Obseva

nature meets nurture

Q3 2020 interim report

Interim Condensed Consolidated IFRS Financial Statements for the three-month and nine-month periods ended September 30, 2020

Unaudited Condensed Consolidated Balance Sheets

(in USD '000)	Notes	September 30, 2020	December 31, 2019
ASSETS			
Current assets			
Cash and cash equivalents	4	50,597	69,370
Other receivables		516	1,044
Prepaid expenses		5,183	4,359
Total current assets		**56,296**	**74,773**
Non-current assets			
Right-of-use assets		1,579	2,042
Furniture, fixtures and equipment		168	245
Intangible assets	5	26,608	26,608
Other long-term assets		285	275
Total non-current assets		**28,640**	**29,170**
Total assets		**84,936**	**103,943**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Other payables and current liabilities		14,538	8,432
Accrued expenses		12,064	10,418
Current lease liabilities		665	618
Total current liabilities		**27,267**	**19,468**
Non-current liabilities			
Non-current lease liabilities		1,091	1,541
Non-current borrowings	6	25,204	24,917
Post-employment obligations		8,310	7,946
Other long-term liabilities		878	1,116
Total non-current liabilities		**35,483**	**35,520**
Shareholders' equity			
Share capital		4,370	3,499
Share premium		353,651	320,955
Reserves		25,991	21,912
Accumulated losses		(361,826)	(297,411)
Total shareholders' equity	7	**22,186**	**48,955**
Total liabilities and shareholders' equity		**84,936**	**103,943**

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

Unaudited Condensed Consolidated Statements of Comprehensive Loss

(in USD '000, except per share data)	Notes	Three-month period ended September 30, 2020	2019	Nine-month period ended September 30, 2020	2019
Operating income other than revenue		**3**	**5**	**11**	**11**
OPERATING EXPENSES					
Research and development expenses	8	(20,125)	(21,935)	(52,690)	(70,513)
General and administrative expenses		(3,514)	(4,865)	(9,414)	(16,306)
Total operating expenses		**(23,639)**	**(26,800)**	**(62,104)**	**(86,819)**
OPERATING LOSS		**(23,636)**	**(26,795)**	**(62,093)**	**(86,808)**
Finance income		184	219	292	425
Finance expense		(918)	(1,021)	(2,619)	(1,608)
NET LOSS BEFORE TAX		**(24,370)**	**(27,597)**	**(64,420)**	**(87,991)**
Income tax (expense) / benefit	9	(14)	(10)	5	(51)
NET LOSS FOR THE PERIOD		**(24,384)**	**(27,607)**	**(64,415)**	**(88,042)**
Net loss per share					
Basic	10	(0.49)	(0.63)	(1.35)	(2.01)
Diluted	10	(0.49)	(0.63)	(1.35)	(2.01)
OTHER COMPREHENSIVE LOSS					
Items that will not be reclassified to profit and loss					
Remeasurements on post-employment benefit plans		—	—	—	—
Items that may be reclassified to profit or loss					
Currency translation differences		—	—	—	—
TOTAL OTHER COMPREHENSIVE LOSS		**—**	**—**	**—**	**—**
TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		**(24,384)**	**(27,607)**	**(64,415)**	**(88,042)**

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

Unaudited Condensed Consolidated Statements of Cash Flows

(in USD '000)	Notes	Nine-month period ended September 30, 2020	2019
NET LOSS BEFORE TAX FOR THE PERIOD		**(64,420)**	**(87,991)**
Adjustments for:			
Depreciation expense		542	549
Post-employment (benefit) / cost		(19)	99
Share-based compensation expense		6,132	9,433
Income tax paid		(39)	—
Finance result, net		2,326	1,184
Decrease in other receivables		232	103
Increase in prepaid expenses and other long term-assets		(824)	(250)
Increase in other payables and current liabilities		5,889	3,584
Increase in accrued expenses and other long-term liabilities		1,476	5,847
NET CASH FLOWS USED IN OPERATING ACTIVITIES		**(48,705)**	**(67,442)**
Payments for plant and equipment		—	(34)
Payment for intangible assets		—	(5,000)
NET CASH FLOWS USED IN INVESTING ACTIVITIES		**—**	**(5,034)**
Proceeds from issue of shares		33,763	1,364
Proceeds from issue of debt, net of issuance costs		—	24,736
Payment of share issuance costs		(1,755)	(54)
Proceeds from exercise of stock-options		—	193
Principal elements of lease payments		(465)	(425)
Interest paid		(1,751)	(243)
NET CASH FLOWS FROM FINANCING ACTIVITIES		**29,792**	**25,571**
Net decrease in cash and cash equivalents		(18,913)	(46,905)
Cash and cash equivalents as at January 1,		**69,370**	**138,640**
Effects of exchange rate changes on cash and cash equivalents		140	(718)
Cash and cash equivalents as at September 30,		**50,597**	**91,017**

