

# ObsEva Reports Second Quarter 2018 Financial Results and Provides Business Update

- Phase 2b EDELWEISS clinical trial of linzagolix (OBE2109) in endometriosis related pelvic pain achieved primary and secondary endpoints
- Chief Commercial Officer hired as nolasiban moves closer to commercialization
- Net proceeds of \$87 million raised from sale of equity
- Swiss SIX exchange listing completed

**Geneva, Switzerland and Boston, MA – August 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 June 30, 2018, and provided a business update outlining recent corporate progress and upcoming milestones.

"Positive EDELWEISS results for linzagolix announced in June was our second successful major clinical milestone of 2018 following positive IMPLANT2 results of nolasiban in IVF that were disclosed in February" said Ernest Loumaye, co-founder and Chief Executive Officer of ObsEva. "We are very pleased with our clinical development execution and look forward to additional data from both trials in the fourth quarter of this year".

## **Recent Highlights**

- Positive Phase 3 IMPLANT 2 trial top line results were disclosed in February 2018 for ObsEva's oral oxytocin receptor antagonist nolasiban, demonstrating 10-week ongoing pregnancy rate of 35.6% for nolasiban treated patients vs. 28.5% for placebo treated patients, a 25% relative increase (p=0.031). The trial follow-up continues to progress through birth and neonatal periods.
- 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 June 2018. The primary endpoint of the trial was successfully achieved, with patient response (defined as a 30% or greater reduction in verbal rating scale, or VRS 0-3 pain score from baseline) in 61.5% of women at the 75mg dose, 56.4% at 100mg, and 56.3% at 200mg, vs. 34.5% for placebo, respective p values of 0.003, 0.039, and 0.034. In addition, linzagolix treatment was associated with improvement in secondary trial endpoints, including pelvic pain as measured by a 0-10 numerical rating scale



(NRS), dyspareunia and dyschezia pain scores, and patient well-being as assessed by patient global impression of change (PGIC), Endometriosis Health Profile-30 score (EHP-30), and patient global impression of severity (PGIS). Importantly, linzagolix treatment was also observed to be safe and well tolerated.

- Patient enrollment continued 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, one with hormonal add back therapy (ABT) and one without ABT.
- Patient enrollment continued in 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. Positive pharmacokinetic (PK) data support
  moving to Part B of the trial.

#### **Upcoming Milestones**

ObsEva expects to achieve the following clinical and regulatory milestones by the end of 2018:

- Live birth rate results and 28-day neonatal safety from the Phase 3 IMPLANT2 clinical trial of nolasiban in IVF are expected in Q4 of 2018.
- Initiation of a US nolasiban Phase 3 clinical development program is planned by the end of 2018. Consistent with nolasiban progress, the Company announced in late July the hiring of Mr. Wim Souverijns as Chief Commercial Officer, who will be joining the company in Q4 of 2018 to prepare the Company for market access and commercialization both in Europe and the U.S.
- 24-week results from the Phase 2b EDELWEISS clinical trial of linzagolix for the treatment of endometriosis related pelvic pain, including assessment of bone mineral density (BMD), are expected in early Q4 of 2018. An End-of-phase 2 meeting with regulatory authorities to discuss the design of the Phase 3 program for that indication is targeted by the end of 2018.
- Consistent with last quarter's update, completion of patient enrollment in the Phase 3 PRIMROSE
   2 trial of linzagolix for the treatment of uterine fibroids continues to be targeted for the end of
   2018, while PRIMROSE 1 enrollment completion is anticipated in Q1 of 2019.
- Part A of the Phase 2a PROLONG clinical trial of OBE022 in pre-term labor assessing safety, tolerability and pharmacokinetics in pregnant women is presently completing, and initial interim efficacy from Part B of the trial continues to be expected in Q4 of 2018.



#### **Second Quarter 2018 Financial Results**

Net loss for the second quarter of 2018 was \$18.2 million, or (\$0.49) per basic and diluted share, vs. \$17.3 million or (\$0.61) per basic and diluted share for the second quarter of 2017. Research and development expenses were \$14.7 million and general and administrative expenses were \$3.5 million for the quarter ended June 30, 2018, vs. \$14.0 million and \$3.9 million, respectively, for the quarter ended June 30, 2017. Second quarter 2018 net loss included non-cash expenses of \$2.2 million for share-based compensation, which was equivalent to the prior year period.

As of June 30, 2018, ObsEva had cash and cash equivalents of \$166.8 million, which included net proceeds of approximately \$87 million from the sale of equity securities.

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, 2:00 p.m Central European Summer Time, to provide a business update and discuss second quarter 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 6749875. 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 <a href="https://www.obsEva.com">www.obsEva.com</a>.

#### **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 and the timing of enrollment in and data from clinical trials. 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, 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 <a href="http://www.ObsEva.com">http://www.ObsEva.com</a>. 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 June 30,	Six-month period 30,	ended June
	2018	2017	2018	2017
	Unaudited		Unaudited	
Operating income other than revenue	3	2	8	8
OPERATING EXPENSES				
Research and development expenses	(14,694)	(14,016)	(31,036)	(27,073)
General and administrative expenses	(3,501)	(3,855)	(7,150)	(6,600)
Total operating expenses	(18,195)	(17,871)	(38,186)	(33,673)
OPERATING LOSS	(18,192)	(17,869)	(38,178)	(33,665)
Finance income	31	602	186	860
Finance expense	-	-	-	-
NET LOSS BEFORE TAX	(18,161)	(17,267)	(37,992)	(32,805)
Income tax (expense)	(25)	(57)		(57)
NET LOSS FOR THE PERIOD	(18,186)	(17,324)	(37,992)	(32,862)



# Net loss per share

Basic	(0.49)	(0.61)	(1.03)	(1.19)
Diluted	(0.49)	(0.61)	(1.03)	(1.19)
Weighted Average Shares Outstanding	37,617,569	28,469,064	37,004,673	27,582,897



## **Consolidated Balance Sheet**

(In USD '000)	June 30, 2018	December 31, 2017
	unaudited	audited
ASSETS		
Current assets		
Cash and cash equivalents	166,835	110,841
Other receivables	630	783
Prepaid expenses	2,082	1,490
Total current assets	169,547	113,114
Non-current assets		
Furniture, fixtures and equipment	305	323
Intangible assets	21,608	21,608
Other long-term assets	188	190
Total non-current assets	22,101	22,121
Total assets	191,648	135,235
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities		
Current tax liability	40	51
Other payables and current liabilities	1,446	2,865
Accrued expenses	10,428	6,514
Total current liabilities	11,914	9,430



## **Non-current liabilities**

Post-employment obligations	3,034	3,099
Other long-term liabilities	52	55
Total non-current liabilities	3,086	3,154
Shareholders' equity		
Share capital	3,375	2,864
Share premium	307,743	219,335
Reserves	10,189	7,119
Accumulated losses	(144,659)	(106,667)
Total shareholders' equity	176,648	122,651
Total liabilities and shareholders' equity	191,648	135,235

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