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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**For the Month of November 2018**

**Commission File Number: 001-37993**

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**OBSEVA SA**

**(Translation of registrant's name into English)**

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**Chemin des Aulx, 12  
1228 Plan-les-Ouates  
Geneva, Switzerland**  
**(Address of principal executive office)**

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F    Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

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## **INCORPORATION BY REFERENCE**

Exhibits 99.1 and 99.2 to this Report on Form 6-K shall be deemed to be incorporated by reference into the registration statements on Form F-3, as amended (No. 333-222820 and 333-221462) of ObsEva SA (including any prospectuses forming a part of such registration statements) and the registration statement on Form S-8 (Registration Number 333-216170) of ObsEva SA and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit 99.3 to this Report on Form 6-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

## **RISK FACTORS**

The risk factors set forth in the discussion of material risks in Item 3.D of our Annual Report on Form 20-F for the fiscal year ended December 31, 2017 are incorporated herein. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may affect our business, financial condition and/or future operating results.

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## EXHIBIT INDEX

Exhibit No.	Description
99.1	<a href="#">Unaudited Condensed Consolidated Financial Statements</a>
99.2	<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>
99.3	<a href="#">Press Release dated November 8, 2018</a>

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**ObsEva SA**

Date: November 8, 2018

By: /s/ Ernest Loumaye

Name Ernest Loumaye

Title: Chief Executive Officer

## OBSEVA SA

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ObsEva SA  
Condensed Consolidated Financial Statements

Condensed Consolidated Balance Sheets

(in USD '000)	Notes	September 30, 2018 <i>unaudited</i>	December 31, 2017 <i>audited</i>
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents	4	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	5	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>	6	<b>164,833</b>	<b>122,651</b>
<b>Total liabilities and shareholders' equity</b>		<b>180,977</b>	<b>135,235</b>

The accompanying notes form an integral part of these condensed consolidated financial statements.

## ObsEva SA

## Condensed Consolidated Financial Statements

## Condensed Consolidated Statements of Comprehensive Loss

(in USD '000, except per share data)	Notes	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	7	(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 benefit / (expense)	8	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	9	(0.42)	(0.59)	(1.45)	(1.78)
Diluted	9	(0.42)	(0.59)	(1.45)	(1.78)
<b>OTHER COMPREHENSIVE LOSS</b>					
<i>Items that will not be reclassified to profit and loss</i>					
Remeasurements on post-employment benefit plans		—	—	—	—
<i>Items that may be reclassified to profit or loss</i>					
Currency translation differences		—	—	—	—
<b>TOTAL OTHER COMPREHENSIVE LOSS</b>		<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>TOTAL COMPREHENSIVE LOSS FOR THE PERIOD</b>		<b>(18,590)</b>	<b>(16,994)</b>	<b>(56,582)</b>	<b>(49,856)</b>

The accompanying notes form an integral part of these condensed consolidated financial statements.

## ObsEva SA

## Condensed Consolidated Financial Statements

## Condensed Consolidated Statement of Cash Flows

(in USD '000)	Notes	Nine-month period ended September 30,	
		2018	2017
		<i>unaudited</i>	
<b>NET LOSS BEFORE TAX FOR THE PERIOD</b>		<b>(56,605)</b>	<b>(49,820)</b>
Adjustments for:			
Depreciation expense		80	45
Post-employment (benefit) / cost		(95)	8
Share-based compensation expense		6,561	6,825
Income tax paid		(12)	—
Finance result		(616)	(753)
Decrease in other receivables		88	100
(Increase) / decrease in prepaid expenses and other long term-assets		(179)	532
(Decrease) / increase in other payables and current liabilities		(1,308)	258
Increase in accrued expenses and other long-term liabilities		5,798	1,266
<b>NET CASH FLOWS USED IN OPERATING ACTIVITIES</b>		<b>(46,288)</b>	<b>(41,539)</b>
Cash used for rental deposits		(83)	(96)
Payments for plant and equipment		(129)	(148)
Payments for intangible assets		—	(5,000)
<b>NET CASH FLOWS USED IN INVESTING ACTIVITIES</b>		<b>(212)</b>	<b>(5,244)</b>
Proceeds from issue of shares		97,855	96,779
Payment of share issuance costs		(6,877)	(7,899)
Proceeds from exercise of stock-options		504	—
Interest received		—	(1)
<b>NET CASH FLOWS FROM FINANCING ACTIVITIES</b>		<b>91,482</b>	<b>88,879</b>
Net increase in cash and cash equivalents		44,982	42,096
<b>Cash and cash equivalents as at January 1,</b>		<b>110,841</b>	<b>25,508</b>
Effects of exchange rate changes on cash and cash equivalents		616	754
<b>Cash and cash equivalents as at September 30,</b>		<b>156,439</b>	<b>68,358</b>

The accompanying notes form an integral part of these condensed consolidated financial statements.



