

---

---

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

---

**FORM 6-K**

---

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

**For the Month of March 2019**

**Commission File Number: 001-37993**

---

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

---

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

---

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):

---

---

## **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 (Registration 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 No. 333-216170) of ObsEva SA and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.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, 2018 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.

---

## 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 May 9, 2019</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: May 9, 2019

By: /s/ Ernest Loumaye

Name Ernest Loumaye

Title: Chief Executive Officer

## OBSEVA SA

## INDEX TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

<a href="#">Condensed Consolidated Balance Sheets as at March 31, 2019 (unaudited) and December 31, 2018</a>	2
<a href="#">Unaudited Condensed Consolidated Statement of Comprehensive Loss for the three-month period ended March 31, 2019</a>	3
<a href="#">Unaudited Condensed Consolidated Statement of Cash Flows for the three-month period ended March 31, 2019</a>	4
<a href="#">Unaudited Condensed Consolidated Statement of Changes in Equity for the three-month period ended March 31, 2019</a>	5
<a href="#">Unaudited Notes to the Condensed Consolidated Financial Statements</a>	6

---

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

**Condensed Consolidated Balance Sheets**

(in USD '000)	Notes	March 31, 2019 <i>unaudited</i>	December 31, 2018 <i>audited</i>
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents	4	117,321	138,640
Other receivables		993	885
Prepaid expenses		5,538	5,715
<b>Total current assets</b>		<b>123,852</b>	<b>145,240</b>
<b>Non-current assets</b>			
Right-of-use assets	2.1	2,505	—
Furniture, fixtures and equipment		297	319
Intangible assets	5	21,608	21,608
Other long-term assets		273	273
<b>Total non-current assets</b>		<b>24,683</b>	<b>22,200</b>
<b>Total assets</b>		<b>148,535</b>	<b>167,440</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
<b>Current liabilities</b>			
Current tax liability		1	—
Other payables and current liabilities		3,630	2,766
Accrued expenses		14,182	14,163
Current lease liabilities	2.1	580	—
<b>Total current liabilities</b>		<b>18,393</b>	<b>16,929</b>
<b>Non-current liabilities</b>			
Non-current lease liabilities	2.1	1,967	—
Post-employment obligations		3,514	3,547
Other long-term liabilities		—	48
<b>Total non-current liabilities</b>		<b>5,481</b>	<b>3,595</b>
<b>Shareholders' equity</b>			
Share capital		3,427	3,420
Share premium		315,456	314,565
Reserves		15,384	12,858
Accumulated losses		(209,606)	(183,927)
<b>Total shareholders' equity</b>	6	<b>124,661</b>	<b>146,916</b>
<b>Total liabilities and shareholders' equity</b>		<b>148,535</b>	<b>167,440</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 March 31,	
