# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

### **FORM 20-F**

•	k One)
	REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934
	OR
X	ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the fiscal year ended December 31, 2020
	OR
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	For the transition period from to
	OR
	SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
	Date of event requiring this shell company report
	Commission File Number 001-37993
	OBSEVA SA
	(Exact name of registrant as specified in its charter and translation of registrant's name into English)
	Switzerland (Jurisdiction of incorporation or organization)
	Chemin des Aulx, 12 1228 Plan-les-Ouates
	Geneva, Switzerland (Address of principal executive offices)
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### Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol	Name of each exchange on which registered					
Common shares, par value CHF 1/13 per share	OBSV	The Nasdaq Stock Market LLC					

Sect	irides registered o	r to be registered pursuant to Section 12(g) of the Act. None	
Securities	for which there is	a reporting obligation pursuant to Section 15(d) of the Act. None	
Indicate the number of outstanding sha report.	res of each of the is	ssuer's classes of capital or common stock as of the close of the period cove	ered by the annual
Common shares, pa	r value CHF 1/13	per share: 57,552,578 common shares outstanding as of December 31,	2020
Indicate by check mark if the registrant	is a well-known se	easoned issuer, as defined in Rule 405 of the Securities Act. $\square$ Yes $\boxtimes$ N	ō
	report, indicate by o Yes ⊠ No	check mark if the registrant is not required to file reports pursuant to Section	n 13 or 15(d) of the
	such shorter period	d all reports required to be filed by Section 13 or 15(d) of the Securities Exol that the registrant was required to file such reports), and (2) has been subj	
		ed electronically every Interactive Data File required to be submitted pursu eding 12 months (or for such shorter period that the registrant was required	
		ccelerated filer, an accelerated filer, a non-accelerated filer, or an emerging er," and "emerging growth company" in Rule 12b-2 of the Exchange Act.	growth company. See
Large accelerated filer		Accelerated filer	$\boxtimes$
Non-accelerated filer		Emerging growth company	$\boxtimes$
		statements in accordance with U.S. GAAP, indicate by check mark if the rth any new or revised financial accounting standards provided pursuant to	
		report on and attestation to its management's assessment of the effectivenes nes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm	
† The term "new or revised financial a Standards Codification after April 5, 20	_	refers to any update issued by the Financial Accounting Standards Board	to its Accounting
Indicate by check mark which basis of	accounting the regi	istrant has used to prepare the financial statements included in this filing:	
U.S. GAAP □		ational Financial Reporting Standards as issued International Accounting Standards Board ⊠	Other $\square$
If "Other" has been checked in respons follow. □ Item 17 □ Item 18	e to the previous q	uestion, indicate by check mark which financial statement item the registra	nt has elected to
If this is an annual report, indicate by c $\square$ Yes $\boxtimes$ No	heck mark whether	the registrant is a shell company (as defined in Rule 12b-2 of the Exchang	ge Act).

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#### INTRODUCTION

Unless otherwise indicated, "ObsEva," "the Company," "our Company," "we," "us" and "our" refer to ObsEva SA and our consolidated subsidiaries.

We own various trademark registrations and applications, and unregistered trademarks and servicemarks, including "ObsEva" and the ObsEva logo. Trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 20-F are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Annual Report on Form 20-F may be referred to without the <sup>®</sup> and <sup>™</sup> symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

We present our consolidated financial statements in U.S. dollars and in accordance with International Financial Reporting Standards, or IFRS. None of the financial statements were prepared in accordance with generally accepted accounting principles in the United States.

The terms "dollar," "USD" or "\$" refer to U.S. dollars and the terms "Swiss Francs" or "CHF" refer to the legal currency of Switzerland. Unless otherwise indicated, all references to currency amounts in this Annual Report on Form 20-F are in U.S. dollars.

We have made rounding adjustments to some of the figures included in this Annual Report on Form 20-F. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this Annual Report on Form 20-F, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this Annual Report on Form 20-F, the words "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 identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost, timing and potential indications of our product candidates' development activities and clinical trials, including our ongoing and future trials of linzagolix, ebopiprant (formerly OBE022) and nolasiban;
- our ability to obtain and maintain regulatory approval of our product candidates, including linzagolix, ebopiprant 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, ebopiprant 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 this section of this Annual Report on Form 20-F titled "Item 3.D—Risk Factors."

You should refer to the section of this Annual Report on Form 20-F titled "Item 3.D—Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 20-F will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this Annual Report on Form 20-F and the documents that we reference in this Annual Report on Form 20-F and have filed as exhibits to this Annual Report on Form 20-F completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 20-F, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

This Annual Report on Form 20-F contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this Annual Report on Form 20-F is generally reliable, such information is inherently imprecise.

#### SUMMARY OF RISK FACTORS

Our business faces significant risks. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. You should carefully review and consider the full discussion of our risk factors set forth under the caption "Risk Factors" in Item 3.D. in Part I of this Annual Report on Form 20-F. Some of the more significant risks include the following:

- We have incurred significant operating losses since inception and anticipate we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability;
- We have a limited operating history and have never generated any revenue from product sales, which may make it difficult to evaluate the success of our business to date and to assess our future viability;
- If we are unable to raise capital when needed or on terms favorable to us, we could be forced to curtail our planned operations and the pursuit of our growth strategy; in addition, the incurrence of debt may impact our financial position and subject us to additional financial and operating restrictions;
- Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams;
- Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic:
- If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or experience significant delays in doing so, we may never become profitable;
- Clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes, and may be
  delayed, suspended or terminated for many reasons. Furthermore, results of earlier preclinical studies and clinical trials may not be
  predictive of future results;
- The regulatory approval process of the FDA, EMA or any comparable foreign regulatory agency may be lengthy, time-consuming and unpredictable, and the results of our clinical trials may not satisfy the requirements of the FDA or other applicable foreign regulatory authorities, and we may incur additional costs or experience delays in completing, or be unable to complete, the development and commercialization of such product candidate;
- Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates;
- We may not be successful in our efforts to in-license or acquire additional product candidates;
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- We may become exposed to costly and damaging liability claims at either the clinical or commercial stage, and our product liability insurance may not cover all damages from such claims;
- We have never commercialized a product candidate and we may not be able to successfully commercialize any of our products that receive regulatory approval on our own or with collaborators;
- Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue;
- Even if we obtain regulatory approval for linzagolix, ebopiprant, nolasiban or future product candidates, they will remain subject to ongoing regulatory oversight;
- Off-label use is common in the indications for which our product candidates are under development, which may result in enforcement actions by the FDA and other regulatory agencies for violations of the laws and regulations prohibiting the promotion of off-label uses;
- Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success;
- If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, or if we fail to achieve adequate pricing or reimbursement we will not be successful in commercializing our product candidates, if approved;
- If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, private litigation, increased compliance costs and/or adverse publicity:
- If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business; disagreements over contract interpretations could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors;