## ObsEva SA

## Condensed Consolidated Financial Statements

## Condensed Consolidated Statement of Changes in Equity

(in USD '000)

<i>unaudited</i>	Share capital	Share premium	Share-based payments reserve	Foreign currency translation reserve	Total reserves	Accumulated losses	Total
<b>January 1, 2017</b>	<b>1,740</b>	<b>71,966</b>	<b>2,423</b>	<b>(489)</b>	<b>1,934</b>	<b>(39,599)</b>	<b>36,041</b>
Loss for the period	—	—	—	—	—	(49,856)	(49,856)
Other comprehensive loss	—	—	—	—	—	—	—
<b>Total comprehensive loss</b>	—	—	—	—	—	<b>(49,856)</b>	<b>(49,856)</b>
Issuance of shares - IPO	496	96,254	—	—	—	—	96,750
Issuance of shares - Incentive Plan	29	2,984	(2,984)	—	(2,984)	—	29
Share issuance costs	—	(8,222)	—	—	—	—	(8,222)
Share-based remuneration	—	—	6,825	—	6,825	—	6,825
<b>September 30, 2017</b>	<b>2,265</b>	<b>162,982</b>	<b>6,264</b>	<b>(489)</b>	<b>5,775</b>	<b>(89,455)</b>	<b>81,567</b>
<b>January 1, 2018</b>	<b>2,864</b>	<b>219,335</b>	<b>7,608</b>	<b>(489)</b>	<b>7,119</b>	<b>(106,667)</b>	<b>122,651</b>
Loss for the period	—	—	—	—	—	(56,582)	(56,582)
Other comprehensive loss	—	—	—	—	—	—	—
<b>Total comprehensive loss</b>	—	—	—	—	—	<b>(56,582)</b>	<b>(56,582)</b>
Issuance of shares - Incentive Plan	21	2,291	(2,291)	—	(2,291)	—	21
Issuance of shares - Follow-on Offering	392	77,431	—	—	—	—	77,823
Issuance of shares - ATM program	130	19,881	—	—	—	—	20,011
Share issuance costs	—	(6,156)	—	—	—	—	(6,156)
Exercise of stock-options	6	846	(348)	—	(348)	—	504
Share-based remuneration	—	—	6,561	—	6,561	—	6,561
<b>September 30, 2018</b>	<b>3,413</b>	<b>313,628</b>	<b>11,530</b>	<b>(489)</b>	<b>11,041</b>	<b>(163,249)</b>	<b>164,833</b>

The accompanying notes form an integral part of these condensed consolidated financial statements.

**ObsEva SA**  
**Condensed Consolidated Financial Statements**

**Notes to the Condensed Consolidated Financial Statements for the three-month and nine-month periods ended September 30, 2018**  
**(unaudited)**

**1. General information**

ObsEva SA (the “Company”) was founded on November 14, 2012, and its address is 12 Chemin des Aulx, 1228 Plan-les-Ouates, Geneva, Switzerland. The terms “ObsEva” or “the Group” refer to ObsEva SA together with its subsidiaries included in the scope of consolidation (note 2.3).

The Group is focused on the development and commercialization of novel therapeutics for serious conditions that compromise women’s reproductive health and pregnancy. The Group has a portfolio of three mid- to late-stage development in-licensed compounds (linzagolix (OBE2109), nolasiban (OBE001) and OBE022) being developed in four indications. The Group has no currently marketed products.

These condensed consolidated financial statements are presented in dollars of the United States (USD), rounded to the nearest thousand except share and per share data, and have been prepared on the basis of the accounting principles described in note 2.

These condensed consolidated financial statements were authorized for issue by the Audit Committee of the Company’s Board of Directors (the “Board of Directors”) on November 5, 2018.

**2. Accounting principles and scope of consolidation**

**2.1 Basis of preparation and accounting principles**

These unaudited three-month and nine-month condensed interim consolidated financial statements (the “condensed consolidated financial statements”) are prepared in accordance with International Accounting Standard (“IAS”) 34 *Interim Financial Reporting* as issued by the International Accounting Standards Board (the “IASB”).

On January 1, 2018, the Group adopted IFRS 9 *Financial Instruments*, which replaced IAS 39 *Financial Instruments: Recognition and Measurement*. The adoption of the standard had no impact on the Group’s condensed consolidated financial statements.

In January 2016, the IASB issued IFRS 16 *Leases*, which replaced IAS 17 *Leases and Related Interpretations*. The new standard, which will be effective on January 1, 2019 requires lessees to recognize a lease liability reflecting future lease payments and a right-of-use asset for virtually all lease contracts, removing the distinction between operating and finance leases. As at September 30, 2018, the Group has non-cancellable operating lease commitments of USD 3 million (excluding short-term and low-value leases) and expects to recognise right-of-use assets and lease liabilities of approximately USD 2.7 million on January 1, 2019. The Group does not expect a significant impact on the net profit after tax resulting from the adoption of IFRS 16.

Other accounting policies used in the preparation and presentation of these condensed consolidated financial statements are consistent with those used in the consolidated financial statements for the year ended December 31, 2017 (the “annual financial statements”), which should be read in conjunction with these condensed consolidated financial statements as they provide an update of previously reported information.

The Group believes it will be able to meet all of its obligations as they fall due for at least 12 months from September 30, 2018, hence, the unaudited condensed consolidated financial statements have been prepared on a going concern basis.

**2.2 Use of estimates and assumptions**

The preparation of condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and disclosure of contingent liabilities at the date of the interim financial statements. If in the future such estimates and assumptions, which are based on management’s best judgment at the date of the condensed consolidated financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate during the period in which the circumstances change.

**2.3 Scope of consolidation**

There was no change to the scope of consolidation during the reporting period and the Company consolidates the financial operations of its two fully-owned subsidiaries, ObsEva Ireland Ltd, which is registered in Cork, Ireland and organized under the laws of Ireland,

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and ObsEva USA Inc., which is registered and organized under the laws of Delaware, USA. ObsEva Ireland Ltd had no operations and no results of operations to report as of September 30, 2018 and 2017.

**3. Fair value estimation and financial instruments**

The carrying value less impairment provision of receivables and payables approximate their fair values due to their short-term nature.

All financial assets and liabilities, respectively, are held at their amortized cost.

The Group's financial assets and liabilities consist of cash and cash equivalents, other receivables, other payables and accruals which are classified as loans and receivables at amortized cost according to IFRS 9.