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

Unaudited Condensed Consolidated Statements of Changes in Equity

(in USD '000)	Share capital	Share premium	Share-based payments reserve	Foreign currency translation reserve	Total reserves	Accumulated losses	Total
January 1, 2019	**3,420**	**314,565**	**13,347**	**(489)**	**12,858**	**(183,927)**	**146,916**
Loss for the period	—	—	—	—	—	(88,042)	(88,042)
Other comprehensive loss	—	—	—	—	—	—	—
Total comprehensive loss	**—**	**—**	**—**	**—**	**—**	**(88,042)**	**(88,042)**
Issuance of shares - EIP 2013	16	2,035	(2,035)	—	(2,035)	—	16
Issuance of shares - ATM program	10	1,354	—	—	—	—	1,364
Share issuance costs	—	(54)	—	—	—	—	(54)
Exercise of stock-options - EIP 2017	2	326	(134)	—	(134)	—	194
Share-based remuneration	—	—	9,433	—	9,433	—	9,433
September 30, 2019	**3,448**	**318,226**	**20,611**	**(489)**	**20,122**	**(271,969)**	**69,827**
January 1, 2020	**3,499**	**320,955**	**22,401**	**(489)**	**21,912**	**(297,411)**	**48,955**
Loss for the period	—	—	—	—	—	(64,415)	(64,415)
Other comprehensive loss	—	—	—	—	—	—	—
Total comprehensive loss	**—**	**—**	**—**	**—**	**—**	**(64,415)**	**(64,415)**
Issuance of shares - EIP 2013	14	2,053	(2,053)	—	(2,053)	—	14
Issuance of shares - Underwritten Offering	510	19,407	—		—		19,917
Issuance of shares - ATM program	347	13,150	—	—	—	—	13,497
Share issuance costs	—	(1,914)	—	—	—	—	(1,914)
Share-based remuneration	—	—	6,132	—	6,132	—	6,132
September 30, 2020	**4,370**	**353,651**	**26,480**	**(489)**	**25,991**	**(361,826)**	**22,186**

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

Unaudited Notes to the Condensed Consolidated Financial Statements

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, OBE022 and nolasiban) 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 2, 2020.

2. Accounting principles and scope of consolidation

2.1 Basis of preparation and accounting principles

These unaudited three-month and nine-month interim condensed 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").

Accounting policies

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, 2019 (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 Company has incurred recurring losses since inception, including net losses of USD 64.4 million for the nine-month period ended September 30, 2020. As of September 30, 2020, the Company had accumulated losses of USD 392.4 million, out of which USD 30.6 million were offset with share premium. The Company expects to continue to generate operating losses in the foreseeable future, even though certain spending associated with its ongoing clinical trials has been and may be further delayed as a result of the COVID-19 pandemic. As of September 30, 2020, the Company had cash and cash equivalents of $50.6 million. The Company expects that its current cash and cash equivalents will be sufficient to fund its operations and meet all of its obligations as they fall due through the second quarter of 2021 (without any consideration of the potential third Tranche under the Oxford credit facility) and, as a result, there is substantial doubt about its ability to continue as a going concern for one year from the date of the issuance of these condensed consolidated financial statements for the nine-month period ended September 30, 2020. The unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The future viability of the Company is dependent on its ability to raise additional capital to finance its future operations. The Company will seek additional funding through public or private financings, debt financing or collaboration agreements. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company's ability to pay dividends or make other distributions to shareholders. The inability to obtain funding, as and when needed, would have a negative impact on the Company's financial condition and ability to pursue its business strategies. If the Company is unable to obtain the required funding to run its operations and to develop and commercialize its product candidates, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Management is currently pursuing plans to obtain additional funding to finance its operations, especially through collaborations with third parties for the future potential commercialization of linzagolix in Europe and the United States. However, there is no assurance that the Company will be successful in raising funds, closing a collaboration agreement and obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all, which could have material adverse effect on the Group's business, results of operations and financial conditions.

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. The Company bases the estimates on historical experience and on various other assumptions that the Company believes are reasonable, the results of which form the basis for making judgments about the carrying value of assets, liabilities and equity and the amount of revenues and expenses. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including but not limited to expenses, progress of the Company's clinical trials, research and development costs and employee related amounts, will depend on future developments that are highly uncertain, including the duration and spread of the pandemic, and the actions taken to contain it, such as the impact and effectiveness of current and any future governmental measures implemented in response thereto, or new information that may emerge concerning COVID-19, as well as the extent to which the COVID-19 pandemic has impacted and will continue to impact worldwide macroeconomic conditions, including interest rates, employment rates and health insurance coverage, the speed of the anticipated recovery, and governmental and business reactions to the pandemic. The Company has made estimates of the impact of COVID-19 within these condensed consolidated 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 September 30, 2020 and 2019.

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, 2020	December 31, 2019
Bank deposits	50,597	69,370
Interest bearing deposits	—	—
Total cash and cash equivalents	**50,597**	**69,370**

5. Intangible assets

As at September 30, 2020 and December 31, 2019, the Group holds a number of licenses to develop and commercialize several biopharmaceutical product candidates, the value of which is recorded at USD 26.6 million.

On May 9, 2019, the Group announced the initiation of its Phase 3 clinical program for linzagolix in endometriosis, which includes the EDELWEISS 2 and EDELWEISS 3 clinical trials. On July 19, 2019, the Group randomized the first patient as part of the EDELWEISS 2 trial, resulting in a milestone payment of USD 5 million to Kissei Pharmaceutical Co., Ltd., accounted for as an intangible asset.

6. Borrowings

In August 2019, the Company entered into a loan and security agreement with Oxford Finance for a term loan of up to USD 75.0 million, subject to funding in three tranches. The Company received gross proceeds of USD 25.0 million, net of transaction costs of USD 0.3 million, from the first tranche of the credit facility upon entering into the agreement and intends to use the funds for its various clinical trials programs. The Company could not draw the second tranche of USD 25.0 million due to the failure to meet the primary endpoint of the Phase 3 IMPLANT 4 clinical trial of nolasiban. Pursuant to an amendment to the loan and security agreement signed in April 2020, the third tranche of USD 25.0 million may be drawn at any time between April 7, 2020 and August 1, 2024 upon request of the Company and at the lender's discretion.