- We rely on third parties to conduct our preclinical studies and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed;
- The inability to obtain supply of the materials for our product candidates or the failure of, or loss of, our exclusive supplier for the API for linzagolix would materially and adversely affect our business;
- Any future collaborations with third parties may not be successful;
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed;
- Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set;
- Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties;
- If we fail to comply with our obligations under any existing or future intellectual property licenses with third parties or if such licenses are subject to a disagreement over contract interpretation, we could lose license rights that are important to our business or be subject to a narrowing of the scope of our rights to the relevant intellectual property or technology or an increase of our obligations to our licensors;
- If we are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively;
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on our business;
- We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful. Our inability to protect our intellectual property rights, confidential information and trade secrets could harm our business and competitive position;
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties;
- Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel;
- Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties;
- We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations;
- Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements;
- Concentration of ownership of our common shares among our existing executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions;
- As a Swiss stock corporation, the rights of our shareholders may be different from the rights of shareholders in companies governed by the
  laws of U.S. jurisdictions; as a foreign private issuer, we have the option to follow certain home country governance practices rather than the
  corporate governance requirements of Nasdaq;
- Our status as a Swiss stock corporation means that our shareholders enjoy certain rights and we are subject to certain corporate limitations that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs;
- If we are a "passive foreign investment company," or PFIC, there could be adverse U.S. federal income tax consequences to U.S. Holders;
- As a result of changes in tax laws, treaties, rulings, regulations or agreements, or their interpretation, of Switzerland or any other country in
  which we operate, the loss of a major tax dispute or a successful challenge to our operating structure, intercompany pricing policies or the
  taxable presence of our key subsidiaries in certain countries, or other factors, our effective income tax rates may increase in the future,
  which could adversely affect our net income and cash flows. In addition, future changes to tax laws could materially adversely affect our
  company and reduce net returns to our shareholders.

#### Item 1. Identity of Directors, Senior Management and Advisers.

Not applicable.

#### Item 2. Offer Statistics and Expected Timetable.

Not applicable.

#### Item 3. Key Information.

### A. Selected Financial Data

We have derived the selected consolidated statements of comprehensive loss for the years ended December 31, 2020, 2019, and 2018 presented below and the selected consolidated balance sheet data as of December 31, 2020 and 2019 presented below from our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F. The selected consolidated statement of comprehensive loss for the years ended December 31, 2017 and 2016 and the selected consolidated balance sheet data as of December 31, 2018, 2017 and 2016 have been derived from our audited consolidated financial statements not included in this Annual Report on Form 20-F. This data should be read together with, and is qualified in its entirety by reference to, "Item 5. Operating and Financial Review and Prospects" as well as our financial statements and notes thereto appearing elsewhere in this Annual Report on Form 20-F. Our historical results are not necessarily indicative of the results to be expected in the future.

We present the audited consolidated financial statements in U.S. dollars and in accordance with IFRS. On January 1, 2019, we adopted IFRS 16 *Leases*, which replaced IAS 17 *Leases and Related Interpretations*, applied until December 31, 2018. As a result of this new adoption, we recognized right-of-use assets and lease liabilities of \$2.7 million. The adoption of IFRS 16 *Leases* did not have a material impact on our net loss after tax or on our loss per share for the years ended December 31, 2020 and 2019.

	 Year ended December 31,								
	 2020		2019		2018		2017		2016
	(in thousands, except share and per share data)								
Consolidated Statements of Comprehensive Loss:									
Operating income other than revenue	\$ 17	\$	16	\$	15	\$	16	\$	22
Operating expenses:									
Research and development expenses	(67,536)		(88,053)		(62,872)		(54,912)		(23,711)
General and administrative expenses	(12,182)		(19,058)		(14,297)		(12,568)		(6,452)
Total operating expenses	 (79,718)		(107,111)		(77,169)		(67,480)		(30,163)
Operating loss	 (79,701)		(107,095)		(77,154)		(67,464)		(30,141)
Finance income	648		854		393		590		36
Finance expense	(3,879)		(2,482)		-		(1)		(97)
Net loss before tax	 (82,932)		(108,723)		(76,761)		(66,875)		(30,202)
Income tax (expense) / benefit	(34)		(67)		45		(51)		_
Net loss	\$ (82,966)	\$	(108,790)	\$	(76,716)	\$	(66,926)	\$	(30,202)
Net loss per share, basic and diluted(1)	\$ (1.67)	\$	(2.49)	\$	(1.91)	\$	(2.25)	\$	(1.40)

<sup>(1)</sup> See Note 19 to our audited consolidated financial statements and appearing elsewhere in this Annual Report on Form 20-F for a description of the method used to compute basic and diluted net loss per share attributable to common shareholders.

	As of December 31,									
(in thousands)		2020		2019		2018		2017		2016
Consolidated Balance Sheet Data:										
Cash and cash equivalents	\$	31,183	\$	69,370	\$	138,640	\$	110,841	\$	25,508
Working capital(1)		15,264		55,305		128,311		103,684		22,054
Total assets		65,447		103,943		167,440		135,235		45,525
Total liabilities		57,093		54,988		20,524		12,584		9,484
Share capital		4,574		3,499		3,420		2,864		1,740
Accumulated losses		(379,395)		(297,411)		(183,927)		(106,667)		(39,599)
Total shareholders' equity		8,354		48,955		146,916		122,651		36,041

<sup>(1)</sup> We define working capital as current assets less current liabilities. See our audited consolidated financial statements included elsewhere in this Annual Report on Form 20-F for further details regarding our current assets and current liabilities.

### **B.** Capitalization and Indebtedness

Not applicable.

#### C. Reasons for the Offer and Use of Proceeds

Not applicable.

#### D. Risk Factors

Our business faces significant risks. You should carefully consider all of the information set forth in this Annual Report and in our other filings with the United States Securities and Exchange Commission, or the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

#### Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was \$83.0 million, \$108.8 million and \$76.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had accumulated losses of \$410.0 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 have devoted substantially all of our efforts to in-licensing and developing our product candidates, linzagolix, ebopiprant and nolasiban, as well as capital raising, and building our management team. Even though we have submitted a Marketing Authorization Approval, or MAA, to the European Medicines Agency, or EMA, for YSELTY® (linzagolix 100mg and linzagolix 200mg) for the treatment of women with uterine fibroids and our application has been validated by the EMA, we cannot assure you that YSELTY® will receive regulatory approval or, if YSELTY® were to receive regulatory approval, that the commercialization of YSELTY® would be successful. We may be unable to commercialize our product candidates on a timely basis or at all. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will remain significant if and as we:

- continue the ongoing and planned clinical development of linzagolix, ebopiprant and nolasiban and make required milestone payments for linzagolix under license agreements;
- conduct nonclinical studies required for the continued development and regulatory approval of our existing clinical programs, including an
  environmental assessment for linzagolix;

- initiate preclinical studies and clinical trials for any additional indications for our current product candidates and any future product candidates that we may pursue;
- continue to build our portfolio of product candidates through the acquisition or in-license of additional product candidates or technologies;
- continue to develop, maintain, expand and protect our intellectual property portfolio;
- pursue regulatory approvals for our current and future product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- prepare for the commercialization of certain product candidates;
- hire additional clinical, regulatory, scientific, commercial and accounting personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