**4. Cash and cash equivalents**

(in USD '000)	September 30, 2018	December 31, 2017
	<i>unaudited</i>	<i>audited</i>
Bank deposits	156,439	110,841
Interest bearing deposits	—	—
<b>Total cash and cash equivalents</b>	<b>156,439</b>	<b>110,841</b>

**5. Intangible assets**

As at September 30, 2018 and December 31, 2017, the Group holds a number of licenses to develop and commercialize several biopharmaceutical product candidates, the value of which is recorded at USD 21.6 million.

**6. Shareholders' equity**

On January 30, 2017, the Company completed an IPO and issued 6,450,000 common shares at a subscription price of USD 15.00 per share and a par value of 1/13 of a Swiss franc per share. The gross proceeds of USD 96.8 million have been recorded in equity net of directly related share issuance costs of USD 8.2 million.

On October 13, 2017, the Company completed a private placement with institutional investors and issued 7,500,000 common shares at a subscription price of USD 8.00 per share and a par value of 1/13 of a Swiss franc per share. The gross proceeds of USD 60.0 million have been recorded in equity net of directly related share issuance costs of USD 3.7 million.

On March 16, 2018, the Company issued 3,499,990 common shares at par value of 1/13 of a Swiss franc per share. The shares were subscribed by the Company and are held as treasury shares, hence the operation did not impact the share capital. Share issuance costs of USD 11 thousand related to the operation were recorded as a deduction in equity.

On May 17 and 25, 2018, the Company sold 1,000,851 and 600,000 treasury shares, respectively, at a price of USD 12.50 per share, from its "at the market" (ATM) program, generating gross proceeds of USD 20.0 million. Directly related share issuance costs of USD 0.6 million were recorded as a deduction in equity.

On June 22, 2018, the Company completed an underwritten public offering of 4,750,000 common shares at a price of USD 15.39 per share, with an option to issue to an additional 712,500 common shares (the "follow-on offering"). The gross proceeds of USD 73.1 million resulting from this transaction have been recorded in equity net of directly related share issuance costs of USD 5.1 million. Subsequent to the initial closing of the follow-on offering, on July 19, 2018, the Company sold an additional 306,721 common shares for total gross proceeds of USD 4.7 million (USD 15.39 per share). These shares were sold pursuant to the 30-day option granted in connection with the follow-on offering to purchase up to an additional 712,500 common shares ("green-shoe"). Directly related share issuance costs amounted to USD 0.3 million.

As at September 30, 2018, the total outstanding share capital of USD 3.4 million, fully paid, consists of 43,342,232 common shares, excluding 508,502 non-vested shares and 1,602,601 treasury shares. As at December 31, 2017, the total outstanding share capital of USD 2.9 million, fully paid, consists of 36,342,945 common shares, excluding 778,134 non-vested shares and 10,183 treasury shares. All shares have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date.

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**Condensed Consolidated Financial Statements**

**7. Research and development expenses**

Due to the difficulty in assessing when research and development projects would generate revenue, the Group expenses all research and development costs to the profit and loss accounts.

**8. Income tax expense**

The Group is subject to income taxes in Switzerland, Ireland and the United States.

The Company is subject in Switzerland to a municipal and cantonal income tax rate of 22.6% and to a federal tax rate of 8.5% on its profits after tax. It is entitled to carry forward any loss incurred for a period of seven years and can offset such losses carried forward against future taxes. In 2015, the Company was granted by the State Council of the Canton of Geneva an exemption of income and capital tax at municipal and cantonal levels for the period from 2013 until 2022. Because of this exemption, and the fact that the Company has incurred net losses since its inception, no income tax expense at the municipal, cantonal or federal levels was recorded in the Company for the three-month and nine-month periods ended September 30, 2018 and 2017. Additionally, due to the uncertainty as to whether it will be able to use its net loss carryforwards for tax purposes in the future, no deferred taxes have been recognized on the balance sheet of the Company as of September 30, 2018 and December 31, 2017.

The Company's Irish subsidiary has no activity, and, therefore, no income tax expense was recorded in that entity for the three-month and nine-month periods ended September 30, 2018 and 2017.

The Company's U.S. subsidiary is a service organization for the Group and is therefore subject to taxes on the revenues generated from its services to the Group that are charged based upon the U.S. subsidiary's cost plus arrangement with the Group. The profits of the U.S. subsidiary during the three-month and nine-month periods ended September 30, 2018 and 2017 were subject to a total U.S. income tax rate of 27.3% and 39.3%, respectively, based on both the U.S. federal and Massachusetts state tax rates.

**9. Loss per share**

As of September 30, 2018 and 2017, the Company has one category of shares, which are common shares. The basic loss per share is calculated by dividing the loss of the period attributable to the common shares by the weighted average number of common shares outstanding during the period as follows:

	Three-month period ended September 30, 2018	Nine-month period ended September 30, 2018
	<i>unaudited</i>	<i>unaudited</i>
Net loss attributable to shareholders (in USD '000)	(18,590)	(56,582)
Weighted average number of common shares outstanding	43,196,686	39,092,256
<b>Basic and diluted loss per share (in USD)</b>	<b>(0.42)</b>	<b>(1.45)</b>

  

	Three-month period ended September 30, 2017	Nine-month period ended September 30, 2017
	<i>unaudited</i>	<i>unaudited</i>
Net loss attributable to shareholders (in USD '000)	(16,994)	(49,856)
Weighted average number of common shares outstanding	28,627,148	28,047,694
<b>Basic and diluted loss per share (in USD)</b>	<b>(0.59)</b>	<b>(1.78)</b>

For the three-month and nine-month periods ended September 30, 2018, 508,502 non-vested shares, 1,602,601 treasury shares and 1,802,157 shares issuable upon the exercise of stock-options, which would have an anti-dilutive impact on the calculation of the diluted earnings per share, were excluded from the calculation. For the three-month and nine-month periods ended September 30, 2017, 862,980 non-vested shares, 10,183 treasury shares and 693,450 shares issuable upon the exercise of stock-options, which would have an anti-dilutive impact on the calculation of the diluted earnings per share, are excluded from the calculation.