		2019	2018
		<i>unaudited</i>	
<b>Operating income other than revenue</b>		<b>5</b>	<b>5</b>
<b>OPERATING EXPENSES</b>			
Research and development expenses	7	(20,140)	(16,342)
General and administrative expenses		(5,255)	(3,649)
<b>Total operating expenses</b>		<b>(25,395)</b>	<b>(19,991)</b>
<b>OPERATING LOSS</b>		<b>(25,390)</b>	<b>(19,986)</b>
Finance income		262	155
Finance expense		(544)	—
<b>NET LOSS BEFORE TAX</b>		<b>(25,672)</b>	<b>(19,831)</b>
Income tax (expense) / benefit	8	(7)	25
<b>NET LOSS FOR THE PERIOD</b>		<b>(25,679)</b>	<b>(19,806)</b>
<b>Net loss per share</b>			
Basic	9	(0.59)	(0.54)
Diluted	9	(0.59)	(0.54)
<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>TOTAL COMPREHENSIVE LOSS FOR THE PERIOD</b>		<b>(25,679)</b>	<b>(19,806)</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	Three-month period ended March 31,	
		2019	2018
		<i>unaudited</i>	
<b>NET LOSS BEFORE TAX FOR THE PERIOD</b>		<b>(25,672)</b>	<b>(19,831)</b>
Adjustments for:			
Depreciation expense		183	26
Post-employment cost / (benefit)		5	(36)
Share-based compensation expense		3,317	2,421
Income tax paid		—	—
Finance result, net		282	(155)
Increase in other receivables		(113)	(8)
Decrease / (increase) in prepaid expenses and other long term-assets		177	(298)
Increase / (decrease) in other payables and current liabilities		869	(1,169)
Increase in accrued expenses and other long-term liabilities		19	4,288
<b>NET CASH FLOWS USED IN OPERATING ACTIVITIES</b>		<b>(20,933)</b>	<b>(14,762)</b>
Payments for plant and equipment		(9)	(96)
<b>NET CASH FLOWS USED IN INVESTING ACTIVITIES</b>		<b>(9)</b>	<b>(96)</b>
Proceeds from issue of shares		—	8
Payment of share issuance costs		—	(710)
Proceeds from exercise of stock-options		101	—
Principal elements of lease payments		(140)	—
Interest received		—	—
Interest paid		(32)	—
<b>NET CASH FLOWS USED IN FINANCING ACTIVITIES</b>		<b>(71)</b>	<b>(702)</b>
Net decrease in cash and cash equivalents		(21,013)	(15,560)
<b>Cash and cash equivalents as at January 1,</b>		<b>138,640</b>	<b>110,841</b>
Effects of exchange rate changes on cash and cash equivalents		(306)	154
<b>Cash and cash equivalents as at March 31,</b>		<b>117,321</b>	<b>95,435</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, 2018</b>	2,864	219,335	7,608	(489)	7,119	(106,667)	122,651
Loss for the period	—	—	—	—	—	(19,806)	(19,806)
Other comprehensive loss	—	—	—	—	—	—	—
<b>Total comprehensive loss</b>	—	—	—	—	—	(19,806)	(19,806)
Issuance of shares - EIP 2013	7	819	(819)	—	(819)	—	7
Share issuance costs	—	(13)	—	—	—	—	(13)
Share-based remuneration	—	—	2,421	—	2,421	—	2,421
<b>March 31, 2018</b>	2,871	220,141	9,210	(489)	8,721	(126,473)	105,260
<b>January 1, 2019</b>	3,420	314,565	13,347	(489)	12,858	(183,927)	146,916
Loss for the period	—	—	—	—	—	(25,679)	(25,679)
Other comprehensive loss	—	—	—	—	—	—	—
<b>Total comprehensive loss</b>	—	—	—	—	—	(25,679)	(25,679)
Issuance of shares - EIP 2013	6	720	(720)	—	(720)	—	6
Exercise of stock-options - EIP 2017	1	171	(71)	—	(71)	—	101
Share-based remuneration	—	—	3,317	—	3,317	—	3,317
<b>March 31, 2019</b>	3,427	315,456	15,873	(489)	15,384	(209,606)	124,661