To become and remain profitable, we must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of linzagolix, ebopiprant and nolasiban, developing commercial scale manufacturing processes, obtaining marketing approval, manufacturing, marketing and selling any current and future product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We are only in the preliminary stages of most of these activities and, in some cases, have not yet commenced certain of these activities. We may never succeed in any or all of these activities and, even if we do, we may never generate sufficient revenue to achieve profitability.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will obtain marketing approval to commercialize any of our product candidates. If we are required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities such as the European Medicines Agency, or EMA, to perform studies and trials in addition to those currently expected, or if there are any delays in the development, or in the completion of any planned or future preclinical studies or clinical trials of our current or future product candidates, including due to the COVID-19 pandemic or other health pandemics, our expenses could increase and profitability could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We have a limited operating history and have never generated any revenue from product sales, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2012, and our operations to date have been largely focused on in-licensing and developing our product candidates, including conducting preclinical studies and clinical trials, raising capital, and building our management team and infrastructure. We have not yet demonstrated an ability to successfully obtain regulatory approvals, manufacture products on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Additionally, the markets for our product candidates are competitive, complex and have characteristics that differ by geography. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

We expect our financial condition and operating results to continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. We will need to eventually transition from a company with a research and development focus to a company capable of undertaking commercial activities. We may encounter unforeseen expenses, difficulties, complications and delays, and may not be successful in such a transition.

We will need substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed or on terms favorable to us, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect our expenses to remain significant in connection with our ongoing activities, particularly as we continue to develop our product candidates. Our expenses could increase beyond our current expectations if the FDA, EMA or other foreign regulatory agencies require us to perform clinical trials and other studies in addition to those that we currently anticipate. In addition, our product candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that may not become commercially available for a number of years, if at all. Additionally, if we obtain marketing approval for our product candidates, we expect to incur significant expenses related to manufacturing, marketing, sales and distribution. We also expect to continue to incur additional costs associated with operating as a public company.

As of December 31, 2020, our cash and cash equivalents was \$31.2 million. We raised \$88.5 million in net proceeds from our initial public offering in January 2017, \$56.3 million in net proceeds from our private placement in October 2017 and \$72.4 million in net proceeds from our underwritten public offering in June 2018. In August 2019, we borrowed \$25.0 million under our senior secured term loan credit facility. In addition, between 2018 and 2020, we sold treasury shares from our "at the market" (ATM) program, generating net proceeds of \$39.3 million. In September 2020, we raised \$ 20.0 million in net proceeds from our underwritten public offering (including exercise of pre-funded warrants) and concurrent private placement. Subsequent to December 31, 2020, we raised additional proceeds of \$55.6 million from the sale of additional treasury shares as part of our ATM program, and the exercise of the warrants included in the units sold in our underwritten public offering in September 2020. We expect our current cash and cash equivalents will be sufficient to fund our operations (without consideration of any commercialization expenses) into the second quarter of 2022. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities and changes in regulation. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing, planned and any future required clinical trials for linzagolix, ebopiprant and nolasiban;
- the timing and amount of milestone 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.

We will require additional capital to complete our planned clinical development and commercialization programs for our current product candidates to seek regulatory approval and may determine to engage in equity or debt financings or enter into credit facilities for other reasons. If we receive regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates, if approved.

In addition, we may not be able to timely secure debt or equity financing on favorable terms or at all. Any debt financing obtained by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital and to pursue business opportunities. If we raise additional funds through further issuances of equity, convertible debt securities or other securities convertible into equity, our existing shareholders could suffer significant dilution in their percentage ownership of our company, and any new equity securities we issue could have rights, preferences and privileges senior to those of holders of our common shares. Further, as a Swiss corporation we have less flexibility to raise capital, particularly in a quick and efficient manner. As a result, we may not be able to access the capital markets as frequently as comparable U.S. companies. See the Risk Factor entitled "Our status as a Swiss corporation means that our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs" for additional information related to our ability to timely raise capital. If we are unable to obtain funding on a timely basis on acceptable terms, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired.

### The incurrence of debt may impact our financial position and subject us to additional financial and operating restrictions.

In August 2019, we entered into a \$75.0 million senior secured term loan credit facility, or the 2019 Facility, with Oxford Finance LLC, or Oxford, which is subject to funding in three tranches. Upon entry into the 2019 Facility, we borrowed \$25.0 million. 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. In April 2020, we entered into an amendment to the 2019 Facility, pursuant to which 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. Our overall leverage and certain covenants and obligations contained in the related documentation could adversely affect our financial health and business and future operations by, among other things:

- making it more difficult to satisfy our obligations, including under the terms of the 2019 Facility;
- limiting our ability to refinance our debt on terms acceptable to us or at all;
- limiting our flexibility to plan for and adjust to changing business and market conditions and increasing our vulnerability to general adverse economic and industry conditions;
- · limiting our ability to use our available cash flow to fund future acquisitions and to make dividend payments; and
- limiting our ability to obtain additional financing for working capital, to fund growth or for general corporate purposes, even when necessary to maintain adequate liquidity.

Furthermore, substantially all of our assets, including our intellectual property, secure the 2019 Facility. If an event of default under the 2019 Facility occurs and is continuing, Oxford may request the acceleration of the related debt and foreclose on the underlying security interests.

#### The LIBOR calculation method may change and LIBOR is expected to be phased out after 2021.

Interest on the outstanding principal balance of the loans under the 2019 Facility is calculated based on one-month LIBOR, plus an applicable margin. On July 27, 2017, the U.K. Financial Conduct Authority, or the FCA, announced that it will no longer require banks to submit rates for the calculation of LIBOR after 2021. In the meantime, actions by the FCA, other regulators or law enforcement agencies may result in changes to the method by which LIBOR is calculated. At this time, it is not possible to predict the effect of any such changes or any other reforms to LIBOR that may be enacted in the United Kingdom or elsewhere.

### Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.

Until such time as we can generate substantial product revenue, if ever, we expect to finance our operations through a combination of equity offerings, royalty financing, debt financings, and license and development agreements in connection with any future collaborations. Other than the 2019 Facility, we do not have any committed external source of funds. In the event we seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, our shareholders may experience substantial dilution, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common shares. Royalty financing, if available, may

only provide future payments contingent upon development, regulatory or commercial milestones and royalty payments as a percentage of our future sales. Debt financing, if available, could result in increased fixed payment obligations and may involve agreements that include restrictive covenants, such as limitations on our ability to incur additional debt, make capital expenditures, acquire, sell or license intellectual property rights or declare dividends, and other operating restrictions that could hurt our ability to conduct our business.

Further, if we raise additional capital through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us.