**10. Segment information**

The Group operates in one segment, which is the research and development of innovative women's reproductive, health and pregnancy therapeutics. The marketing and commercialization of such therapeutics depend, in large part, on the success of the

**ObsEva SA**  
**Condensed Consolidated Financial Statements**

development phase. The Chief Executive Officer of the Company reviews the consolidated statement of operations of the Group on an aggregated basis and manages the operations of the Group as a single operating segment. The Group currently generates no revenue from the sales of therapeutics products, and the Group's activities are not affected by any significant seasonal effect.

The geographical analysis of non-current assets is as follows:

(in USD '000)	September 30, 2018	December 31, 2017
	<i>unaudited</i>	<i>audited</i>
Switzerland	21,917	21,832
USA	256	289
<b>Total non-current assets</b>	<b>22,173</b>	<b>22,121</b>

The geographical analysis of operating expenses is as follows:

<i>unaudited</i> (in USD '000)	Three-month period ended September 30,		Nine-month period ended September 30,	
	2018	2017	2018	2017
	Switzerland	18,070	15,849	54,209
USA	975	1,062	3,022	2,405
<b>Total operating expenses</b>	<b>19,046</b>	<b>16,911</b>	<b>57,231</b>	<b>50,584</b>

**11. Events after the reporting period**

There were no material events after the balance sheet date.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

We are 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. We are focused on providing therapeutic solutions for women between the ages of 15 and 49 who suffer from reproductive health conditions that affect their quality of life, ability to conceive or that complicate pregnancy and the health of newborns. Our goal is to build the leading women's reproductive health and pregnancy company focused on these conditions where current treatment options are limited and significant unmet needs exist.

We are developing linzagolix (formerly OBE2109) as a novel, oral gonadotropin releasing hormone, or GnRH, receptor antagonist, for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. We are currently conducting a multiple-dose, placebo-controlled Phase 2b clinical trial of linzagolix in approximately 330 patients with endometriosis, or the EDELWEISS clinical trial. In June 2018, we announced that the EDELWEISS clinical trial successfully met its primary endpoint, a statistically significant increase in patient response rate vs. placebo following 12 weeks of treatment. Patient response was measured by a 30% reduction from baseline combined menstrual and non-menstrual pelvic pain on a verbal rating scale (VRS) of 0-3. Observed response rates were 34.5% for placebo, 49.4% for 50mg linzagolix, 61.5% for 75mg linzagolix, 56.4% for 100mg linzagolix, and 56.3% for 200mg linzagolix. Respective p values were 0.155, 0.003, 0.039, and 0.034.

In September 2018, we announced positive 24-week treatment results from the EDELWEISS clinical trial, including bone mineral density (BMD) safety assessments. The 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, with patient response in 70.8% of women at the 75mg once daily dose vs. 61.5% for placebo, and patient response in 77.3% of women at the 200mg once daily dose vs. 56.3% for placebo. The key safety endpoint of mean change in BMD at the lumbar spine, which is the site of greatest bone loss, was -0.8% at the 75mg once daily dose and -2.6% at the 200mg once daily dose. We believe the BMD results support our plan to pursue further development of two doses of linzagolix for the treatment of endometriosis, including a 75 mg once daily dose without low dose hormonal add-back therapy (ABT), and a 200mg once daily dose in combination with low dose ABT. We intend to have an end-of-Phase 2 meeting with the FDA before the end of 2018 to finalize the design of our planned two pivotal Phase 3 clinical trials, which are planned to begin in early 2019. For the uterine fibroids indication, in April 2017, we initiated a Phase 3 clinical development program with two Phase 3 clinical trials, or the PRIMROSE 1 and 2 clinical trials. We expect to complete enrollment of approximately 500 patients in each of PRIMROSE 1 in the first quarter of 2019, and in PRIMROSE 2 by the end of 2018. Based upon the assumption that recent strength in U.S. patient screening trends translate into patient randomization, we anticipate announcing 6-month primary endpoint results from both trials in the second half of 2019.

We are also developing nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing in-vitro fertilization, or IVF. We completed randomization of 778 patients in our European Phase 3 clinical trial in women undergoing IVF (D3 and D5 fresh single embryo transfer or SET), or the IMPLANT 2 clinical trial, in 2017 and reported positive results for the primary endpoint of ongoing pregnancy 10 weeks post embryo transfer (ET) in February 2018. Ongoing pregnancy rate 10 weeks post ET was achieved in 35.6% of patients receiving nolasiban, vs. 28.5% of patients in the placebo group, a p value of 0.031. Patients who underwent ET 5 days post oocyte retrieval achieved ongoing pregnancy 10 weeks post ET at a rate of 45.9% when administered nolasiban, vs. 34.7% of those who received placebo, a p value of 0.034. In October 2018, we announced live birth rate results from the IMPLANT 2 trial, which were consistent with the benefit seen in pregnancy rates for patients treated with nolasiban. Live birth rate, reflecting the ultimate goal of IVF procedures, taking home a baby, showed a statistically and clinically significant benefit in favor of patients receiving nolasiban, 34.8% vs. 27.7% for placebo, 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%, p=0.025. We expect to receive 28-day neonatal safety from the IMPLANT 2 trial later in the fourth quarter of 2018, followed by results from our 6-month infant follow-up in mid-2019.

