ObsEva Reports Fourth Quarter and Full Year 2018 Financial Results, Provides Business Update

Major 2018 Accomplishments Driven by Positive Clinical Trial Results

-Significant increase in rates of pregnancy and live birth (up to 35% increase in Day 5 ET) in Phase 3 IMPLANT 2 trial of nolasiban in IVF procedures

-Significant reduction in pain symptoms (3/4 of patients meeting responder criteria) and BMD safety as expected in Phase 2b EDELWEISS trial of linzagolix in endometriosis related pelvic pain

-Positive initial PK-PD and safety results in the open label Part A of Phase 2a PROLONG trial of OBE022 in acute pre-term labor

2019: A Transformational Year with Several Expected Key Milestones

-As many as six Phase 3 trials ongoing, with linzagolix endometriosis and fibroid programs and confirmatory IMPLANT4 EU trial of nolasiban in IVF underway

-Primary endpoint results from IMPLANT4 trial of nolasiban expected by Q4:19 and MAA regulatory filing planned prior to the end of 2019

-Additional FDA feedback on nolasiban development expected in 2019, which may lead to commencement of the US Phase 3 program in H2:19

-Phase 3 primary endpoint results from PRIMROSE trial program of linzagolix in uterine fibroids starting in Q4:19

Geneva, Switzerland and Boston, MA – March 5, 2019 – ObsEva SA (NASDAQ: OBSV / SIX: OBSN), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that compromise a woman's reproductive health and pregnancy, today reported financial results for the fourth quarter and the year ending December 31, 2018. It has also provided a business update outlining recent corporate progress and upcoming milestones.

*"2*018 was a year of tremendous pipeline advancement with successful clinical data readouts that have positioned ObsEva to take the next step in 2019 towards the transition to a commercial company," said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. "We are looking forward to Phase 3 data this year for both nolasiban and linzagolix, followed by our first regulatory filing planned for Europe."

Recent Highlights

- In November 2018, ObsEva announced the initiation of the Phase 3 IMPLANT4 trial of the oxytocin receptor antagonist nolasiban in IVF. IMPLANT4 is planning to enroll approximately 820 patients undergoing a Day 5 single embryo transfer (SET) at approximately 50 clinical sites in 10 countries primarily in Europe (n=41), Canada (n=4) and Russia (n=4).

- In December 2018, patient recruitment was completed in the Phase 3 PRIMROSE 2 trial of the oral GnRH receptor antagonist linzagolix for the treatment of uterine fibroids. Along with the PRIMROSE 1 trial in the U.S., these trials are targeting enrollment of approximately 1,000 women and are designed to assess the effect of the linzagolix treatment on heavy menstrual bleeding (HMB) associated with uterine fibroids. The efficacy and safety of two linzagolix doses being studied are 100mg without ABT and 200mg with ABT.

- Also during the quarter, ObsEva completed a successful end-of-Phase 2 meeting with the FDA to review the Phase 3 clinical trial program for linzagolix in endometriosis, which is commencing this quarter. The EDELWEISS 2 and 3 trials are expected to enroll approximately 900 patients in total with endometriosis associated pain, comparing two, once-daily, dosing regimens of linzagolix to placebo; 75mg without ABT, and 200mg with ABT.

- In early 2019, ObsEva announced the completion of the open label Part A of the PROLONG Phase 2a trial of the oral prostaglandin F2 alpha receptor antagonist OBE022, for the treatment of pre-term labor in pregnant women between 24 and 34 weeks of gestation. The randomized, double-blinded, placebo-controlled Part B of the trial is presently enrolling patients after observing 8 of 9 patients successfully completing the 7-day dosing period without delivering a baby, as well as a positive pharmacokinetic (PK) and safety data.

Upcoming Milestones

ObsEva expects to achieve the following clinical and regulatory milestones in 2019:

- In the second quarter of 2019, results for the final prospectively designed endpoint are expected from the IMPLANT2 trial of nolasiban, which is the 6-month pediatric safety follow-up.
- In the first half of 2019, the Week 48 (6-month post treatment follow-up) and the Week 52 (treatment extension up to 12 months) results in the EDELWEISS phase 2b trial.
- In the second quarter of 2019, ObsEva expects to announce completion of patient recruitment in the IMPLANT 4 trial of nolasiban with expected primary endpoint, 10-week ongoing pregnancy results expected in the fourth quarter of 2019. Assuming confirmatory results, a European Marketing Authorization Application (MAA) regulatory submission is planned for late 2019.
- For U.S. nolasiban development, additional FDA feedback on trial design is expected in the second quarter of 2019, which may lead to commencement of the Phase 3 program in the second half of 2019.
- Six-month primary endpoint data from the PRIMROSE 2 trial of linzagolix for the treatment of uterine fibroids is expected in the fourth quarter of 2019, and recruitment completion for the PRIMROSE 1 trial is now expected in the second quarter of 2019 with primary endpoint data anticipated in early 2020. Accordingly, an NDA for linzagolix in uterine fibroids remains targeted for 2020.
- Part B of the Phase 2a PROLONG clinical trial of OBE022 in acute pre-term labor is presently ongoing, with initial interim analysis of the primary endpoint for the first 30 patients expected by H1:19.