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**  
**(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, nolasiban 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 May 6, 2019.

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

**2.1 Basis of preparation and accounting principles**

These unaudited three-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”).

**IFRS 16 - Leases**

On January 1, 2019, the Group adopted IFRS 16 *Leases*, which replaced IAS 17 *Leases and Related Interpretations*. The Group has adopted IFRS 16 retrospectively from January 1, 2019, but has not restated comparatives for the year ended December 31, 2018, as permitted under the specific transitional provisions in the standard. The reclassifications and the adjustments arising from the new leasing rules are therefore recognized in the opening balance sheet on January 1, 2019. The new standard requires lessees to recognize a lease liability measured at the present value of the remaining lease payments and a right-of-use asset for virtually all lease contracts, removing the distinction between operating and finance leases.

The following table presents the reconciliation between the non-cancellable operating lease commitments reported as of December 31, 2018 and the lease liabilities recognized on January 1, 2019. The weighted average lessee’s incremental borrowing rate applied to the lease liabilities on January 1, 2019 was 4.9%.

(in USD '000)	<u>Total</u> <u>unaudited</u>
<b>Operating lease commitments disclosed as at December 31, 2018</b>	<b>3,074</b>
<b>Discounted using the Group’s incremental borrowing rate at the date of initial application</b>	<b>2,772</b>
(Less): short-term and low-value leases recognized on a straight-line basis as expense	(37)
(Less): adjustments relating to changes in the index or rate affecting variable payments	(28)
<b>Lease liability recognized as at January 1, 2019</b>	<b>2,707</b>
<i>Of which are:</i>	
Current lease liabilities	577
Non-current lease liabilities	2,130

Right-of-use assets were measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease recognised in the balance sheet as at December 31, 2018. Right-of-use assets mainly relate to office buildings.

The adoption of IFRS 16 *Leases* did not have a material impact on the Group’s net loss after tax or on the Group’s loss per share.

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

**Other accounting policies**

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, 2018 (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.

**Going concern**

The Group believes it will be able to meet all of its obligations as they fall due for at least 12 months from the date these financial statements are issued, 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, 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 March 31, 2019 and 2018.

**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)	March 31, 2019	December 31, 2018
	<i>unaudited</i>	<i>audited</i>
Bank deposits	117,321	138,640
Interest bearing deposits	—	—
<b>Total cash and cash equivalents</b>	<b>117,321</b>	<b>138,640</b>

**5. Intangible assets**

As at March 31, 2019 and December 31, 2018, 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 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.

## ObsEva SA

### Condensed Consolidated Financial Statements

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 5.3 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 March 31, 2019, the total outstanding share capital of USD 3.4 million, fully paid, consists of 43,534,994 common shares, excluding 354,021 non-vested shares and 1,602,601 treasury shares. As at December 31, 2018, the total outstanding share capital of USD 3.4 million, fully paid, consists of 43,443,911 common shares, excluding 430,625 non-vested shares and 1,602,601 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.

#### 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

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 periods ended March 31, 2019 and 2018. 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 March 31, 2019 and December 31, 2018.

The Company’s Irish subsidiary has no activity, and, therefore, no income tax expense was recorded in that entity for the three-month periods ended March 31, 2019 and 2018.

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 periods ended March 31, 2019 and 2018 were each subject to a total U.S. income tax rate of 27.3% based on both the U.S. federal and Massachusetts state tax rates.

#### 9. Loss per share

As of March 31, 2019 and 2018, 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:

	<b>Three-month period ended March 31, 2019</b>
	<i>unaudited</i>
Net loss attributable to shareholders (in USD ‘000)	(25,679)
Weighted average number of common shares outstanding	43,488,440
<b>Basic and diluted loss per share (in USD)</b>	<b>(0.59)</b>

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

	<b>Three-month period ended March 31, 2018</b>
	<i>unaudited</i>
Net loss attributable to shareholders (in USD '000)	(19,806)
Weighted average number of common shares outstanding	36,389,578
<b>Basic and diluted loss per share (in USD)</b>	<b>(0.54)</b>

For the three-month period ended March 31, 2019, 354,021 non-vested shares and 3,067,750 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 period ended March 31, 2018, 684,868 non-vested shares and 1,881,740 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 development phase. The Chief Executive Officer of the Company reviews the consolidated statements 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:

	<b>March 31, 2019</b>	<b>December 31, 2018</b>
<i>(in USD '000)</i>	<i>unaudited</i>	<i>audited</i>
Switzerland	23,718	21,954
USA	965	246
<b>Total non-current assets</b>	<b>24,683</b>	<b>22,200</b>

The geographical analysis of operating expenses is as follows:

	<b>Three-month period ended March 31,</b>	
<i>unaudited</i> <i>(in USD '000)</i>	<b>2019</b>	<b>2018</b>
Switzerland	24,253	19,018
USA	1,142	973
<b>Total operating expenses</b>	<b>25,395</b>	<b>19,991</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 conditions where current treatment options are limited and significant unmet needs exist.

#### ***Linzagolix for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids.***

We are developing linzagolix 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. Aimed at addressing the need of the largest possible population in each indication, our clinical trials for both of these indications are designed to assess and potentially support the registration of two regimens of administrations for linzagolix i.e. (i) a moderate dose of linzagolix without hormonal add-back therapy (ABT) and (ii) a high dose of linzagolix with hormonal ABT.