The credit facility is secured by substantially all of the Company's assets, including the Company's intellectual property. Each tranche bears interest at a floating interest rate of thirty day U.S. LIBOR, plus 6.25%, or a minimum of 8.68% per year in total. The Company is required to make monthly interest-only payments on each tranche through the amortization start date on August 1, 2022. The credit facility will mature on August 1, 2024, at which date a final fee payment of 6.75% of each funded tranche will be due, resulting in an effective interest rate of 10.32% per year. The credit facility contains customary conditions to borrowings and events of default and contains various negative covenants limiting the Company's ability to, among other things, transfer or sell certain assets, allow changes in business, ownership or business locations, consummate mergers or acquisitions, incur additional indebtedness, create liens, pay dividends or make other distributions and make investments. As of September 30, 2020, the Company was in compliance with its covenants.

7. Shareholders' equity

In 2019, the Company sold a total of 691,133 treasury shares at an average price of USD 5.14 per share, as part of its "at the market" (ATM) program initiated in May 2018. These multiple daily transactions generated total gross proceeds of USD 3.6 million. Directly related share issuance costs of USD 0.1 million were recorded as a deduction in equity.

During the nine-months ended September 30, 2020, the Company sold a total of 4,416,583 treasury shares at an average price of USD 3.06 per share, as part of its ATM program. These multiple daily transactions generated total gross proceeds of USD 13.5 million. Directly related share issuance costs of USD 0.4 million were recorded as a deduction in equity.

In April 2020 and September 2020, the Group issued 3,308,396 and 2,320,266 common shares, respectively, at par value of 1/13 of a Swiss franc per share. The shares were fully subscribed for by the Group and listed on the SIX Swiss Exchange accordingly. The shares were initially held as treasury shares, hence the operation did not impact the outstanding share capital.

In September 2020, the Company completed an underwritten offering of 6,448,240 units at an effective price of USD 2.869 per unit, with each unit comprised of one common share (or pre-funded warrant) and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share. In addition to the securities being sold in the underwritten offering, the Company's Chief Executive Officer purchased 516,352 units at an effective price of USD 2.905 per unit, with each unit comprised of one common share and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share, in a concurrent private placement. The net proceeds from the offering and the concurrent private placement were approximately USD 18.4 million, after deducting underwriting discounts, commissions and other offering expenses paid by the Company.

As at September 30, 2020, the total outstanding share capital of USD 4.4 million, fully paid, consists of 55,015,024 common shares, excluding 5,187,595 treasury shares. As at December 31, 2019, the total outstanding share capital of USD 3.5 million, fully paid, consisted of 44,423,448 common shares, excluding 168,641 non-vested shares and 3,975,516 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.

8. 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. Research and development expenses consist of costs incurred in performing research and development activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, manufacturing expenses as well as external costs of vendors engaged to conduct preclinical development activities and clinical trials.

As a result of the COVID-19 pandemic, research and development activities associated with certain ongoing clinical trials have been and may be further delayed, that may consequently impact and also delay the timing of recognition of such research and development activities in the profit and loss accounts. On March 23, 2020, the Group announced its decision to place a temporary hold on further screening and randomization of patients into its EDELWEISS 2 and EDELWEISS 3 clinical trials. During the second quarter of 2020, new patient enrollment in the EDELWEISS 2 and EDELWEISS 3 clinical trials resumed in several European countries, as well as in selective areas of the United States, based on local conditions with respect to the prevalence and spread of the COVID-19 pandemic. As the COVID-19 pandemic continues to rapidly evolve, the Group does not yet know the full extent of the pandemic's potential effects on its business, its clinical trials, its anticipated timelines for the development of the Group's product candidates, or on the supply chain for its clinical supplies. These effects could have a material adverse impact on the Group's business and financial condition.

9. Income tax

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

Since January 1, 2020, the Company is subject in Switzerland to a municipal and cantonal income tax rate of 14.0% and to a federal tax rate of 8.5% on its profits after tax (2019: 22.6% and 8.5%, respectively). 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, 2020 and 2019. 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, 2020 and December 31, 2019.

On May 19, 2019, the Canton of Geneva approved the implementation of the national proposal of the tax law named "Federal Act on Tax Reform and AHV Financing" (TRAF). This new tax law results in the abolition of special tax status companies at cantonal level (privileged taxation as holding company, mixed company and domiciliary company), and introduces a range of tax measures including the reduction of corporate income tax rate and capital tax base. Since the Company has incurred recurring losses since inception, it does not expect a significant impact resulting from the implementation of the TRAF.

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, 2020 and 2019.

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, 2020 and 2019 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.

10. Loss per share

As of September 30, 2020 and 2019, 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, 2020	Nine-month period ended September 30, 2020
Net loss attributable to shareholders (in USD '000)	(24,384)	(64,415)
Weighted average number of common shares outstanding	50,086,923	47,848,862
Basic and diluted loss per share (in USD)	**(0.49)**	**(1.35)**

	Three-month period ended September 30, 2019	Nine-month period ended September 30, 2019
Net loss attributable to shareholders (in USD '000)	(27,607)	(88,042)
Weighted average number of common shares outstanding	43,739,938	43,693,245
Basic and diluted loss per share (in USD)	**(0.63)**	**(2.01)**

For the three-month and nine-month periods ended September 30, 2020, 5,446,230 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, 2019, 221,249 non-vested shares and 3,433,148 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.