### Fluctuations in exchange rates may adversely affect our results of operations.

Our reporting and functional currency is in U.S. dollars. A change in the concentration of our business activities could result in an increased effect of exchange rates on our financial position and results of operations. Although we do currently hedge against certain currency risks, see "Item 11—Quantitative and Qualitative Disclosures about Market Risks" for more information regarding our exposure to currency fluctuations. There is no assurance that we will, in the future, be successful in fully or even adequately hedging our currency risk.

### **Risks Related to the Development of Our Product Candidates**

We depend entirely on the success of a limited number of product candidates, which are in clinical development. If we do not obtain regulatory approval for and successfully commercialize one or more of our product candidates or we experience significant delays in doing so, we may never become profitable.

We do not have any products that have received regulatory approval and may never be able to develop marketable product candidates. We expect that a substantial portion of our efforts and expenses over the next few years will be devoted primarily to linzagolix and ebopiprant, and as a result, our business currently depends heavily on the successful development, regulatory approval and commercialization of these product candidates. We cannot be certain that our product candidates will receive regulatory approval or will be successfully commercialized even if they receive regulatory approval. The research, testing, manufacturing, safety, efficacy, labeling, approval, sale, marketing and distribution of our product candidates are, and will remain, subject to comprehensive regulation by the FDA, EMA and comparable foreign regulatory agencies. Failure to obtain regulatory approval for our product candidates in the United States, the European Union or other jurisdictions will prevent us from commercializing and marketing our product candidates. The success of our product candidates will depend on several additional factors, including:

- completing clinical trials that demonstrate their efficacy and safety;
- need for additional clinical trials necessitated by future interactions with regulatory authorities;
- receiving marketing approvals from applicable regulatory authorities;
- completing any post-marketing studies required by applicable regulatory authorities;
- establishing and maintaining commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- the prevalence and severity of adverse events experienced with our product candidates;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval;
- obtaining and maintaining coverage and adequate reimbursement from third-party payors for our product candidates;
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidates, if approved; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

Many of these factors are beyond our control, including the time needed to adequately complete clinical testing, the regulatory submission process, potential threats to our intellectual property rights and changes in the competitive landscape.

It is possible that none of our product candidates will ever obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete clinical trials, obtain regulatory approval or, if approved, commercialize our product candidates, which would harm our business, financial condition and results of operations.

### Clinical trials are very expensive, time-consuming and difficult to design and implement and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical trial process.

In addition, the results of preclinical studies and earlier clinical trials may not be predictive of the results of later-stage clinical trials. The results generated to date in preclinical studies or clinical trials for our product candidates do not ensure that later preclinical studies or clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical and earlier stage clinical trials. For example, we announced on November 7, 2019 that the IMPLANT 4 Phase 3 clinical trial of nolasiban in women undergoing embryo transfer following in-vitro fertilization, or IVF, did not meet the primary endpoint of an increase in ongoing pregnancy rate at 10 weeks. Based on these results, we discontinued our previously ongoing nolasiban IVF program. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks for our other product candidates. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. Additionally, in the case of our late-stage clinical product candidates, results may differ in general on the basis of the larger number of clinical trial sites and additional countries and languages involved in Phase 3 clinical trials. Different countries have different standards of care and different levels of access to care for patients. These differences may, in part, drive the heterogeneity of the patient populations that enroll in our studies and that may affect clinical trial results.

In addition, because we in-licensed linzagolix from Kissei Pharmaceutical Co., Ltd., or Kissei, and ebopiprant and nolasiban from Ares Trading S.A., an affiliate of Merck Serono, we were not involved in and had no control over the preclinical and clinical development of these product candidates prior to entering into these in-license agreements. In addition, we are relying on Kissei and Merck Serono to have conducted such research and development in accordance with the applicable protocol, legal, regulatory and scientific standards, having accurately reported the results of all clinical trials conducted prior to our acquisition of linzagolix, ebopiprant and nolasiban, and having correctly collected and interpreted the data from these studies and trials. To the extent any of these has not occurred, expected development time and costs may be increased which could adversely affect the marketing approval for and any future revenue from these product candidates.

### Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our product candidates.

We may experience delays in our ongoing or future preclinical studies or clinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. The completion of clinical trials for our clinical product candidates may be delayed, suspended or terminated as a result of many factors, including:

the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;

- the delay or refusal of regulators, Ethics Committees or institutional review boards, or IRBs, to authorize us to commence a clinical trial at a prospective trial site and changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects:
- having clinical sites deviate from the trial protocol or dropping out of a trial;
- negative or inconclusive results, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks:
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- the inability to enroll a sufficient number of patients in clinical trials due to social and cultural stigmas or sensitivities around reproductive therapies;
- disruptions or difficulties, or other restrictions, in initiating, enrolling, conducting or completing clinical trials due to the COVID-19 pandemic;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of the product candidate falling below acceptable standards;
- · the inability to produce or obtain sufficient quantities of the product candidate to complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

For example, 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. In January 2021, we announced our decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing COVID-19 pandemic.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board for such trial, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, which we are doing for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to the clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries. Similarly, conducting clinical trials in the United States, which we are doing for our product candidates, presents risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in the United States to adhere to the clinical protocol, managing additional administrative burdens associated with United States regulatory schemes, as well as economic risks relevant to the United States.

If we experience delays in the completion, or termination, of any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate product revenue from sales of any of these product candidates will be delayed or not realized at all.

We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue from product sales. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

### The regulatory approval process of the FDA, EMA or any comparable foreign regulatory agency may be lengthy, time-consuming and unpredictable.

Our future success is dependent upon our ability to successfully develop, obtain regulatory approval for and then successfully commercialize one or more of our product candidates. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States or abroad until we receive regulatory approval of a New Drug Application, or NDA, from the FDA or approval of a Marketing Authorization Application, or MAA, from the EMA or other applicable foreign regulatory agency.

Prior to obtaining approval to commercialize a product candidate in any jurisdiction, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, EMA or any comparable foreign regulatory agency, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. The FDA, EMA or any comparable foreign regulatory agency can delay, limit or deny approval of our product candidates or require us to conduct additional preclinical or clinical testing or abandon a program for many reasons, including:

- the FDA, EMA or the applicable foreign regulatory agency's disagreement with the design or implementation of our clinical trials;
- negative or ambiguous results from our clinical trials or results that may not meet the level of statistical significance required by the FDA,
   EMA or any comparable foreign regulatory agency for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate to the satisfaction of the FDA, EMA or the applicable foreign regulatory agency that our product candidates are safe and effective for their proposed indications;
- the FDA's, EMA's or the applicable foreign regulatory agency's disagreement with the interpretation of data from preclinical studies or clinical trials;

- our inability to demonstrate the clinical and other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's, EMA's or the applicable foreign regulatory agency's requirement for additional preclinical studies or clinical trials;
- the FDA's, EMA's or the applicable foreign regulatory agency's disagreement regarding the formulation, labeling or the specifications of our product candidates;
- the FDA's, EMA's or the applicable foreign regulatory agency's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA, EMA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval.

