ObsEva Reports First Quarter 2019 Financial Results

2019 Phase 3 Data Readouts on track for nolasiban in IVF and linzagolix in uterine fibroids; MAA submission for nolasiban IVF therapy targeted by year-end

GENEVA, Switzerland and BOSTON, MA. (May 9, 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 first quarter ending March 31, 2019 and provided a business update.

Recent Highlights

Nolasiban to improve IVF outcomes

- ObsEva continued enrolling patients in IMPLANT 4, ObsEva's confirmatory Phase 3 trial for the oxytocin receptor antagonist nolasiban in IVF. Approximately 820 patients who are undergoing a Day 5 single embryo transfer will be enrolled at approximately 40 sites primarily in Europe.
- ObsEva reported final follow-up safety data from the nolasiban IMPLANT 2 trial. The results showed no difference from placebo in the developmental health of infants at six months post-birth, as measured by the About Ages and Stages Questionaire-3 (ASQ-3), a broadly validated assessment of infant development.

Linzagolix for the treatment of endometriosis associated pain and heavy menstrual bleeding due to uterine fibroids

- ObsEva reported positive long-term data from the Phase 2b EDELWEISS trial of linzagolix in endometriosis. Some patients were treated for 52 weeks in the extension study and others were followed for six months off treatment after the initial six-month treatment period. The results were consistent with prior data, showing durable efficacy as well as favorable bone mineral density impact within expected ranges for partial and full suppression of estrogen.
- ObsEva made strong enrollment progress in PRIMROSE 1, the Company's U.S. Phase 3 trial for linzagolix in the treatment of uterine fibroids. The PRIMROSE 1 and PRIMROSE 2 trials are targeting enrollment of approximately 1,000 women with heavy menstrual bleeding associated with uterine fibroids. The efficacy and safety of two doses of linzagolix are being studied, including 100mg without low dose hormonal add-back therapy (ABT) and 200mg with ABT.

OBE022 for the treatment of preterm labor

- ObsEva announced encouraging Part A results leading to the initiation of Part B of PROLONG, a proof-of-concept Phase 2a trial of the oral prostaglandin F2 alpha receptor antagonist OBE022 for the treatment of preterm labor. Part A results showed that OBE022 was well tolerated by mothers and their fetuses and supported prior favorable pharmacokinetic analysis. Eight of nine patients achieved the treatment goal of seven-days without delivering a baby.

- Ongoing part B is the multicenter, randomized, double-blind, placebo-controlled portion of the trial that will enroll up to 120 patients with preterm labor at a gestational age of between 24 and 34 weeks.

"We are thrilled with our progress this past quarter as we advanced all three of our Phase 3 clinical programs, and have initiated two Phase 3 trials for endometriosis this year. 2019 is a transformational year for us as we work toward the MAA filing of nolasiban later this year. We are excited about developing our commercial capabilities in anticipation of a planned European launch in 2021," said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva.

2019 Milestones

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

Nolasiban

- In the second quarter of 2019, ObsEva expects to complete patient recruitment in the IMPLANT 4 trial of nolasiban, and to report primary endpoint results (10-week ongoing pregnancy) in the fourth quarter of 2019.
- Assuming positive IMPLANT 4 results, the Company plans to submit a European Marketing Authorization Application (MAA) in late 2019.
- In the second quarter of 2019, the Company anticipates additional FDA feedback on the U.S. trial design for nolasiban in IVF, and targets U.S. Phase 3 development initiation in the second half of 2019.

Linzagolix

- In the second quarter of 2019, ObsEva expects to complete recruitment in the PRIMROSE 1 trial of linzagolix for the treatment of uterine fibroids, and to report 6-month primary endpoint data in the first quarter of 2020.
- In the fourth quarter of 2019, the Company expects to report six-month primary endpoint data from the PRIMROSE 2 trial of linzagolix for the treatment of uterine fibroids.
- In the second quarter of 2019, the Company expects to enroll patients in the Phase 3 EDELWEISS 2 and EDELWEISS 3 trials for the treatment of endometriosis-associated pain.

OBE022

- In the second quarter of 2019, ObsEva anticipates an initial interim efficacy analysis of the first 30 patients from Part B of the Phase 2a PROLONG clinical trial of OBE022 in acute preterm labor.

First Quarter 2019 Financial Results

Net loss for the first quarter of 2019 was $25.7 million, or $0.59 per share, compared with a net loss of $19.8 million, or $0.54 per share, for the first quarter of 2018. Research and development expenses were $20.1 million and general and administrative expenses were $5.3 million for the first quarter of 2019, compared with $16.3 million and $3.6 million, respectively, for the first quarter of 2018. The net loss for the first quarter of 2019 included non-cash expenses of $3.3 million for stock-based compensation, compared with $2.4 million in the prior-year period.

As of March 31, 2019, ObsEva had cash and cash equivalents of $117.3 million, compared with $138.6 million as of December 31, 2018.

To access the financial reports section of the Company's website, please click [here].

Conference Call

ObsEva will host a conference call and audio webcast today beginning at 8:00 a.m. Eastern Time/2:00 p.m. Central European Time, to provide a business update and discuss the first quarter results. Investors may participate by dialing (844) 419-1772 for U.S. callers or (213) 660-0921 for international callers and referring to conference ID 9375906. A webcast of the conference call 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 Statement of Comprehensive Loss

(in USD '000, except share and per share data)	Three-month period ended March 31,	
	2019	2018
	unaudited	
Operating income other than revenue	**5**	**5**
OPERATING EXPENSES		
Research and development expenses	(20,140)	(16,342)
General and administrative expenses	(5,255)	(3,649)
Total operating expenses	**(25,395)**	**(19,991)**
OPERATING LOSS	**(25,390)**	**(19,986)**
Finance income	262	155
Finance expense	(544)	—
NET LOSS BEFORE TAX	**(25,672)**	**(19,831)**
Income tax (expense) / benefit	(7)	25
NET LOSS FOR THE PERIOD	**(25,679)**	**(19,806)**
Net loss per share		
Basic	(0.59)	(0.54)
Diluted	(0.59)	(0.54)
Weighted Average Number of Shares Outstanding	**43,488,440**	**36,389,578**

Consolidated Balance Sheet

(in USD '000)	March 31, 2019 *unaudited*	December 31, 2018 *audited*
ASSETS		
Current assets		
Cash and cash equivalents	117,321	138,640
Other receivables	993	885
Prepaid expenses	5,538	5,715
Total current assets	**123,852**	**145,240**
Non-current assets		
Right-of-use assets	2,505	—
Furniture, fixtures and equipment	297	319
Intangible assets	21,608	21,608
Other long-term assets	273	273
Total non-current assets	**24,683**	**22,200**
Total assets	**148,535**	**167,440**
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Current tax liability	1	—
Other payables and current liabilities	3,630	2,766
Accrued expenses	14,182	14,163
Current lease liabilities	580	—
Total current liabilities	**18,393**	**16,929**
Non-current liabilities		
Non-current lease liabilities	1,967	—
Post-employment obligations	3,514	3,547
Other long-term liabilities	—	48
Total non-current liabilities	**5,481**	**3,595**
Shareholders' equity		
Share capital	3,427	3,420
Share premium	315,456	314,565
Reserves	15,384	12,858
Accumulated losses	(209,606)	(183,927)
Total shareholders' equity	**124,661**	**146,916**
Total liabilities and shareholders' equity	**148,535**	**167,440**

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