11. 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:

(in USD '000)	September 30, 2020	December 31, 2019
Switzerland	28,044	28,391
USA	596	779
Total non-current assets	**28,640**	**29,170**

The geographical analysis of operating expenses is as follows:

(in USD '000)	Three-month period ended September 30,		Nine-month period ended September 30,	
	2020	2019	2020	2019
Switzerland	23,070	25,592	60,427	83,403
USA	569	1,208	1,677	3,416
Total operating expenses	**23,639**	**26,800**	**62,104**	**86,819**

12. Events after the reporting period

There were no material events after the balance sheet date.

Financial Review

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 puberty and menopause 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 heavy menstrual bleeding associated with uterine fibroids and pain associated with endometriosis.

We are developing linzagolix as a novel, oral gonadotropin releasing hormone (GnRH), receptor antagonist, for the treatment of pain associated with endometriosis and heavy menstrual bleeding (HMB), 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 administration for linzagolix i.e. (i) a moderate dose of linzagolix without hormonal add-back therapy (ABT) (ABT; 1mg E2 / 0.5mg NETA) and (ii) a high dose of linzagolix with hormonal ABT.

We are conducting two Phase 3 clinical trials of linzagolix in patients with HMB associated with uterine fibroids, the PRIMROSE 1 (conducted in the United States, which enrolled 526 women with uterine fibroids) and the PRIMROSE 2 (conducted in Europe and in the United States, which enrolled 535 women with uterine fibroids) clinical trials. In both trials, patients were administered linzagolix doses of 100 mg or 200mg, both with and without hormonal ABT, or placebo. The primary endpoint of the PRIMROSE 1 and PRIMROSE 2 clinical trials was the reduction in HMB at 24 weeks; responders were defined as patients with menstrual blood loss volume of ≤ 80 mL and a 50 percent or greater reduction from baseline in menstrual blood loss (MBL), volume, measured using the alkaline hematin method. Secondary endpoints included amenorrhea, time to reduced MBL, hemoglobin (Hb), pain, and quality of life (QoL). Safety endpoints included bone mineral density (BMD), and adverse events (AEs). Calcium/vitamin D were not provided. BMD was measured centrally via Dual Energy X-ray Absorptiometry (DEXA) scan at baseline, 24 weeks, 52 weeks and 76 weeks (6-month post treatment assessment).

As further discussed below, the primary endpoint was successfully met in both the PRIMROSE 1 and PRIMROSE 2 clinical trials. We intend to proceed with regulatory submissions for the uterine fibroid indication, planned for the fourth quarter of 2020 in Europe and the first half of 2021 in the United States.

In July 2020, we announced positive Phase 3 trial results from the PRIMROSE 1 trial of linzagolix. The responder rate was 75.5% ($p < 0.001$) for patients receiving 200 mg with ABT and 56.4% for patients receiving 100 mg without ABT ($p = 0.003$), compared to 35.0% in the placebo group. Both doses achieved significant rates of amenorrhea ($p < 0.001$ for 200 mg+ ABT and $p = 0.009$ for 100 mg), reduction in pain ($p < 0.001$), and improvement in quality of life ($p < 0.001$ for 200 mg +ABT and $p = 0.002$ for 100 mg). Additionally, significant improvement was observed in Hb level ($p<0.001$ for 200mg +ABT and $p = 0.019$ for 100mg), a reduction in number of days of bleeding ($p<0.001$). The overall safety profile was in line with expectations. The most frequently observed adverse events (occurring in > 5% of patients) were headache and hot flushes. Mean percentage change from baseline in BMD was as expected for treatment with a GnRH antagonist in the studied population.

In December 2019, we announced positive Phase 3 trial results from the PRIMROSE 2 trial of linzagolix for the treatment of HMB due to uterine fibroids. The responder rate was 93.9% ($p < 0.001$) for patients receiving 200 mg with ABT and 56.7% for patients receiving 100 mg without ABT ($p < 0.001$), compared to 29.4% in the placebo group. Both doses achieved significant rates of amenorrhea ($p< 0.001$), reduction in pain ($p < 0.001$), and improvement in quality of life ($p < 0.001$). Additionally, significant improvement ($p< 0.001$) in Hb levels, a reduction in number of days of bleeding and reduction in uterine volume were observed. A significant reduction in fibroid volume was also observed for the 200 mg dose without ABT ($p = 0.008$). The overall safety profile was in line with expectations. The most frequently observed adverse events (occurring in > 5% of patients) were headache, hot flushes, and anemia. Mean percentage change from baseline in BMD was consistent with previous clinical data.

We believe that based on pooled week 24 clinical data from these two Phase 3 trials linzagolix has the potential for a best-in-class profile, with a pooled responder rate of 84.5% in women receiving linzagolix 200 mg with ABT, and 56.5% in women receiving linzagolix 100 mg without ABT.

In July 2020, we announced positive 52-week treatment results from the PRIMROSE 2 trial. These new data from PRIMROSE 2 demonstrated that continued treatment with linzagolix for 52 weeks provided sustained efficacy. Responder rates of 91.6% and 53.2% were observed in women receiving 200 mg with ABT and 100 mg without ABT, respectively, both of which are similar to the responder rates observed at week 24 of the trial. In addition, a small incremental change in BMD was observed at week 52 compared to week 24. Additional follow-up data to be collected from PRIMROSE 1 and PRIMROSE 2 includes 52-week treatment results, and 6-month post treatment assessment. The above results were presented as two late-breaking posters at the ASRM 2020 Virtual Scientific Congress and Expo, discussing the potential for the low-dose option (100 mg) of linzagolix to fill an unmet need for medical treatment of uterine fibroids in women who cannot or prefer to avoid hormonal add-back therapy (ABT).

Based on the positive PRIMROSE 1 and PRIMROSE 2 primary endpoint results and additional follow-up data, plus feedback from scientific advice meetings with national European regulatory agencies, we expect to submit a Marketing Authorization Application (MAA) submission to the European Medicines Agency (EMA) in the fourth quarter 2020, and a New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) in the first half of 2021.