Full Year 2018 Financial Results

Net loss for the fourth quarter and full year of 2018 was $20.1 million and $76.8 million, or ($0.46) and ($1.91) per basic and diluted share, vs. $17.1 million and $66.9 million or ($0.47) and ($2.25) per basic and diluted share for the fourth quarter and full year of 2017. Research and development expenses were $62.9 million and general and administrative expenses were $14.3 million for the year ended December 31, 2018, vs. $54.9 million and $12.6 million, respectively, for the year ended December 31, 2017. Full year 2018 net loss included non-cash expenses of $9.2 million for share-based compensation, as compared to $8.9 million in the prior period.

As of December 31, 2018, ObsEva had cash and cash equivalents of $138.6 million.

To access the financial reports section of our website, please click here

Conference Call Information

Today, ObsEva will host a conference call and audio webcast at 8:00 a.m. Eastern Time/2:00 p.m. Central European Time, to provide a business update and discuss the fourth quarter and year-end 2018 financial results. To participate in the conference call, please dial 844-419-1772 (U.S.) or +1 (213) 660-0921 (international) and refer to conference ID 6474005. The webcast can be accessed under the “Investors” section of ObsEva’s website www.obseva.com

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 woman'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 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, clinical development and related interactions with regulators, ObsEva’s reliance on third parties over which it may not always have full control, 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, 2018, 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 per share data)	Three-month period ended December 31, 2018	Three-month period ended December 31, 2017	Twelve-Month Period Ended December 31, 2018	Twelve-Month Period Ended December 31, 2017
	Unaudited		*Audited*	
Operating income other than revenue	**5**	**5**	**15**	**16**
OPERATING EXPENSES				
Research and development expenses	$ (15,927)	$ (13,929)	$ (62,872)	$ (54,912)
General and administrative expenses	(4,010)	(2,967)	(14,297)	(12,568)
Total operating expenses	**(19,937)**	**(16,896)**	**(77,169)**	**(67,480)**
OPERATING LOSS	**(19,932)**	**(16,891)**	**(77,154)**	**(67,464)**
Finance income	(224)	(164)	393	590
Finance expense	—	—	—	(1)
NET LOSS BEFORE TAX	**(20,156)**	**(17,055)**	**(76,761)**	**(66,875)**
Income tax (expense)/benefit	22	(15)	45	(51)
NET LOSS FOR THE PERIOD	**$ (20,134)**	**$ 17,070)**	**$ (76,716)**	**$ (66,926)**
Net loss per share				
Basic	(0.46)	(0.48)	(1.91)	(2.25)
Diluted	(0.46)	(0.48)	(1.91)	(2.25)
Other Comprehensive Loss				
Remeasurements on post-employment benefit plans	(544)	(142)	(544)	(142)
Total Comprehensive Loss	**(20,678)**	**(17,212)**	**(77,260)**	**(67,068)**
Weighted average number of shares outstanding	43,393,072	35,239,817	40,172,498	29,799,047

Consolidated Balance Sheet

(in USD '000)	December 31, 2018 *Audited*	December 31, 2017 *Audited*
ASSETS		
Current assets		
Cash and cash equivalents	138,640	110,841
Other receivables	885	783
Prepaid expenses	5,715	1,490
Total current assets	**145,240**	**113,114**
Non-current assets		
Furniture, fixtures and equipment	319	323
Intangible assets	21,608	21,608
Other long-term assets	273	190
Total non-current assets	**22,200**	**22,121**
Total assets	**167,440**	**135,235**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Current tax liability	—	51
Other payables and current liabilities	2,766	2,865
Accrued expenses	14,163	6,514
Total current liabilities	**16,929**	**9,430**
Non-current liabilities		
Post-employment obligations	3,547	3,099
Other long-term liabilities	48	55
Total non-current liabilities	**3,595**	**3,154**
Shareholders' equity		
Share capital	3,420	2,864
Share premium	314,565	219,335
Reserves	12,858	7,119
Accumulated losses	(183,927)	(106,667)
Total shareholders' equity	**146,916**	**122,651**
Total liabilities and shareholders' equity	**167,440**	**135,235**

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