Any of our current or future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

While we have previously sought, and intend to seek in the future, formal advice and guidance from the FDA or other applicable foreign regulatory agencies prior to advancing our product candidates into further studies or pivotal clinical trials, the results of our clinical trials may not satisfy the requirements of the FDA or other applicable foreign regulatory authorities, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.

In December 2018, we sought guidance from the FDA on our endometriosis Phase 3 clinical development program for linzagolix at an End of Phase 2 meeting. Based upon FDA feedback, we initiated a Phase 3 clinical development program for linzagolix for the endometriosis indication which initially included the EDELWEISS 2 and EDELWEISS 3 clinical trials in May 2019.

In July 2019, we sought guidance from the FDA on our uterine fibroid Phase 3 clinical development program for linzagolix at a Type C meeting regarding key secondary endpoints for the ongoing Phase 3 PRIMROSE 1 and PRIMROSE 2 trials to support labeling claims in an NDA. Our statistical analysis plan was updated based upon FDA feedback.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and other key global markets. With regard to each of our product candidates, we may experience delays or encounter issues in the development program in the relevant jurisdictions, including imposition of a clinical hold, failed studies, inconclusive or hard-to-interpret results, safety or efficacy issues, refusal to file the application, or refusal to approve it. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdiction. Failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. Failure to obtain marketing authorization for our product candidates will result in the inability to market and sell such products. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates or may grant approvals for more limited patient populations than requested.

Even if we eventually complete clinical testing and receive approval of an NDA or foreign marketing application for our product candidates, the FDA or the applicable foreign regulatory agency may grant approval contingent on the performance of costly additional clinical trials, including Phase 4 clinical trials or the implementation of a Risk Evaluation and Mitigation Strategy, or REMS, which may be required to ensure safe use of the drug after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials, such as our initial Phase 2 clinical trial for nolasiban and our IMPLANT 4 Phase 3 clinical trial of nolasiban, often fail to demonstrate definitive efficacy or safety of the product candidate studied for the target indication.

Moreover, undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Accordingly, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in preclinical or early-stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

For example, in evaluation of linzagolix to date, patients have experienced adverse events consistent with the suppression of estradiol, including hot flashes and irregular uterine bleeding. Occurrence of serious treatment-related side effects could impede subject recruitment and clinical trial enrollment or the ability of enrolled patients to complete the trial, require us to halt the clinical trial, and prevent receipt of regulatory approval from the FDA, EMA or any comparable foreign regulatory agency. They could also adversely affect physician or patient acceptance of our product candidates or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by these product candidates, a number of potentially significant negative consequences could result, including:

- withdrawal by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a "black box" warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive additional safety studies prior to launch as a prerequisite of approval by regulatory authorities of such product;
- · commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of legal action against us claiming to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be adversely affected.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in the study until its conclusion. If patients are unwilling to participate in our clinical trials because of a lack of familiarity with our approach to the treatment of reproductive health conditions, negative publicity from adverse events in the reproductive health field or for other reasons, including competitive clinical trials for similar patient populations and general social or cultural stigmas and sensitivities towards reproductive health, our timelines for recruiting patients, conducting clinical trials and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of our clinical trials altogether.

We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors including:

- the eligibility criteria for the trial in question;
- the perceived risks and benefits of the product candidate in the trial;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating or drugs that may be used off-label for these indications;
- the size of the patient population required for analysis of the trial's primary endpoints;
- competition for patients for competitive product candidates undergoing clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the design of the trial;
- the patient referral practices of physicians;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion;
- the ability to obtain and maintain patient consents;
- the proximity and availability of clinical trial sites for prospective patients;
- any delays, disruptions or restrictions due to the COVID-19 pandemic or other health pandemics; and
- the efficiency with which our external vendor, or contract research organization (CRO), manages the logistics of patient recruitment, randomization, and follow-up within the clinical trial.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. We expect that some trial sites that participate in our clinical trials may also participate in clinical trials being conducted to develop competitive compounds, which will reduce the number of patients who are available for our clinical trials at such clinical trial site.

For example, enrollment in our Phase 3 clinical trial of linzagolix for the treatment of uterine fibroids and endometriosis may be impacted by other compounds being developed for those indications, as well as the fact that a competitive oral GnRH receptor antagonist received FDA approval for treating endometriosis associated pain in 2018 and is now commercially available. In addition, for the clinical trials for ebopiprant, we are enrolling pregnant women presenting with pre-term labor, a patient population that may be reluctant to enroll in clinical trials, given the sensitivity around pregnancy. As a result, enrollment in our planned clinical trials for ebopiprant is difficult to predict and may take longer or cost more than we anticipate.

In addition, 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. In January 2021, we announced our decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing COVID-19 pandemic.

Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that may lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

### We may not be successful in our efforts to in-license or acquire additional product candidates for other serious conditions compromising women's reproductive health and pregnancy.

A significant element of our strategy is to further build and expand our pipeline of product candidates through in-licensing or acquiring additional product candidates for other serious conditions compromising women's reproductive health and pregnancy. Currently, we do not have the internal expertise, nor do we intend to develop the internal expertise, necessary to discover new chemical entities for therapeutic purposes. As a result, if we are not able to identify and acquire additional product candidates, we will not be able to expand our pipeline. Even if we are successful in continuing to build our pipeline through in-licensing or acquisitions, the potential product candidates that we in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance.

## We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We have limited financial and managerial resources. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, a substantial portion of our efforts and expenses have been devoted to nolasiban, and we announced on November 7, 2019 that the IMPLANT 4 Phase 3 clinical trial of nolasiban in women undergoing embryo transfer following IVF did not meet the primary endpoint of an increase in ongoing pregnancy rate at 10 weeks. Based on these results, we discontinued our previously ongoing nolasiban IVF program. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

### We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. We currently have no products that have been approved for commercial sale. However, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend, and could compromise the market acceptance of our product candidates or any prospects for commercialization of our product candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Although we maintain standard product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

### **Risks Related to Commercialization of Our Product Candidates**

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.

We have never commercialized a product candidate. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, in-licensing or acquiring our product candidates and undertaking preclinical studies and clinical trials of our product candidates. We currently have no sales force, marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party. While we have a Chief Commercial Officer to lead the strategic and logistical planning of these activities, including market access, the success of such activities once undertaken may be influenced by several factors outside of our control.

Factors that may affect our ability to commercialize our product candidates on our own include securing adequate numbers of effective sales and marketing personnel, obtaining access to and educating an adequate numbers of physicians as to the benefits of our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the European Union or other key global markets. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

#### We operate in a highly competitive and rapidly changing industry.

Biopharmaceutical product development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the United States, the European Union and other jurisdictions.