In addition to linzagolix development for uterine fibroids, we are presently conducting two Phase 3 clinical trials of linzagolix for the treatment of endometriosis associated pain, the EDELWEISS 2 (conducted in the United States) and EDELWEISS 3 (conducted in Europe and in the United States) clinical trials which were initiated in May 2019. These Phase 3 trials will each enroll approximately 450 patients with endometriosis associated pain, with a co-primary endpoint of response on both dysmenorrhea (menstrual pain) and non-menstrual pelvic pain. Both trials include a 75 mg once daily dose without hormonal ABT, and a 200 mg once daily dose in combination with hormonal ABT (1mg E2 / 0.5mg NETA). Subjects who have completed the initial six-month treatment period for each of the EDELWEISS 2 and EDELWEISS 3 trials will have the option to enter a 6-month treatment extension (the EDELWEISS Extension trials).

In view of the expected logistical challenges with initial screening and uncertainty about continuity of treatment for randomized patients because of the COVID-19 pandemic, as announced in March 2020, we placed a temporary hold on further screening and randomization of patients into our EDELWEISS 2 and EDELWEISS 3 clinical trials. EDELWEISS 2 and EDELWEISS 3 clinical trial sites managed all randomized patients already on treatment to proceed with enhanced safety measures and the trial protocol whenever feasible. During the second quarter of 2020, new patient enrollment was resumed for the EDELWEISS 2 and EDELWEISS 3 clinical trials in several European countries, as well as in selective areas of the United States, based on local conditions with respect to the prevalence and spread of the COVID-19 pandemic. As the COVID-19 pandemic continues to rapidly evolve, we do not yet know the full extent of the pandemic's potential effects on our business, our clinical trials, our anticipated timelines for the development of our product candidates, or on the supply chain for our clinical supplies. These effects could have a material adverse impact on our business and financial condition.

OBE022 for the treatment of preterm labor

We are developing OBE022, an oral and selective prostaglandin F2α receptor antagonist, for preterm labor in weeks 24 to 34 of pregnancy. In December 2017, we announced the initiation of our 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 in pregnant women, who were already 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. In the first quarter of 2020, the Independent Data Monitoring Committee (IDMC) recommended continuing the ongoing PROLONG trial with no modifications based on safety data from the first 90 patients enrolled in Part B. Enrollment of PROLONG Part B was completed in March 2020 and final PROLONG trial results (up to 28 days follow-up after all infant deliveries) are anticipated in the fourth quarter of 2020. Pending positive PROLONG trial results, we anticipate potentially beginning a Phase 2b dose ranging trial of OBE022, and to seek interaction with the FDA on the US clinical development program.

Nolasiban for the improvement of pregnancy and birth rates in women undergoing embryo transfer following in-vitro fertilization.

We have been 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, or the IMPLANT 2 clinical trial, in 2017 and reported positive results for the primary endpoint of ongoing pregnancy 10 weeks post embryo transfer in February 2018, and positive live birth rate results in October 2018. Nolasiban was observed to be well tolerated with a safety profile not different from placebo. 28-day neonatal safety data 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 Europe, with some additional sites in Canada and Russia, also known as the IMPLANT 4 trial. In June 2019, we announced completion of patient recruitment in the IMPLANT 4 trial. In addition, we announced the clearance of our investigational new drug (IND) in October 2019 for the U.S. Phase 3 clinical trial of nolasiban, known as IMPLANT 3.

In November 2019, we announced that the IMPLANT 4 trial did not meet the primary endpoint of an increase in ongoing pregnancy rate at 10 weeks, (39.1 % placebo vs 40.5 % nolasiban) ($p = 0.745$). As these results did not confirm the prior positive Phase 3 IMPLANT 2 trial findings, we discontinued our previously ongoing development of nolasiban for IVF, and are exploring further development of the compound through assessment of higher dose levels and longer exposure to nolasiban based upon results from a meta-analysis of all clinical trials and a mechanism of action study. In this respect, we have presented, in October 2020, data and results as a poster at the ASRM 2020 Virtual Scientific Congress and Expo, supporting the further evaluation of higher doses and/or alternate regimens of nolasiban. In January 2020, we and Hangzhou YuYuan BioScience Technology Co., Ltd. (YuYuan) entered into

a sublicense agreement to develop and commercialize nolasiban for improving clinical pregnancy and live birth rates in women undergoing embryo transfer as part of an IVF cycle in the People's Republic of China (PRC). Under the terms of the agreement, YuYuan has the exclusive rights to develop and commercialize nolasiban in the PRC, and will fund all development and registration activities in the PRC, starting with the commitment to conduct Phase 1 trials and a Phase 2 proof-of-concept trial in China. We retain all rights to nolasiban outside of PRC, and will collaborate with YuYuan on its global development. Our development and commercialization partnership with YuYuan proceeded during the first quarter of 2020 with steering committee meetings to define the development plan for nolasiban in China for women undergoing ET following IVF. In July 2020, we announced that YuYuan submitted a pre-IND meeting request to the Center for Drug Evaluation at the Chinese National Medical Products Administration (NMPA). This submission represents the first milestone in the process to enable a Phase 1 and Phase 2 proof of concept study in China.

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, OBE022 and nolasiban 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 mostly through the sale of equity. To date, we have raised an aggregate of $365.7 million of net proceeds from the sale of equity securities, as well as $25.0 million from the issuance of debt instruments.