In 2018 we successfully completed a 24-week treatment of 330-patient multiple-dose, placebo-controlled Phase 2b EDELWEISS clinical trial of linzagolix in endometriosis patients across 70 sites in the United States and 15 sites in Central and Eastern Europe. Results support efficacy in treating pelvic pain associated with endometriosis as well as bone mineral density (BMD) safety. 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 ABT, and a 200 mg once daily dose in combination with low dose ABT. We recently completed 52 weeks of treatment in the EDELWEISS trial. These results were consistent with the positive primary findings from the trial that were disclosed in 2018. Following an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in December 2018 to discuss the Phase 3 clinical development plan we are presently initiating the EDELWEISS 2 and EDELWEISS 3 clinical trials.

In addition, we are conducting two Phase 3 clinical trials of linzagolix in patients with heavy menstrual bleeding associated with uterine fibroids, the PRIMROSE clinical trials. The PRIMROSE clinical trials each have a target enrollment of approximately 500 patients and are being conducted in the United States and in Europe. We announced that the PRIMROSE 2 trial, conducted in the United States and in Europe, completed patient recruitment in December 2018, and we expect the PRIMROSE 1 trial being conducted in the United States to complete patient recruitment in the second quarter of 2019. We expect to report primary endpoint results following 24 weeks of treatment from the PRIMROSE 1 and 2 clinical trials in the first quarter of 2020 and fourth quarter of 2019, respectively, with a new drug application (NDA) submission with the FDA based on 52 weeks of treatment duration in both trials, planned prior to the end of 2020.

#### ***Nolasiban to improve IVF outcomes.***

We are developing nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing in-vitro fertilization, or IVF. In 2018, we reported positive results for the primary endpoint of ongoing pregnancy 10 weeks post embryo transfer and the secondary endpoint of live birth rate from the European Phase 3 clinical trial in 778 women undergoing IVF, or the IMPLANT 2 clinical trial.

Nolasiban was observed to be well tolerated with a safety profile not different from placebo. Safety follow-up for 28-day neonates and infants 6 months following birth from the IMPLANT 2 trial did not reveal any adverse consequences from nolasiban treatment.

Based on feedback received in the third quarter of 2018 from regulatory authorities in Europe on our nolasiban development program, we initiated in November 2018 an additional Phase 3 trial primarily in European, Canadian and CIS or Russian centers, or the IMPLANT 4 trial. The IMPLANT 4 trial will enroll approximately 800 patients, with the primary endpoint readout (10-week ongoing pregnancy results) expected in the fourth quarter of 2019, with the filing of a Marketing Authorization Application (MAA) in Europe being planned for late 2019. In late 2018, we hired a chief commercial officer to begin the planning and execution of the commercialization of nolasiban in anticipation for potential initial commercial launch in early 2021.

For U.S. clinical development of nolasiban, we are presently in the process of further interactions with the FDA on trial design, and expect to provide updated feedback by the end of the second quarter of 2019. We have also begun strategic assessment of nolasiban for the large market opportunity of China, exploring the clinical trial pathway and potential options for commercialization.

### ***OBE022 for the treatment of preterm labor***

We are developing OBE022, an oral and selective prostaglandin F2 $\alpha$  receptor antagonist, for preterm labor in weeks 24 to 34 of pregnancy. In December 2017, we announced the initiation of a Phase 2a proof-of-concept clinical trial of OBE022, known as PROLONG which is being conducted in two parts: Part A and Part B.

Part A is an open-label trial assessing the safety and pharmacokinetics of OBE022 administered to pregnant women, who are receiving standard of care therapy for preterm labor, atosiban infusion. Part B is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of OBE022. In December 2018, following completion of the open-label Part A and based on the favorable safety and pharmacokinetics results, we announced the initiation of the randomized placebo-controlled Part B of the trial. Part B will enroll up to 120 women at 24-34 weeks gestation who are experiencing preterm labor symptoms and are receiving standard of care. Patients will be randomized to OBE022 or placebo. We expect initial interim efficacy results to be available from the first 30 patients in the second 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 \$330.6 million of net proceeds from the sale of equity securities.