With respect to linzagolix, in 2018, the first compound from the oral gonadotropin-releasing hormone, or GnRH, receptor antagonist class, elagolix, received regulatory approval in the United States for the treatment of pain associated with endometriosis. AbbVie Inc. has been commercializing elagolix, brand named Orilissa, in the United States since August 2018. In May 2020, AbbVie received regulatory approval for elagolix for the management of heavy menstrual bleeding associated with uterine fibroids. We are aware of one other oral GnRH receptor antagonist product candidate being developed in Phase 3 clinical trials for endometriosis and uterine fibroids indications, relugolix from Myovant Sciences, Inc. In 2019, Myovant reported positive 6month results for the two Phase 3 trials in the fibroid indication (LIBERTY 1 and 2) and filed a MAA and an NDA on the basis of 52-week treatment data in March 2020 and in June 2020 (with a PDUFA set to June 2021), respectively. We also anticipate competing with GnRH receptor agonists, including Lupron (leuprolide acetate), marketed by AbbVie Inc. and Takeda Pharmaceuticals, the progestin Visanne (dienogest), which is approved for the treatment of endometriosis outside the United States and marketed by Bayer, and ulipristal acetate, a Selective Progesterone Receptor Modulator, or SPRM, which is approved for the treatment of moderate-to-severe symptoms of uterine fibroids outside the United States and marketed by Gedeon Richter in Europe and other regions, and by Allergan in Canada. Ulipristal acetate, experienced severe label restrictions of usage in 2018 which were further restricted early 2021, due to post marketing liver safety issues. Allergan had submitted an NDA for ulipristal acetate but disclosed receipt of a complete response letter from the FDA in August 2018 that the NDA is not approvable in its current form and requesting additional information. Enrollment in Phase 3 clinical trials of vilaprisan, another SPRM developed by Bayer Schering for the treatment of uterine fibroids and endometriosis, was halted by Bayer Schering after longterm toxicology studies in rodents indicated a potential problem. In addition, oral contraceptives and nonsteroidal anti-inflammatory drugs, or NSAIDs, are routinely used as a firstline therapy for the treatment of symptoms associated with endometriosis and uterine fibroids and have a meaningful success rate at mitigating the symptoms associated with these conditions.

With respect to ebopiprant, Tractotile (atosiban) is approved to delay preterm birth outside of the United States, and we anticipate potential competition as a single agent, if not used in combination with ebopiprant given their different mechanisms of action. In terms of clinical development, it is our understanding that GlaxoSmithKline terminated the in-house development of retosiban, an oxytocin receptor antagonist, designed to delay preterm birth. Currently available prostaglandin synthesis inhibitors, such as NSAIDs may also represent competitive therapies, some of which may be used off-label as standard of care, despite risk of serious side effects for the neonates. Another potential competitive therapy frequently used off-label are calcium channel blockers, such as nifedipine. Makena, which is registered in the USA for preventing preterm delivery in high-risk patients, is seen as a complement rather than a competitor for ebopiprant, due to its mechanism of action in the prevention rather than treatment of preterm labor. However, in October 2020, the FDA proposed that Makena be withdrawn from the market based on its conclusion that the available evidence does not show Makena is effective for its approved use.

With respect to nolasiban, there are no other oxytocin receptor antagonists approved either for oral administration or for use in connection with IVF. However, it is our understanding that Ferring Pharmaceuticals Inc. has barusiban in its development pipeline, an oxytocin receptor antagonist, to be administered subcutaneously, that may be developed for use in connection with IVF. Nevertheless, to our knowledge, no new clinical trial activity has been publicly announced since completion of a Phase 2 trial in 2015. Ferring Pharmaceuticals' atosiban, an oxytocin receptor antagonist, to be administered by continuous infusion, has been used off-label in investigator-initiated trials in connection with IVF outside the United States.

We may also compete with other companies acquiring and developing or marketing drug therapies or products for women's reproductive health diseases. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors.

Competition may further increase as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are more effective or less costly than any product candidate that we may develop.

Established biopharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving FDA, EMA or any comparable foreign regulatory agency approval for or commercializing drugs before we do, which would have an adverse impact on our business and results of operations.

The availability of our competitors' products could limit the demand and the price we are able to charge for any product candidate we commercialize, if any. The inability to compete with existing or subsequently introduced drugs would harm our business, financial condition and results of operations.

The successful commercialization of certain of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage and adequate reimbursement levels, as well as pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and adequate reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors, are essential for most patients to be able to afford products such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaboration partners to invest in the development of our product candidates. Coverage under certain government programs, such as Medicare, Medicaid and Tricare, may not be available for

certain of our product candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for any product that we may develop, and any reimbursement that may not be adequate to make our products affordable for patients or profitable for us and may become available, may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing drugs may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

In the European Union, for example, the main legal instrument at the European Union level governing the pricing and reimbursement of medicinal products is Council Directive 89/105/EEC, or the Price Transparency Directive. The aim of the Price Transparency Directive is to ensure the transparency of measures established by European Union countries to control the pricing and reimbursement of medicinal products. It defines a series of procedural requirements designed to verify that national pricing and reimbursement decisions do not create obstacles to the pharmaceutical trade within the European Union's Internal Market. The Price Transparency Directive does not, however, provide any guidance concerning the specific criteria on the basis of which pricing and reimbursement decisions are to be made in individual EU member states, except as far as is necessary to achieve the level of transparency required by the Price Transparency Directive. The national authorities of the individual EU member states are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some individual EU member states adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other EU member states adopt a system of reference pricing, basing the price or reimbursement level in their territory either, on the pricing and reimbursement levels in other countries, or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Furthermore, some EU member states impose direct or indirect controls on the profitability of the company placing the medicinal product on the market.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

### Even if we obtain regulatory approval for linzagolix, ebopiprant, nolasiban or future product candidates, they will remain subject to ongoing regulatory oversight.

Even if we obtain any regulatory approval for linzagolix, ebopiprant, nolasiban or future product candidates, they will be subject to extensive and ongoing regulatory requirements for manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling and record-keeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practices, or cGMP, regulations and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for linzagolix, ebopiprant, nolasiban or future product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Moreover, if there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could adversely affect our business, financial condition and results of operations.

### Off-label use is common in the indications for which our product candidates are under development, which may result in enforcement actions by the FDA and other regulatory agencies for violations of the laws and regulations prohibiting the promotion of off-label uses.

Although physicians, in the practice of medicine, may prescribe approved drugs for unapproved indications, pharmaceutical companies are prohibited from marketing or promoting their drug products for uses outside the approved label, a practice known as off-label promotion. Certain of our product candidates, including ebopiprant and nolasiban, are under development for indications for which off-label use is common. For example, nifedipine and NSAIDS are prescribed off-label for the treatment of preterm labor, although they are not approved for this use. Similarly, the anticipated market for linzagolix is characterized by the use of oral contraceptives as a first-line therapy, which have been prescribed off-label for the treatment of a variety of indications. To the extent the price of our product candidates, if approved, is significantly higher than the prices of commercially available products that are frequently prescribed off-label, physicians may recommend and prescribe these commercial alternatives instead of writing prescriptions for our products. Either of these outcomes may adversely impact our results of operations by limiting how we price our product and increasing our competition.