We have never been profitable and have incurred significant net losses in each period since our inception. Our net losses were $24.4 million, and $27.6 million for the three-month periods ended September 30, 2020 and 2019, respectively, and $64.4 million and $88.0 million for the nine-month periods ended September 30, 2020 and September 30, 2019, respectively. As of September 30, 2020, we had accumulated losses of $392.4 million, out of which $30.6 million were offset with share premium. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We used $48.7 million and $67.4 million of cash in operations in the nine-month periods ended September 30, 2020 and September 30, 2019, respectively, and we anticipate that our expenses will remain significant 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 PRIMROSE 1 and 2, EDELWEISS 2 and 3 (including their extensions), 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 and general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- identify and in-license or acquire additional product candidates;
- prepare for the commercialization of certain 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 are also exploring various alternatives for the future potential commercialization of linzagolix, including through collaborations with third parties.

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 do not have a commercialization organization.

COVID-19 Business Update

With the global spread of the ongoing COVID-19 pandemic which continues to date, we implemented a number of plans and policies designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business. We continue to closely monitor the COVID-19 situation and will evolve our plans and policies as needed going forward. In March 2020, some of our workforce transitioned to working remotely. While we were able to reopen our offices in the second quarter of 2020 to allow employees to return on a voluntary basis, consistent with local government requirements, and with a focus on employee safety, there is no guarantee that prior or new restrictions will not be reinstated in response to the continued spread of COVID-19. If the COVID-19 pandemic continues to persist for an extended period of time and begins to impact essential distribution systems, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing of clinical trial supply. For some of our clinical development programs, we are experiencing, and may continue to experience, a disruption or delay in our ability to initiate trial sites and enroll and assess patients. Although enrollment in EDELWEISS 2 and EDELWEISS 3 resumed in the second quarter following a temporary hold on screening that we implemented in March 2020 at the onset of the COVID-19 pandemic, enrollment delays may further occur in the coming months, and we are working closely with our vendors to manage our supply chain activities and mitigate any potential disruptions to our clinical trial supplies as a result of the COVID-19 pandemic. In addition, we rely on

CROs or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic.

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 initiations of the Phase 3 clinical programs for linzagolix in (i) uterine fibroids in the second quarter of 2017 and (ii) endometriosis in the third quarter of 2019, two milestone payments of $5.0 million each were 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.

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.

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.

In January 2020, we entered into a sublicense agreement, or the 2020 sublicense agreement, with YuYuan, pursuant to which we granted to YuYuan an exclusive sublicense under certain of our patents, trademarks and know-how to use, register, import, develop, market, promote, distribute, offer for sale and commercialize nolasiban for use in humans in the PRC, including Hong Kong and Macau. In consideration for entering into the 2020 sublicense agreement, YuYuan has agreed to make aggregate milestone payments of up to $17.0 million upon the achievement of specified development, regulatory and first sales milestones and aggregate milestone payments of up to $115.0 million upon the achievement of additional, tiered sales milestones. In addition, YuYuan has agreed to pay tiered royalties on net sales at percentages ranging from high-single digit to low-second decile, subject to specified reductions, until

the later of the expiration of the last valid claim covering the product in China and ten years from the first commercial sale of the product in China.

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 September 30, 2020, we have incurred $313.3 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, 2020 and September 30, 2019, respectively.

	Three-month period ended September 30,		Nine-month period ended September 30,	
	2020	2019	2020	2019
	(in thousands) (unaudited)			
Linzagolix	$ (15,567)	$ (14,386)	$ (37,334)	$ (42,617)
Nolasiban	(122)	(2,999)	(1,317)	(14,685)
OBE022	(494)	(582)	(1,487)	(1,905)
Total outsourced research and development expenses	$ (16,183)	$ (17,967)	$ (40,138)	$ (59,207)

We expect our research and development expense will remain significant 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 duration, severity and impact on our operations of the COVID-19 pandemic;
- 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 expenses will remain significant in the future to support continued research and development activities. We also anticipate that we will keep spending material 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 expense associated with our lease liabilities and debt instruments, as well as 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, 2019, we had tax loss carryforwards totaling $287.6 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 nine-month periods ended September 30, 2020 and September 30, 2019, and our US 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, 2020 and September 30, 2019

Operating Expenses

Research and Development Expenses

	Three-month period ended September 30,		
	2020	2019	Change
	(in thousands) (unaudited)		
Research and development expenses by product candidate			
Linzagolix	$ (15,567)	$ (14,386)	$ (1,181)
Nolasiban	(122)	(2,999)	2,877
OBE022	(494)	(582)	88
Unallocated expenses			
Staff costs	(3,350)	(3,062)	(288)
Other research and development costs	(592)	(907)	315
Total research and development expenses	$ (20,125)	$ (21,935)	$ 1,810

Research and development expenses decreased by $1.8 million in the three-month period ended September 30, 2020 compared to the three-month period ended September 30, 2019, primarily due to lower costs for our nolasiban program which was discontinued in the fourth quarter of 2019 after the results of our IMPLANT 4 trial conducted in 2019, partially offset by increased costs for our linzagolix program, especially for our ongoing EDELWEISS Phase 3 trials.

General and Administrative Expenses

	Three-month period ended September 30, 2020	2019	Change
		(in thousands) (unaudited)	
Staff costs	$ (1,686)	$ (3,218)	$ 1,532
Professional fees	(1,053)	(1,193)	140
Other general and administrative costs	(775)	(454)	(321)
Total general and administrative expenses	$ (3,514)	$ (4,865)	$ 1,351

General and administrative expenses in the three-month periods ended September 30, 2020 decreased by $1.4 million compared to the three-month period ended September 30, 2019, primarily due to lower staff costs of $1.5 million, which resulted from (i) a reversal in share-based compensation associated with forfeited unvested awards of departing employees, and (ii) a lower employee headcount compared to the prior year period.