We have never been profitable and have incurred significant net losses in each period since our inception. Our net losses were \$25.7 million, and \$19.8 million for the three-month periods ended March 31, 2019 and 2018, respectively. As of March 31, 2019, we had accumulated losses of \$240.2 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 \$20.9 million and \$14.8 million of cash in operations in the three-month periods ended March 31, 2019 and 2018, respectively, and 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 in connection with our ongoing EDELWEISS, PRIMROSE 1 and 2, IMPLANT 4 and PROLONG clinical trials, and any additional clinical trials, nonclinical studies and pre-commercial activities that we may conduct for product candidates;
- hire additional research and development, pre-commercial, and general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- identify and in-license or acquire additional product candidates;
- continue to incur additional costs associated with operating as a public company;
- continue to build our commercialization organization.

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.

### **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 was paid. 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 we do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for one of our product candidates.

### ***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 March 31, 2019, we have incurred \$192.7 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 periods ended March 31, 2019 and March 31, 2018, respectively.

	Three-month period ended March 31,	
	2019	2018
	(in thousands) (unaudited)	
Linzagolix	\$ (11,293)	\$ (10,824)
Nolasiban	(4,570)	(1,577)
OBE022	(508)	(592)
Total outsourced research and development expenses	<u>\$ (16,371)</u>	<u>\$ (12,993)</u>

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 (including pre-commercialization activities), 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, 2018, we had tax loss carryforwards totaling \$184.2 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 periods ended March 31, 2019 and March 31, 2018, 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 March 31, 2019 and March 31, 2018

#### Operating Expenses

##### Research and Development Expenses

	Three-month period ended March 31,	
	2019	2018
	(in thousands) (unaudited)	
Research and development expenses by product candidate		
Linzagolix	\$ (11,293)	\$ (10,824)
Nolasiban	(4,570)	(1,577)
OBE022	(508)	(592)
Unallocated expenses		
Staff costs	(3,040)	(2,822)
Other research and development costs	(729)	(527)
Total research and development expenses	<u>\$ (20,140)</u>	<u>\$ (16,342)</u>

Research and development expenses increased by \$3.8 million in the three-month period ended March 31, 2019 compared to the three-month period ended March 31, 2018 primarily due to increased costs related to nolasiban and the progress made in our IMPLANT 4 clinical trial (including cost of supplies).

##### General and Administrative Expenses

	Three-month period ended March 31,	
	2019	2018
	(in thousands) (unaudited)	
Staff costs	\$ (3,217)	\$ (2,271)
Professional fees	(1,715)	(906)
Other general and administrative costs	(323)	(472)
Total general and administrative expenses	<u>\$ (5,255)</u>	<u>\$ (3,649)</u>

General and administrative expenses in the three-month period ended March 31, 2019 increased by \$1.6 million compared to the three-month period ended March 31, 2018, primarily due to increased staff costs of \$0.9 million associated with increased headcount, as well as higher professional fees of \$0.8 million resulting from increased efforts in communication and building our commercial strategy and organization.

#### Finance Result, Net

	Three-month period ended March 31,	
	2019	2018
	(in thousands) (unaudited)	
Foreign exchange (loss) / gain	\$ (250)	\$ 155
Lease interest expense	(32)	—
Finance result, net	<u>\$ (282)</u>	<u>\$ 155</u>

Finance result, net in the three-month periods ended March 31, 2019 and March 31, 2018 primarily consisted of foreign exchange loss and gain, respectively.

## 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 March 31, 2019, we have raised an aggregate of \$330.6 million of net proceeds from the sale of equity securities.

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 \$67.8 million in net proceeds after deducting \$5.3 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 March 31, 2019, we had \$117.3 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 second quarter 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 three-month periods ended March 31, 2019 and March 31, 2018:

	<b>Three-month period ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
	<b>(in thousands) (unaudited)</b>	
Cash and cash equivalents at beginning of period	\$ 138,640	\$ 110,841
Net cash used in operating activities	(20,933)	(14,762)
Net cash used in investing activities	(9)	(96)
Net cash used in financing activities	(71)	(702)
Effect of exchange rates	(306)	154
Cash and cash equivalents at end of period	<u>\$ 117,321</u>	<u>\$ 95,435</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 three-month period ended March 31, 2019, cash used in operating activities was \$20.9 million, primarily as the result of our net loss before tax of \$25.7 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to \$3.8 million and mainly consisted of share-based payments. Changes in the net working capital included primarily a \$0.9 million increase in other payables and current liabilities mainly due to the invoice phasing of certain Phase 1 and non-clinical studies.