In addition, if any of our product candidates are approved, our product labeling, advertising and promotional materials would be subject to regulatory requirements and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress and the public. If we are found to have improperly promoted off-label uses of our product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. If we are found to have promoted our products for any such off-label uses, the federal government could levy civil, criminal or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also require that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute drug products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs. These false claims statutes include, among others, the federal civil False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These false claims lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have an adverse effect on our business, financial condition, results of operations and prospects.

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if the FDA, EMA or any comparable foreign regulatory agency approves the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If linzagolix, ebopiprant, nolasiban or any future product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations. The degree of market acceptance of linzagolix, ebopiprant, nolasiban or any of our future product candidates that are approved for commercial sale will depend on a variety of factors, including:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- our ability to offer our products, if approved, for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects;
- · any restrictions on the use of our products, if approved, together with other medications; and
- other potential advantages over alternative treatment methods.

Our efforts to educate physicians, patients, third-party payors and others in the medical community on the benefits of our products, if approved, may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our product candidates. Because we expect sales of our product candidates, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidates to find market acceptance would harm our business and could require us to seek additional financing.

In addition, the potential market opportunity for linzagolix, ebopiprant, nolasiban or any other product candidate we may develop is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for linzagolix, ebopiprant, nolasiban or our future product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for linzagolix, ebopiprant, nolasiban or our future product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability.

We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, or if we fail to achieve adequate pricing or reimbursement we will not be successful in commercializing our product candidates, if approved.

We currently have no marketing, sales and distribution capabilities and our product candidates are still in clinical development. If any of our product candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, or to outsource these functions to a third party. Either of these options would be expensive and time-consuming. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

### Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our product candidates could be delayed.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation, increased compliance costs and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health

information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us, including civil and/or criminal penalties, private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our products) that are subject to privacy and security requirements under the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by HITECH. Although we are not directly subject to HIPAA—other than potentially with respect to providing certain employee benefits—we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA generally requires that healthcare providers and other covered entities obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). In addition, HIPAA does not replace federal, state, international or other laws that may grant individuals even greater p

On June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

In the European Union, the General Data Protection Regulation, or GDPR, took effect on May 25, 2018, introducing sweeping new data protection requirements that carry potential fines of up to the greater of 20 million Euros or 4% of annual global revenue. The GDPR introduces strict requirements for processing personal data, including potentially burdensome documentation requirements, more stringent requirements for obtaining valid consent (where applicable), obligations to honor expanded rights of individuals to control the use and retention of their personal data, and requirements to notify regulators and affected individuals of certain personal data breaches. The GDPR also imposes heightened restrictions on processing of special categories of personal data, such as health and genetic personal data. In addition, the GDPR prohibits the transfer of personal data to countries outside of the EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, they are subject to pending legal challenges that, if successful, could invalidate these mechanisms, restrict our ability to process personal data of European residents outside of Europe and adversely impact our business. The GDPR has increased our responsibility and potential liability in relation to personal data that we process, exposes us to substantial potential fines in the event of violations, increases our compliance costs and could restrict our operations in Europe.

### **Risks Related to Our Dependence on Third Parties**

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

We are party to several license agreements under which we in-license patent rights and other intellectual property related to our business, including a license and supply agreement with Kissei, under which we were granted an exclusive license relating to linzagolix and license agreements with Merck Serono, pursuant to which we were granted exclusive worldwide licenses relating to ebopiprant and nolasiban. We may enter into additional license agreements in the future. Our license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. Any uncured, material breach under these license agreements could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under these agreements, and could compromise our development and commercialization efforts for linzagolix, ebopiprant and nolasiban, or any future product candidates. See "Item 4.B—Business Overview" for a more detailed description of our current license agreements.

### We may be required to make significant payments in connection with our license and supply agreement with Kissei.

We acquired exclusive rights to linzagolix pursuant to our license and supply agreement with Kissei in November 2015. Under the terms of the Kissei license and supply agreement, we are obligated to share certain development costs with Kissei in addition to our own direct development costs. Additionally, we may make significant payments in connection with certain milestones and the sale of resulting products. If these obligations become due under the terms of the Kissei license and supply agreement within the next eighteen months, our development efforts may be delayed and/or we may have to seek additional funding earlier than currently planned.

### Our intellectual property in-licensed from third parties may be subject to disagreements over contract interpretations, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

The agreements under which we currently in-license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could harm our business, financial condition, results of operations and prospects. If any of our current or future licenses or material relationships or any in-licenses upon which our current or future licenses are based are terminated or breached, we may:

- lose our rights to develop and market linzagolix, ebopiprant, nolasiban or any future product candidates;
- lose patent protection for linzagolix, ebopiprant, nolasiban or any future product candidates;
- experience significant delays in the development or commercialization of linzagolix, ebopiprant, nolasiban or any future product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- · incur liability for damages.

If we experience any of the foregoing, it could harm our business, financial condition and results of operations.

### We rely on third parties to conduct our preclinical studies and clinical trials and if these third parties perform in an unsatisfactory manner, our business could be substantially harmed.

We currently do not have the ability to independently conduct preclinical studies that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements. We also do not currently have the ability to independently conduct any clinical trials. We have relied upon and plan to continue to rely upon medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product candidates properly and on time, and may not currently have all of the necessary contractual relationships in place to do so. Once we have established contractual relationships with such third-party CROs, we will have only limited control over their actual performance of these activities.

We and our CROs and other vendors are required to comply with cGMP, GCP and GLP, which are regulations and guidelines enforced by the FDA, the EMA and any comparable foreign regulatory authorities for all of our product candidates in preclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators, clinical trial sites and other contractors. Although we rely on CROs to conduct any current or planned GLP-compliant preclinical studies and GCP-compliant clinical trials and have limited influence over their actual performance, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, EMA or any comparable foreign regulatory agency may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory agency, such regulatory agency will determine that all of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced under cGMP requirements. Our failure to comply with these requirements may require us to repeat clinical trials, which would delay the regulatory approval process.

While we will have agreements governing their activities, our CROs will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our future preclinical and clinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

If our relationship with these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business and financial condition.

We rely on our third-party manufacturers to source the supply of the materials for our product candidates and, in the case of linzagolix, Kissei is the exclusive supplier of API. The inability to obtain supply of the materials for our product candidates or the failure of, or loss of, our exclusive supplier to supply us with the API for linzagolix would materially and adversely affect our business.

We currently rely on and expect to continue to rely on third parties for the manufacturing and supply of chemical compounds for the clinical trials of our product candidates and, if approved, our commercial supply. Further, Kissei has the exclusive right to supply us with the active pharmaceutical ingredient, or API, for linzagolix for our clinical trials and commercial supplies, if approved, subject to limited specified exceptions within the control of Kissei. Reliance on third-party suppliers may expose us to different risks than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory agency. Although we have auditing rights with all our manufacturing counterparties, we do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters.

