



## **ObsEva Reports Third Quarter 2018 Financial Results and Provides Business Update**

- ***IMPLANT 4 trial of nolasiban in IVF starting in Q4 2018, European MAA filing expected late 2019***
- ***24-week data from Phase 2b EDELWEISS clinical trial of linzagolix in endometriosis supports 75mg without ABT and 200mg with low dose ABT for Phase 3 trials planned for 2019***
- ***Phase 3 PRIMROSE 1 and 2 trials in uterine fibroids continue enrolling, 6-month results anticipated 2H 2019***

**Geneva, Switzerland and Boston, MA – November 8, 2018** – 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 quarter ended September 30, 2018, and provided a business update outlining recent corporate progress and upcoming milestones.

“We continued to make significant progress this quarter with two positive data readouts; the live birth rate results from the IMPLANT 2 trial of nolasiban in IVF, and 24-week data from the Phase2b EDELWEISS trial of linzagolix in endometriosis,” said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. “With recent regulatory feedback on nolasiban, we plan to initiate IMPLANT 4 before year end and, assuming positive data, intend to file an MAA in late 2019. We are excited by the progress of this program and have begun preparation for commercialization in Europe.”

### **Recent Highlights**

- Additional positive Phase 3 IMPLANT 2 trial results were announced in October 2018. Live birth rate, reflecting the ultimate goal of IVF procedures, taking home a baby, showed a 34.8% vs. 27.7% statistically and clinically significant benefit in favor of patients receiving nolasiban, a 26% relative improvement, p=0.025. For patients undergoing Day 5 ET, the live birth rate benefit was even more pronounced for nolasiban, 44.8% vs. 33.2%, a 35% relative improvement, p=0.025. In addition, IMPLANT 2 trial results were presented at the Annual Meeting of the American Society for Reproductive Medicine (ASRM), October 6-10 in Denver

Colorado, and received the 2018 Prize Paper Award from the Society for Assisted Reproductive Technologies (SART).

- Additional positive Phase2b EDELWEISS clinical trial results of ObsEva's oral GnRH receptor antagonist linzagolix in the treatment of endometriosis related pelvic pain were announced in September 2018. The 24-week data showed an improvement in patient response rate (defined as a 30% or greater reduction in verbal rating scale, or VRS 0-3 pain score from baseline) at 24 weeks vs. 12 weeks for key doses, 70.8% of women vs. 61.5% with 75mg once daily, and 77.3% of women vs. 56.3% with 200mg once daily. The key safety endpoint of mean change in bone mineral density (BMD) at the lumbar spine (site of greatest bone loss) was -0.8% at the 75mg once daily dose and -2.6% at the 200mg once daily dose, which ObsEva believes supports its expectation to further develop the once daily 75mg dose without low dose hormonal add-back therapy (ABT) and the once daily 200mg dose with low dose ABT.
- Patient enrollment is continuing in the PRIMROSE 1 and PRIMROSE 2 Phase 3 clinical trials of linzagolix for the treatment of uterine fibroids, with a target enrollment of approximately 1,000 women in total (US and Europe). These trials are designed to reduce heavy menstrual bleeding (HMB) associated with uterine fibroids, with efficacy and safety of two doses being studied, 200mg with ABT and 100mg without ABT.
- Enrollment of 8 patients was completed in the open label Part A of the PROLONG Phase 2a clinical trial of OBE022, ObsEva's oral prostaglandin F2 alpha receptor antagonist for the treatment of pre-term labor in pregnant women between 24 and 34 weeks of gestation. Given the positive pharmacokinetic (PK) and safety data, ObsEva began the randomized, double blinded, placebo controlled, Part B of the trial this quarter.

### **Upcoming Milestones**

ObsEva expects to achieve the following clinical and regulatory milestones in 2018 and 2019:

- Following recent feedback from regulatory authorities in Europe, ObsEva plans to begin a Phase 3 trial prior to the end of 2018, or the IMPLANT 4 trial, primarily in European, Canadian and CIS or Russian centers. ObsEva is planning to submit the European Marketing Authorization Application (MAA) in late 2019, and has commenced commercial planning. Recent feedback received from the FDA did not provide the clarity that we were hoping to see on the design of pivotal clinical trials to support an IVF indication in the US. We are working with the FDA to get agreement on certain elements, e.g. time of patient randomization, primary and secondary endpoints and potential stratification by patient age. Upon agreement with the FDA, which we hope will be achieved in 2019, ObsEva is planning to pursue its clinical trial program in the United States.
- Enrollment completion for the PRIMROSE 2 trial of linzagolix for the treatment of uterine fibroids continues to be targeted for Q4 of 2018, while PRIMROSE 1 enrollment completion is anticipated in Q1 of 2019. Six-month primary endpoint data from both trials are expected in H2 of 2019.

- For linzagolix in endometriosis, ObsEva will have an end-of-Phase 2 meeting with the FDA prior to the end of 2018, and plans to begin Phase 3 clinical trials in Q1 of 2019.
- Part B of the Phase 2a PROLONG clinical trial of OBE022 in pre-term labor has commenced, and depending upon the rate of enrollment, initial interim efficacy results from the trial in 30 patients is expected in Q1 of 2019.