Based upon results of the IMPLANT 1 and IMPLANT 2 trials, we have sought feedback from regulatory authorities in Europe and in the United States on any additional future registration requirements. Based on feedback recently received from regulatory authorities in Europe, we intend to initiate an additional Phase 3 trial primarily in European, Canadian and CIS or Russian centers, or the IMPLANT 4 trial, prior to the end of 2018. We plan to enroll approximately 800 patients undergoing IVF (D5 fresh SET) in the IMPLANT 4 trial, with a primary endpoint of ongoing pregnancy 10 weeks post ET. Assuming IMPLANT4 trial results confirm IMPLANT 1 and IMPLANT 2 results, we intend to use this data to file a European marketing authorization application (MAA), which we expect will be in late 2019, and have commenced pre-commercial strategic planning. Feedback recently 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 United States. 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, we are

ready to pursue our clinical trial program in the United States. In the meantime, we anticipate not to incur any significant cost for the U.S. clinical program.

In addition, we are developing OBE022, an oral and selective prostaglandin F2 $\alpha$  receptor antagonist, for preterm labor in weeks 24 to 34 of pregnancy. Based upon results of Phase 1 clinical trials completed in the first quarter of 2017, we initiated a Phase 2a proof-of-concept clinical trial, known as PROLONG, in December 2017. We have completed the open label Part A of this trial in eight patients to initially assess OBE022 safety and pharmacokinetic (PK) profile. Based on these data, we began the randomized Part B of the trial in the fourth quarter of 2018 to assess efficacy in delaying childbirth in women at 24 to 34 weeks gestation who are experiencing symptoms of preterm labor and potentially preterm delivery. Depending on the pace of patient enrollment in Part B of the trial, we expect to report interim efficacy results in 30 patients in the first quarter of 2019.

We were founded in November 2012 and our operations to date have included organizing and staffing our company, raising capital, in-licensing rights to linzagolix, nolasiban and OBE022 and conducting nonclinical studies and clinical trials. To date, we have not generated any revenue from product sales as none of our product candidates have been approved for commercialization. We have historically financed our operations exclusively through the sale of equity. To date, we have raised an aggregate of \$330.3 million of net proceeds, including \$19.4 million from our “at the market” (ATM) program, \$68.0 million from our follow-on offering in June 2018 and \$4.4 million from the exercise of the green-shoe option in July 2018, and also acquired license rights on product candidates in 2013 and 2015 from the sale of preferred shares.

We have never been profitable and have incurred significant net losses in each period since our inception. Our net losses were \$18.6 million and \$17.0 million for the three-month periods ended September 30, 2018, and 2017, respectively, and \$56.6 million and \$49.9 million for the nine-month periods ended September 30, 2018, and 2017, respectively. As of September 30, 2018, we had accumulated losses of \$193.8 million, out of which \$30.6 million were offset with share premium. This reclassification transaction had no impact on total equity. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We used \$46.3 million and \$41.5 million of cash in operations in the nine-month periods ended September 30, 2018, and 2017, respectively. We anticipate that our expenses will continue to increase significantly in connection with our ongoing activities as we:

- continue to invest in the clinical development of our product candidates and specifically to support our ongoing EDELWEISS, PRIMROSE 1 and 2, IMPLANT 2 and PROLONG clinical trials, and additional planned clinical trials such as IMPLANT 4 and our Phase 3 trials for the treatment of endometriosis, and nonclinical studies that we may conduct for product candidates;
- conduct pre-registration and pre-launch manufacturing activities for our product candidates including production of drug substance and to-be-marketed drug product registration/validation batches and supportive regulatory stabilities;
- conduct pre-commercial activities for our product candidates including market access, pre-marketing and infrastructure/head count investment;
- hire additional research and development, commercial and general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- identify and in-license or acquire additional product candidates; and
- continue to incur additional costs associated with operating as a public company.

We will need substantial additional funding to support our operating activities as we advance our product candidates through clinical development, seek regulatory approval and prepare for and invest in future commercialization of these candidates, if approved. Adequate funding may not be available to us on acceptable terms, or at all.

We have no manufacturing facilities, and all of our manufacturing activities are contracted out to third parties. We currently utilize third-party contract research organizations, or CROs, to carry out our clinical development and trials. Additionally, we are initiating the establishment of an infrastructure to address our potential future pre-commercial and commercial needs.

## **Strategic Licensing Agreements**

### ***Linzagolix***

In November 2015, we entered into the Kissei license and supply agreement with Kissei Pharmaceutical Co., Ltd., or Kissei. Pursuant to the Kissei license and supply agreement we received an exclusive license to develop, manufacture and commercialize products, or the Product, containing the compounds which is a specified GnRH antagonist and covered by certain licensed patent rights, or the Compound, throughout the world except for specified Asian countries. We arranged to exclusively acquire from Kissei the material necessary to produce linzagolix.

In consideration for the license, we made an initial \$10.0 million upfront payment. In addition, we agreed to make aggregate milestone payments of up to \$63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. In connection with the initiation of the Phase 3 clinical program for linzagolix in uterine fibroids in the second quarter of 2017, a \$5.0 million milestone payment was made. With respect to any products we commercialize under the Kissei license and supply agreement, we agreed to make further payments of up to an additional \$125.0 million to Kissei upon the achievement of specified commercial milestones.

Pursuant to the Kissei license and supply agreement, we have agreed to exclusively purchase the active pharmaceutical ingredient for linzagolix from Kissei. During the development stage, we are obligated to pay Kissei a specified supply price. Following the first commercial sale of licensed product, we are obligated to pay Kissei a royalty in the low twenty percent range as a percentage of net sales. This payment includes Kissei's supply of the active pharmaceutical ingredient until the latest of (i) the date that the valid claim of a patent for the Product has expired, (ii) the expiration of our regulatory exclusivity period, or (iii) 15 years from the first commercial sale of such product on a country-by-country and product-by-product basis. During the term, we are restricted from developing, marketing and selling GnRH agonists and GnRH antagonists other than the Compound to the extent allowed by applicable laws.