Finance Result, Net

	Three-month period ended September 30, 2020	2019	Change
		(in thousands) (unaudited)	
Foreign exchange loss	$ (41)	$ (346)	$ 305
Interest expense	(693)	(455)	(238)
Finance result, net	$ (734)	$ (801)	$ 67

Finance result, net in the three-month periods ended September 30, 2020 and September 30, 2019 primarily consisted of foreign exchange loss, as well as interest expense associated with our lease liabilities and debt instruments.

Comparison of the nine-month periods ended September 30, 2020 and September 30, 2019

Operating Expenses

Research and Development Expenses

	Nine-month period ended September 30, 2020	2019	Change
		(in thousands) (unaudited)	
Research and development expenses by product candidate			
Linzagolix	$ (37,334)	$ (42,617)	$ 5,283
Nolasiban	$ (1,317)	(14,685)	13,368
OBE022	$ (1,487)	(1,905)	418
Unallocated expenses			
Staff costs	(10,705)	(9,106)	(1,599)
Other research and development costs	(1,847)	(2,200)	353
Total research and development expenses	$ (52,690)	$ (70,513)	$ 17,823

Research and development expenses decreased by $17.8 million in the nine-month period ended September 30, 2020 compared to the nine-month period ended September 30, 2019 primarily due (i) a $5.3 million decrease in expenses related to our linzagolix programs, including a $10.8 million decrease in expenses related to our PRIMROSE clinical trials, which were fully enrolled at the end of 2019, partially offset by a $7.4 million increase in expenses related to our ongoing EDELWEISS Phase 3 clinical trials (including extension studies), as well as (ii) a $13.4 million decrease in expenses related to our nolasiban program, which was discontinued in the fourth quarter of 2019 after the results of our IMPLANT 4 trial conducted in 2019.

General and Administrative Expenses

	Nine-month period ended September 30, 2020	2019	Change
	(in thousands) (unaudited)		
Staff costs	$ (5,117)	$ (10,094)	$ 4,977
Professional fees	(2,405)	(4,345)	1,940
Other general and administrative costs	(1,892)	(1,867)	(25)
Total general and administrative expenses	$ (9,414)	$ (16,306)	$ 6,892

General and administrative expenses decreased by $6.9 million in the nine-month period ended September 30, 2020 compared to the nine-month period ended September 30, 2019 primarily due to decreased staff costs of $5.0 million, which resulted from (i) a reversal in share-based compensation associated with forfeited unvested awards of departing employees, and (ii) a lower employee headcount compared to the prior year period. Professional fees also decreased by $1.9 million in the nine-month period ended September 30, 2020 compared to the nine-month period ended September 30, 2019, primarily because 2019 included certain communication efforts and other expenditures to build our commercial strategy and organization made prior to the adverse IMPLANT 4 clinical trial results.

Finance Result, Net

	Nine-month period ended September 30, 2020	2019	Change
	(in thousands) (unaudited)		
Foreign exchange loss	$ (295)	$ (668)	$ 373
Interest expense	(2,032)	(515)	(1,517)
Finance result, net	$ (2,327)	$ (1,183)	$ (1,144)

Finance result, net in the nine-month periods ended September 30, 2020 and September 30, 2019, respectively, primarily consisted of foreign exchange loss as well as interest expense associated with our lease liabilities and debt instruments.

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. To date, we have raised an aggregate of $365.7 million of net proceeds from the sale of equity securities. In August 2019, we borrowed $25.0 million under our senior secured term loan credit facility.

During the year ended December 31, 2019, we sold a total of 691,133 treasury shares at an average price of $5.14 per share, as part of our “at the market” (ATM) program initiated in May 2018, and received net proceeds of $3.5 million after deducting $0.1 million of directly-related issuance costs.

During the nine-month period ended September 30, 2020, we sold a total of 4,416,583 treasury shares at an average price of $3.06 per share, as part of our ATM program, for a total gross amount of $13.5 million.

In September 2020, we completed an underwritten offering of 6,448,240 units at an effective price of $2.869 per unit, with each unit comprised of one common share (or pre-funded warrant) and one 15-month purchase warrant to purchase one common share at an exercise price of $3.43 per share. In addition to the securities being sold in the underwritten offering, our Chief Executive Officer has purchased 516,352 units at an effective price per unit of $2.905, with each unit comprised of one common share and one 15-month purchase warrant to purchase one common share at an exercise price of $3.43 per share, in a concurrent private placement. The net proceeds from the offering and concurrent private placement were approximately $18.4 million, after deducting underwriting discounts, commissions and other offering expenses.

In August 2019, we entered into a loan and security agreement, or the Credit Facility Agreement, with Oxford Finance, or Oxford, for a term loan of up to $75.0 million, subject to funding in three tranches. We received gross proceeds of $25.0 million from the first tranche of the credit facility upon entering into the agreement and intend to use the funds as part of our various clinical trials programs. We could not draw the second tranche of $25.0 million due to the failure to meet the primary endpoint of the Phase 3 IMPLANT 4 clinical trial of nolasiban. Pursuant to an amendment to the Credit Facility Agreement signed in April 2020, the third tranche of $25.0 million may be drawn at any time between April 7, 2020 and August 1, 2024 upon our request and at Oxford’s discretion. The credit facility is secured by substantially all of our assets, including our intellectual property. The loan bears a floating

interest rate (partially based on thirty-day U.S. LIBOR rate) currently amounting to 8.68% per year in total and will mature on August 1, 2024.

