56,296**	**74,773**
Non-current assets		
Right-of-use assets	1,579	2,042
Furniture, fixtures and equipment	168	245
Intangible assets	26,608	26,608
Other long-term assets	285	275
Total non-current assets	**28,640**	**29,170**
Total assets	**84,936**	**103,943**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Other payables and current liabilities	14,538	8,432
Accrued expenses	12,064	10,418
Current lease liabilities	665	618
Total current liabilities	**27,267**	**19,468**
Non-current liabilities		
Non-current lease liabilities	1,091	1,541
Non-current borrowings	25,204	24,917
Post-employment obligations	8,310	7,946
Other long-term liabilities	878	1,116
Total non-current liabilities	**35,483**	**35,520**
Shareholders' equity		
Share capital	4,370	3,499
Share premium	353,651	320,955
Reserves	25,991	21,912
Accumulated losses	(361,826)	(297,411)
Total shareholders' equity	**22,186**	**48,955**
Total liabilities and shareholders' equity	**84,936**	**103,943**

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