### ***Nolasiban***

In August 2013, we entered into the 2013 license agreement with Ares Trading S.A., an affiliate of Merck Serono, or Merck Serono, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including nolasiban. In consideration for the license, we issued 914,069 Series A preferred shares to Merck Serono at the time of our Series A financing, which had a fair-value of \$4.9 million based on an exchange rate of \$1.00 for CHF 0.9244 as of the date of the transaction. With respect to any products we commercialize under the 2013 license agreement, we agreed to pay Merck Serono royalties based on a high-single-digit percentage of annual net sales of each product, subject to specified reductions, until the later of (i) the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis, or (ii) ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

### ***OBE022***

In June 2015, we entered into the 2015 license agreement with Merck Serono, which we amended in July 2016, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including OBE022. In consideration for the license, we issued 325,000 Series A preferred shares to Merck Serono in September 2016 upon the initiation of a Phase 1 clinical trial for a licensed product. With respect to any products we commercialize under the 2015 license agreement, we agreed to pay Merck Serono royalties based on a mid-single-digit percentage of annual net sales of each product, subject to specified reductions, until the later of (i) the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or (ii) ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

## **Components of Results of Operations**

### ***Revenue***

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the near term.

### ***Operating Expenses***

#### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred in connection with our research and development activities and consist mainly of direct research and development costs, which include: costs associated with the use of CROs and consultants hired to assist on our research and development activities; personnel expenses, which include salaries, benefits and share-based compensation expenses for our employees; expenses related to regulatory affairs and intellectual property; manufacturing costs in connection with conducting nonclinical studies and clinical trials; and depreciation expense for assets used in research and development activities. Research and development costs are generally expensed as incurred. However, costs for certain activities, such as manufacturing and nonclinical studies and clinical trials, are generally recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and collaborators.

Our employee, consultant and infrastructure resources are typically utilized across our multiple research and development programs. We track outsourced research and development costs by product candidate or nonclinical program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates.



From inception through September 30, 2018, we have incurred \$156.6 million in research and development expenses to advance the development of our product candidates. The following table provides a breakdown of our outsourced research and development expenses that are directly attributable to the specified product candidates for the three-month and nine-month periods ended September 30, 2018 and September 30, 2017, respectively.

	Three-month period ended September 30,		Nine-month period ended September 30,	
	2018	2017	2018	2017
	(in thousands) (unaudited)			
Linzagolix	\$ (9,750)	\$ (7,644)	\$ (29,498)	\$ (24,171)
Nolasiban	(2,732)	(2,743)	(5,836)	(6,519)
OBE022	(431)	(514)	(1,865)	(1,706)
Total outsourced research and development expenses	\$ (12,913)	\$ (10,901)	\$ (37,199)	\$ (32,396)

We expect our research and development expense will increase for the foreseeable future as we seek to advance the development of our product candidates through clinical trials and toward regulatory submissions. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidates. This is due to the numerous risks and uncertainties associated with developing such product candidates, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable patients;
- the number of patients that ultimately participate in the trials;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of our clinical trials; and
- regulatory requirements in support of potential approvals.

In addition, the probability of success for any of our product candidates will depend on numerous factors, including competition, manufacturing capability and commercial viability. A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs, timing and viability associated with the development of that product candidate.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits and share-based compensation expense, related to executive, finance, accounting, business development, legal and human resource functions. General and administrative expense also includes facility costs not otherwise included in research and development expenses, legal fees related to corporate matters, fees for accounting and consulting services, and costs of director and officer insurance.

We anticipate that our general and administrative expense will increase in the future to support continued research and development activities and to set-up our pre-commercialization structure. We also anticipate that we will incur increased accounting, audit, legal, regulatory and compliance costs, as well as investor and public relations expenses, associated with operating as a public company.

#### *Finance Result, Net*

Finance result, net, consists mainly of interest income and expense derived from our cash and cash equivalents and foreign exchange gains and losses.

#### *Taxation*

We are subject to corporate taxation in Switzerland, Ireland and the United States.

In 2015, the Canton of Geneva granted us a ten year tax holiday for all income and capital taxes on a communal and cantonal level commencing in fiscal year 2013 and valid through to 2022, subject to our Swiss domiciliation and compliance with certain reporting provisions. We remain subject to Swiss federal income tax on our profits after tax but have only incurred net losses since our inception. We are entitled under Swiss laws to carry forward any losses incurred for a period of seven years and can offset such losses

carried forward against future taxes. As of December 31, 2017, we had tax loss carryforwards totaling \$118.0 million. We do not believe it is probable that we will generate sufficient profits to avail ourselves of these tax loss carryforwards.

Our Irish subsidiary had no activity in the three-month and nine-month periods ended September 30, 2018 and September 30, 2017, and our U.S. subsidiary, as a service organization to the group under cost plus arrangement, was the only entity to generate income tax expenses during these periods.

## Analysis of Results of Operations

### Comparison of the three-month periods ended September 30, 2018 and September 30, 2017

#### Operating Expenses

##### Research and Development Expenses

	Three-month period ended September 30,	
	2018	2017
	(in thousands) (unaudited)	
<b>Research and development expenses by product candidate</b>		
Linzagolix	\$ (9,750)	\$ (7,644)
Nolasiban	(2,732)	(2,743)
OBE022	(431)	(514)
<b>Unallocated expenses</b>		
Staff costs	(2,452)	(2,573)
Other research and development costs	(544)	(436)
Total research and development expenses	<u>\$ (15,909)</u>	<u>\$ (13,910)</u>

Research and development expenses increased by \$2.0 million in the three-month period ended September 30, 2018 compared to the three-month period ended September 30, 2017 primarily due to the ramp-up of our ongoing PRIMROSE clinical trials.