The credit facility includes affirmative and negative covenants applicable to us and our subsidiaries. The affirmative covenants include, among other things, covenants requiring us to maintain our legal existence and governmental approvals, deliver certain financial reports, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. Further, subject to certain exceptions, the credit facility contains customary negative covenants limiting our ability to, among other things, transfer or sell certain assets, allow changes in business, ownership or business locations, consummate mergers or acquisitions, incur additional indebtedness, create liens, pay dividends or make other distributions and make investments.

Upon the occurrence and during the continuance of an event of default, Oxford may declare all outstanding principal and accrued and unpaid interest under the credit facility immediately due and payable and exercise the other rights and remedies provided for under the credit facility and related loan documents. The events of default under the credit facility include, among other things, payment defaults, breaches of covenants or representations and warranties, material adverse changes, certain bankruptcy events, cross defaults with certain other indebtedness and judgment defaults.

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. Other than our Credit Facility Agreement with Oxford, we have no other ongoing material financing commitments, such as lines of credits or guarantees.

We expect our expenses to remain significant 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 may 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 commercial partners. 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 have incurred recurring losses since inception, including net losses of USD 64.4 million for the nine-month period ended September 30, 2020. As of September 30, 2020, we had accumulated losses of USD 392.4 million, out of which USD 30.6 million were offset with share premium. We expect to continue to generate operating losses in the foreseeable future, even though certain spending associated with its ongoing clinical trials has been and might be further delayed as a result of the COVID-19 pandemic. As of September 30, 2020, we had $50.6 million in cash and cash equivalents. 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 2021 (without consideration of the potential availability of $25.0 million under the Credit Facility Agreement), and as a result, there is substantial doubt about our ability to continue as a going concern for one year from the date of the issuance of our Unaudited Condensed Consolidated Financial Statements for the nine-month period ended September 30, 2020, included in this Q3 2020 interim report. 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. Additional details in respect to our cash reach date and our going concern assumptions are provided in note 2.1 to our Unaudited Condensed Consolidated Financial Statements. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing and future nonclinical studies and clinical trials for linzagolix, OBE022 and nolasiban;
- the cost and timing of ongoing and future manufacturing activities including active pharmaceutical ingredient and drug product pharmaceutical development and clinical trial supplies production for linzagolix, OBE022 and nolasiban;
- 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 duration and severity of the COVID-19 pandemic currently delaying spending on certain of our clinical trials, and the impact of the COVID-19 pandemic on our operations and on global capital markets, which may affect our ability to access our ATM program or conduct other offerings;
- 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, such as the Credit Facility Agreement and others, 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, 2020 and September 30, 2019:

	Nine-month period ended September 30,	
	2020	2019
	(in thousands) (unaudited)	
Cash and cash equivalents at beginning of period	$ 69,370	$ 138,640
Net cash used in operating activities	(48,705)	(67,443)
Net cash used in investing activities	—	(5,034)
Net cash from financing activities	29,792	25,572
Effect of exchange rates	140	(718)
Cash and cash equivalents at end of period	$ 50,597	$ 91,017

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 compensation.

During the nine-month period ended September 30, 2020, cash used in operating activities was $48.7 million, primarily as the result of our net loss before tax of $64.4 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to $8.9 million and mainly consisted of share-based payments. Changes in the net working capital included primarily a $5.9 million increase in other payables and current liabilities as well as a $1.5 million increase in accrued expenses both due to the invoicing schedules of our main vendors and the progress made on our trials.

During the nine-month period ended September 30, 2019, cash used in operating activities was $67.4 million, primarily as the result of our net loss before tax of $88.0 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to $11.3 million and mainly consisted of share-based payments. Changes in the net working capital included primarily a

$3.6 million increase in other payables and current liabilities as well as a $5.8 million increase in accrued expenses both due to the significant progress made on our various Phase 3 trials, and the invoicing schedules of our main vendors.

Investing Activities

During the nine-month period ended September 30, 2019, net cash used in investing activities consisted primarily of investments in leasehold improvements, furniture and fixtures.

Financing Activities

During the nine-month period ended September 30, 2020, net cash from financing activities consisted primarily of the proceeds from our underwritten offering and concurrent private placement completed in 2020 totaling $18.4 million and the sales of treasury shares under our ATM program totaling $13.1 million, which were partially offset by the principal elements of lease payments as well as interest expense associated with our leases and debt instruments.

During the nine-month period ended September 30, 2019, net cash from financing activities consisted primarily of the proceeds from our debt issuance totaling $24.7 million and the sales of treasury shares under our ATM program totaling $1.3 million, which were partially offset by the principal elements of lease payments as well as interest expense associated with our leases and debt instruments.

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 $10.0 million were already paid as of September 30, 2020. 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 (IASB).

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, 2019, 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 International Financial Reporting Standards (IFRS) 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, 2020 had no material impact on our financial position.

Cautionary Statement Regarding Forward-Looking Statements

Forward-looking statements appear in a number of places in this financial review 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:

- the success, cost, timing and potential indications of our product candidates’ development activities and clinical trials, including our ongoing and future trials of linzagolix, OBE022 and nolasiban;
- our ability to obtain and maintain regulatory approval of our product candidates, including linzagolix, OBE022 and nolasiban, 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, OBE022 and nolasiban;
- 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;
- our ability to build our commercialization organization;
- the duration, severity and impact on our operations and clinical trials of the COVID-19 pandemic;
- regulatory developments in the United States and foreign countries; and
- other risks and uncertainties, including those listed in the 2019 Annual Report filed with the SIX Swiss Exchange.

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.

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