### **Third Quarter 2018 Financial Results**

Net loss for the third quarter of 2018 was \$18.6 million, or (\$0.42) per basic and diluted share, vs. \$17.0 million or (\$0.59) per basic and diluted share for the third quarter of 2017. Research and development expenses were \$15.9 million and general and administrative expenses were \$3.1 million for the quarter ended September 30, 2018, vs. \$13.9 million and \$3.0 million, respectively, for the quarter ended September 30, 2017. Third quarter 2018 net loss included non-cash expenses of \$2.0 million for share-based compensation, as compared to \$2.3 million in the prior period.

As of September 30, 2018, ObsEva had cash and cash equivalents of \$156.4 million.

To access the financial reports section of our website, please click [here](#)

### **Conference Call Information**

ObsEva will host a conference call and audio webcast today at 8:00 a.m. Eastern Time, 2p.m Central European Time, to provide a business update and discuss third quarter 2018 financial results. To participate in the conference call, please dial 844-419-1772 (U.S.) or (213) 660-0921 (international) and refer to conference ID 3178666. The webcast can be accessed under the "Investors" section of ObsEva's website [www.obseva.com](http://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](http://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, 2017, 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.

**For further information, please contact:**

**Media Contact Switzerland and Europe:**

Christophe Lamps  
Dynamics Group  
[cla@dynamicsgroup.ch](mailto:cla@dynamicsgroup.ch)  
+41 22 308 6220 Office  
+41 79 476 26 87 Mobile

**Media Contact U.S.:**

Marion Janic  
RooneyPartners LLC  
[mjanic@rooneyco.com](mailto:mjanic@rooneyco.com)  
+1 212 223 4017 Office  
+1 646 537 5649 Mobile

**CEO Office Contact:**

Sauna Dillon  
[Shauna.dillon@obseva.ch](mailto:Shauna.dillon@obseva.ch)  
+41 22 552 1550

**Investor Contact:**

Mario Corso  
Senior Director, Investor Relations  
[mario.corso@obseva.com](mailto:mario.corso@obseva.com)  
+1 857 972 9347 Office  
+1 781 366 5726 Mobile

## Consolidated Statements of Comprehensive Loss

(in USD '000, except per share data)	Three-month period ended September 30,		Nine-Month Period Ended September 30,	
	2018	2017	2018	2017
	<i>unaudited</i>		<i>unaudited</i>	
<b>Operating income other than revenue</b>	<b>2</b>	<b>3</b>	<b>10</b>	<b>11</b>
<b>OPERATING EXPENSES</b>				
Research and development expenses	(15,909)	(13,910)	(46,945)	(40,983)
General and administrative expenses	(3,137)	(3,001)	(10,287)	(9,601)
<b>Total operating expenses</b>	<b>(19,046)</b>	<b>(16,911)</b>	<b>(57,231)</b>	<b>(50,584)</b>
<b>OPERATING LOSS</b>	<b>(19,043)</b>	<b>(16,908)</b>	<b>(57,221)</b>	<b>(50,573)</b>
Finance income	430	(106)	616	754
Finance expense	—	(1)	—	(1)
<b>NET LOSS BEFORE TAX</b>	<b>(18,613)</b>	<b>(17,015)</b>	<b>(56,605)</b>	<b>(49,820)</b>
Income tax expense	23	21	23	(36)
<b>NET LOSS FOR THE PERIOD</b>	<b>(18,590)</b>	<b>(16,994)</b>	<b>(56,582)</b>	<b>(49,856)</b>
<b>Net loss per share</b>				
Basic	(0.42)	(0.59)	(1.45)	(1.78)
Diluted	(0.42)	(0.59)	(1.45)	(1.78)
Weighted Average Number of Shares Outstanding	43,196,686	28,627,148	39,092,256	28,047,694

## Consolidated Balance Sheets

(in USD '000)	September 30, 2018 <i>unaudited</i>	December 31, 2017 <i>audited</i>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	156,439	110,841
Other receivables	695	783
Prepaid expenses	1,670	1,490
<b>Total current assets</b>	<b>158,804</b>	<b>113,114</b>
<b>Non-current assets</b>		
Furniture, fixtures and equipment	292	323
Intangible assets	21,608	21,608
Other long-term assets	273	190
<b>Total non-current assets</b>	<b>22,173</b>	<b>22,121</b>
<b>Total assets</b>	<b>180,977</b>	<b>135,235</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Current tax liability	17	51
Other payables and current liabilities	1,474	2,865
Accrued expenses	11,600	6,514
<b>Total current liabilities</b>	<b>13,091</b>	<b>9,430</b>
<b>Non-current liabilities</b>		
Post-employment obligations	3,004	3,099
Other long-term liabilities	49	55
<b>Total non-current liabilities</b>	<b>3,053</b>	<b>3,154</b>
<b>Shareholders' equity</b>		
Share capital	3,413	2,864
Share premium	313,628	219,335
Reserves	11,041	7,119
Accumulated losses	(163,249)	(106,667)
<b>Total shareholders' equity</b>	<b>164,833</b>	<b>122,651</b>
<b>Total liabilities and shareholders' equity</b>	<b>180,977</b>	<b>135,235</b>

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