##### General and Administrative Expenses

	Three-month period ended September 30,	
	2018	2017
	(in thousands) (unaudited)	
Staff costs	\$ (1,778)	\$ (1,983)
Professional fees	(725)	(554)
Other general and administrative costs	(634)	(464)
Total general and administrative expenses	<u>\$ (3,137)</u>	<u>\$ (3,001)</u>

General and administrative expenses in the three-month period ended September 30, 2018 are consistent with the three-month period ended September 30, 2017.

#### Finance Result, Net

	Three-month period ended September 30,	
	2018	2017
	(in thousands) (unaudited)	
Finance result, net	\$ 430	\$ (107)

Finance result, net in the three-month periods ended September 30, 2018 and September 30, 2017 primarily consisted of foreign exchange gain and loss, respectively.

*Comparison of the nine-month periods ended September 30, 2018 and September 30, 2017*

**Operating Expenses**

*Research and Development Expenses*

	Nine-month period ended September 30,	
	2018	2017
	(in thousands) (unaudited)	
Research and development expenses by product candidate		
Linzagolix	\$ (29,498)	\$ (24,171)
Nolasiban	(5,836)	(6,519)
OBE022	(1,865)	(1,706)
Unallocated expenses		
Staff costs	(7,929)	(7,189)
Other research and development costs	(1,817)	(1,398)
Total research and development expenses	<u>\$ (46,945)</u>	<u>\$ (40,983)</u>

Research and development expenses increased by \$6.0 million in the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017 primarily due to the increased costs of \$5.3 million resulting from our linzagolix programs, including increased costs of \$4.3 million related to our ongoing PRIMROSE clinical trials.

*General and Administrative Expenses*

	Nine-month period ended September 30,	
	2018	2017
	(in thousands) (unaudited)	
Staff costs	\$ (5,975)	\$ (5,937)
Professional fees	(2,712)	(2,317)
Other general and administrative costs	(1,600)	(1,347)
Total general and administrative expenses	<u>\$ (10,287)</u>	<u>\$ (9,601)</u>

General and administrative expenses increased by \$0.6 million in the nine-month period ended September 30, 2018 compared to the nine-month period ended September 30, 2017 primarily due to higher professional fees of \$0.4 million incurred in connection with our Swiss listing and ATM program.

**Finance Result, Net**

	Nine-month period ended September 30,	
	2018	2017
	(in thousands) (unaudited)	
Finance result, net	\$ 616	\$ 753

Finance result in the nine-month periods ended September 30, 2018 and September 30, 2017 primarily consisted of foreign exchange gains.

**Liquidity and Capital Resources**

Since our inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. We have funded our operations primarily through the sale of equity. From inception through September 30, 2018, we have raised an aggregate of \$330.3 million of net proceeds from the sale of equity securities. In January 2017, we completed our initial public offering of 6,450,000 common shares at a public offering price of \$15.00 per share. We received \$88.6 million in net proceeds after deducting \$8.2 million of underwriting discounts and commissions and other offering expenses. Additionally, in October 2017, we raised \$56.3 million of net proceeds after deducting \$3.7 million of placement expenses through the issuance of 7,500,000 shares at a price of \$8.00 per share in a private placement with institutional investors.

In May 2018, we sold 1,600,851 treasury shares at a price of \$12.50 per share as part of our ATM program, receiving net proceeds of \$19.4 million after deducting \$0.6 million of directly related issuance costs. Later in June 2018, we completed a follow-on public offering of common shares and issued 4,750,000 shares at a price of \$15.39 per share, raising \$68.0 million in net proceeds after deducting \$5.1 million of underwriting discounts, commissions and other offering expenses. In July 2018, we raised additional funds for a net amount of \$4.4 million from the exercise of the green-shoe option available with the follow-on offering.

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

Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. We currently have no ongoing material financing commitments, such as lines of credit or guarantees.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue or initiate clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to program sales, marketing, manufacturing and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential collaborators. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2020. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned nonclinical studies and clinical trials for linzagolix, nolasiban and OBE022;
- the cost and timing of ongoing and planned manufacturing activities including active pharmaceutical ingredient and drug product pharmaceutical development and clinical trial supplies production for linzagolix, nolasiban and OBE022;
- the timing and amount of milestone and royalty payments we are required to make under our license agreements;
- the extent to which we in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our ability to establish strategic collaborations; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

Identifying potential product candidates and conducting nonclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Until such time that we can generate substantial product revenue, if ever, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, shareholder ownership interest may be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect the rights of shareholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

The following table shows a summary of our cash flows for the nine-month periods ended September 30, 2018 and September 30, 2017:

	Nine-month period ended September 30,	
	2018	2017
	(in thousands) (unaudited)	
Cash and cash equivalents at beginning of period	\$ 110,841	\$ 25,508
Net cash used in operating activities	(46,288)	(41,539)
Net cash used in investing activities	(212)	(5,244)
Net cash from financing activities	91,482	88,879
Effect of exchange rates	616	754
Cash and cash equivalents at end of period	<u>\$ 156,439</u>	<u>\$ 68,358</u>

#### *Operating Activities*

Net cash used in operating activities consists of net loss before tax adjusted for changes in net working capital, that is current assets less current liabilities, and for non-cash items such as depreciation and amortization and the value of share-based services.