During the three-month period ended March 31, 2018, cash used in operating activities was \$14.8 million, primarily as the result of our net loss before tax of \$19.8 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to \$2.3 million and mainly consisted of share-based payments. Changes in the net working capital included primarily a \$4.3 million increase in accrued expenses, mainly due to the costs of our PRIMROSE clinical trials and CMC formulation development costs for nolasiban, and a \$1.2 million decrease in other payables and current liabilities mainly due to the invoice phasing for our clinical trials with linzaglix.

#### *Investing Activities*

During the three-month periods ended March 31, 2019, and March 31, 2018, net cash used in investing activities consisted primarily of investments in leasehold improvements, furniture and fixtures.

#### *Financing Activities*

During the three-month period ended March 31, 2019, net cash used in financing activities consisted primarily of the principal elements of lease payments and associated interest expense, as a result of the adoption of the new lease standard, net of proceeds from the exercise of stock options.

During the three-month period ended March 31, 2018, net cash used in financing activities consisted primarily of final payments made in relation with our private placement in October 2017, including mainly a 1% Swiss stamp tax due on the amount of gross proceeds.

#### **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 March 31, 2019. 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.

With the exception of the recent accounting pronouncements described below, 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, 2018, 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**

On January 1, 2019, IFRS 16 *Leases* became effective and as a result of this new adoption, we recognized right-of-use assets and lease liabilities of \$2.7 million, as further detailed in note 2.1 of our condensed consolidated interim financial statements.

The adoption of other 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, 2019 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 March 31, 2019, 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, 2018, 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 First Quarter 2019 Financial Results

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

**GENEVA, Switzerland and BOSTON, MA. (May 9, 2019) – ObsEva SA (NASDAQ: OBSV / SIX: OBSN)** clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that compromise a woman's reproductive health and pregnancy, today reported financial results for the first quarter ending March 31, 2019 and provided a business update.

### Recent Highlights

#### **Nolasiban to improve IVF outcomes**

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

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

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

#### **OBE022 for the treatment of preterm labor**

- ObsEva announced encouraging Part A results leading to the initiation of Part B of PROLONG, a proof-of-concept Phase 2a trial of the oral prostaglandin F2 alpha receptor antagonist OBE022 for the treatment of preterm labor. Part A results showed that OBE022 was well tolerated by mothers
-

and their fetuses and supported prior favorable pharmacokinetic analysis. Eight of nine patients achieved the treatment goal of seven-days without delivering a baby.

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

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

## **2019 Milestones**

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

### **Nolasiban**

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

### **Linzagolix**

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

### **OBE022**

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

## **First Quarter 2019 Financial Results**

Net loss for the first quarter of 2019 was \$25.7 million, or \$0.59 per share, compared with a net loss of \$19.8 million, or \$0.54 per share, for the first quarter of 2018. Research and development expenses were \$20.1 million and general and administrative expenses were \$5.3 million for the first quarter of 2019, compared with \$16.3 million and \$3.6 million, respectively, for the first quarter of 2018. The net loss for

---

the first quarter of 2019 included non-cash expenses of \$3.3 million for stock-based compensation, compared with \$2.4 million in the prior-year period.

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

### **Conference Call**

ObsEva will host a conference call and audio webcast today beginning at 8:00 a.m. Eastern Time/2:00 p.m. Central European Time, to provide a business update and discuss the first quarter results. Investors may participate by dialing (844) 419-1772 for U.S. callers or (213) 660-0921 for international callers and referring to conference ID 9375906. A webcast of the conference call can be accessed under the "Investors" section of ObsEva's website [www.obseva.com](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, 2018, and other filings ObsEva makes with the SEC. These documents are available on the Investors page of ObsEva's website at <http://www.obseva.com>. Any forward-looking statements speak only as of the date of this press release and are based on information available to ObsEva as of the date of this release, and ObsEva assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

---

**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:**

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

## Consolidated Balance Sheets

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

###