During the nine-month period ended September 30, 2018, cash use from operating activities was \$46.3 million, primarily as the result of our net loss before tax of \$56.6 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to \$5.9 million and mainly consisted of share-based payments. Changes in the net working capital included primarily a \$5.8 million increase in accrued expenses, mainly due to the costs of our PRIMROSE clinical trials and CMC formulation development costs for nolasiban, and a \$1.3 million decrease in other payables and current liabilities mainly due to the invoice phasing for our clinical trials with linzagolix.

During the nine-month period ended September 30, 2017, net cash used in operating activities was \$41.5 million, primarily as the result of our net loss before tax of \$49.8 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to \$6.1 million and mainly consisted of share-based payments. Changes in the net working capital included primarily a \$1.3 million increase in accrued expenses, mainly due to the costs of our clinical trial supplies for our PRIMROSE and EDELWEISS clinical trials.

#### *Investing Activities*

During the nine-month period ended September 30, 2018, net cash used in investing activities consisted primarily of investments in leasehold improvements, furniture and fixtures.

During the nine-month period ended September 30, 2017, net cash used in investing activities consisted primarily of a \$5.0 million milestone payment to Kissei made upon initiation of the Phase 3 clinical program for linzagolix in uterine fibroids.

#### *Financing Activities*

During the nine-month period ended September 30, 2018, net cash from financing activities consisted primarily of the gross proceeds from (i) the shares sold as part of the ATM program in May 2018 for \$20.0 million and (ii) the follow-on offering completed in June 2018 generating gross proceeds of \$73.1 million, net of (iii) share issuance costs of \$5.7 million.

During the nine-month period ended September 30, 2017, net cash from financing activities consisted primarily of net proceeds from the sale of equity securities in our IPO.

#### **Main Contractual Obligations and Commitments**

Under our license agreements with Kissei and Merck Serono, we may be required to pay royalties in the future. In addition, pursuant to the Kissei license and supply agreement, we have agreed to make aggregate milestone payments of up to \$63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals, out of which \$5.0 million were already paid as of September 30, 2018. With respect to any product we commercialize under the Kissei license and supply agreement, we have agreed to make additional aggregate milestone payments of up to \$125.0 million to Kissei upon the achievement of specified commercial milestones.

We enter into contracts in the normal course of business with CROs for clinical trials, nonclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and we believe that our non-cancelable obligations under these agreements are not material.

### **Off-Balance Sheet Arrangements**

As of the date of this discussion and analysis, and during the periods presented, we did not have any off-balance sheet arrangements.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated interim financial statements, which we have prepared in accordance with International Accounting Standard 34 Interim Financial Reporting as issued by the International Accounting Standards Board.

The accounting policies used in the preparation and presentation of these consolidated interim financial statements are consistent with those used in the consolidated financial statements for the year ended December 31, 2017, which should be read in conjunction with these consolidated interim financial statements and management's discussion and analysis as they provide an update of previously reported information.

The preparation of our consolidated interim financial statements requires us to make estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and disclosure of contingent liabilities at the date of the interim financial statements. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

### **Recent Accounting Pronouncements**

The adoption of IFRS standards as issued by the IASB and interpretations issued by the IFRS interpretations committee that are effective for the first time for the financial year beginning on or after January 1, 2018 had no material impact on our financial position.

### **JOBS Act Exemption**

In April 2012, the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

As an emerging growth company, subject to certain conditions, we are relying on certain of exemptions under the JOBS Act, including without limitation, (1) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the U.S. Securities and Exchange Commission, which means the market value of our common shares that is held by non-affiliates exceeds \$700 million as of the prior June 30, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. As of September 30, 2018, none of these criteria are met by the Company.

### **Cautionary Statement Regarding Forward-Looking Statements**

Forward-looking statements appear in a number of places in this discussion and analysis and include, but are not limited to, statements regarding our intent, belief or current expectations. Many of the forward-looking statements contained in this discussion and analysis can be identified by the use of forward-looking words such as "anticipate", "believe", "continue", "could", "estimate", "expect", "intend", "may", "might", "ongoing", "objective", "plan", "potential", "predict", "should", "will" and "would", or the negative of these and similar expressions. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section entitled "Item 3.D—Risk Factors" in the Annual Report on Form 20-F for the year ended

December 31, 2017, or the Annual Report, filed with the U.S. Securities and Exchange Commission, or the SEC, pursuant to the U.S. Securities and Exchange Act of 1934, as amended. These risks and uncertainties include factors relating to:

- the success, cost, timing and potential indications of our product candidates' development activities and clinical trials, including our ongoing and future trials of linzagolix, nolasiban and OBE022;
- our ability to obtain and maintain regulatory approval of our product candidates, including linzagolix, nolasiban and OBE022, in any of the indications for which we plan to develop them, and any related restrictions, limitations or warnings in the label of an approved product;
- the results of ongoing or future clinical trials, including of linzagolix, nolasiban and OBE022;
- our ability to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our product candidates, and the terms on which we are able to raise that additional capital;
- our plans to research, develop and commercialize our product candidates;
- the timing of our regulatory filings for our product candidates;
- the clinical utility of our product candidates;
- the size and growth potential of the markets for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- the timing and amount of milestone and royalty payments we are required to make under our license agreements;
- our ability to attract and retain qualified employees and key personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the activities of our competitors and the success of competing therapies that are or become available;
- our plans to in-license or acquire additional product candidates;
- how long we will qualify as an emerging growth company or a foreign private issuer;
- our estimates regarding future revenue, expenses and needs for additional financing;
- regulatory developments in the United States and foreign countries; and
- other risks and uncertainties, including those listed in the Annual Report, titled "Item 3.D—Risk Factors."

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.



## 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 AB 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
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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 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.
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- 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).

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## 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.

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### 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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