To meet our projected needs for clinical supplies and support our activities through regulatory approval and commercial manufacturing, the CDMOs with whom we currently work will need to increase scale of production, or we will need to secure alternate suppliers. With respect to linzagolix, we have entered into an exclusive agreement for the supply of the linzagolix API with Kissei. A CDMO that Kissei is using to supply the linzagolix API received a warning letter from the FDA in November 2016 citing deviations from cGMP requirements with respect to its drug manufacturing facility. Kissei now obtains linzagolix cGMP supply from two additional suppliers, both of which are different from the supplier who received the warning letter from the FDA in November 2016. For ebopiprant and nolasiban, we obtain supply on a purchase order basis from a different single source. However, we believe that there are multiple potential sources for our contract manufacturing for ebopiprant and nolasiban. Additionally, any damage to or destruction of our or our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our clinical trials, and we expect to continue to depend on third-party suppliers for the foreseeable future. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained

for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

We rely on our manufacturers and other subcontractors to comply with and respect the proprietary rights of others in conducting their contractual obligations for us. If our manufacturers or other subcontractors fail to acquire the proper licenses or otherwise infringe third-party proprietary rights in the course of completing their contractual obligations to us, we may have to find alternative manufacturers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory agency does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

In addition, the fact that we are dependent on third parties for the manufacture, storage and distribution of our product candidates means that we are subject to the risk that our product candidates and, if approved, commercial products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could result in recalls or regulatory enforcement action that could adversely affect our business, financial condition and results of operations.

### We may in the future enter into collaborations with third parties to develop our product candidates. If these collaborations are not successful, our business could be harmed.

We may potentially enter into collaborations with third parties in the future. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, including:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of these collaborations may not be successful;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our shareholders about the status of such product candidates;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of
  development of any product candidates, may cause delays or termination of the research, development or commercialization of such product
  candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any
  of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- · collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If any such potential future collaborations do not result in the successful development and commercialization of product candidates, or if one of our future collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, the development of our product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization apply to the activities of our potential future collaborators.

### If we are not able to establish or maintain collaborations, we may have to alter some of our future development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional capital to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidates, particularly in Asia. For example, in January 2020, we entered into a sublicense agreement with Hangzhou Yuyuan BioScience Technology Co., Ltd., or Yuyuan, to develop and commercialize nolasiban for improving clinical pregnancy and live birth rates in women undergoing embryo transfer following IVF in the People's Republic of China, or PRC. Under the terms of the sublicense agreement, Yuyuan has the exclusive rights to develop and commercialize nolasiban in the PRC. We are also exploring various alternatives for the future potential commercialization of linzagolix, including through a collaboration with a third party. Furthermore, we may find that our programs require the use of proprietary rights held by third parties, and the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things,

upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or similar foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

### Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to develop and manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, such as trade secrets. Despite these contractual agreements with third parties, sharing trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may harm our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

### **Risks Related to Regulatory Compliance**

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.

In the United States, the European Union, and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which substantially changes the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off
  negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's
  outpatient drugs to be covered under Medicare Part D;
- new requirements to report certain financial arrangements, including reporting "transfers of value" made or distributed to physicians, as
  defined by such law, and teaching hospitals and reporting investment interests held by such healthcare providers and their immediate family
  members:
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test
  innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug
  spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unclear when a decision will be made. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that

limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is also unclear how the Supreme Court rule, other litigation and the healthcare reform measures of the Biden Administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including amendments by the BBA, will remain in effect through 2030, except for a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have an adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it remains unclear how the introduction of the quality payment program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, including several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to drug pricing that seeks to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021, On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial

condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize any of our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries. In international markets, reimbursement and healthcare payment systems vary significantl

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad, particularly in light of the Biden administration. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Our business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although we do not currently have any products on the market, our operations may be directly, or indirectly through health care professionals, consultants, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute, the U.S. federal civil and criminal false claims laws and Physician Payments Sunshine Act and regulations. Healthcare providers, including physicians, and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our current business operations, including our clinical research activities, and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, including physicians, and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

• the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims laws, including the federal civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the criminal health care fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their
  implementing regulations, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the
  privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities
  subject to HIPAA, i.e. health plans, healthcare clearinghouses and certain healthcare providers, and their business associates that perform
  certain services for or on their behalf involving the use or disclosure of individually identifiable health information as well as their covered
  subcontractors:
- the U.S. federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, and certified nurse-midwives;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of sales representatives in the jurisdiction; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, disgorgement, individual

imprisonment, contractual damages, reputational harm, diminished profits, and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the physicians or other providers or entities with whom we expect to do business is found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations.

#### **Risks Related to Our Intellectual Property**

If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties or if such licenses are subject to a disagreement over contract interpretation, we could lose license rights that are important to our business or be subject to a narrowing of the scope of our rights to the relevant intellectual property or technology or an increase of our financial or other obligations to our licensors.

We are party to several license agreements under which we in-license patent rights and other intellectual property related to our business, and we may enter into additional license agreements in the future. See "Risk Factors—Risks Related to Our Dependence on Third Parties" for a more detailed description of risks related to current and future license agreements.

If we are unable to obtain and maintain patent protection for our technology and product candidates, or if the scope of the patent protection obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our development programs and product candidates. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current and future product candidates. We have sought to protect our proprietary position by filing and in-licensing patent applications in the United States and abroad related to our development programs and product candidates. The patent prosecution process is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we have licensed from third parties. We prosecute and maintain certain patent rights for our product candidates and rely on our licensors, Kissei and Merck Serono, to prosecute and maintain other relevant patent rights for linzagolix, ebopiprant and nolasiban. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our current and future product candidates in the United States or in other foreign countries. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, a patent issues from such applications, and then only to the extent the issued claims cover the technology.

If the patent applications we hold or have in-licensed with respect to our development programs and product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our current and future product candidates, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, products. Any such outcome could have a negative effect on our business.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, EU patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, and such prior art could potentially invalidate a one or more of our patents or prevent a patent from issuing from one or more of our pending patent applications. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent

applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. Even if patents do successfully issue and even if such patents cover our current and future product candidates, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated or held unenforceable, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Any successful opposition to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

# We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent which might adversely affect our ability to develop and market our product candidates.

We cannot guarantee that any of our or our licensors' patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our product candidates. We may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents

If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

We are aware of issued patents and pending patent applications, in the United States and abroad, relating to methods of improving embryo implantation outcomes in patients undergoing an embryo transfer procedure. If any such patent, or a patent that issues from any such application, were to be asserted against us, we believe that we have defenses against any such action, including that these patents would not be infringed by our product candidates and/or that these patents are not valid. However, if these patents were asserted against us and our defenses to such an action were unsuccessful, unless we obtain a license to these patents, which may not be available on commercially reasonable terms, or at all, we could be liable

for damages and precluded from commercializing any product candidates that were ultimately held to infringe these patents, which could have a material adverse effect on our business, financial condition, cash flows or results of operations.

### Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering linzagolix, ebopiprant and nolasiban are obtained, once the patent life has expired for a product candidate, we may be open to competition from competitive medications, including biosimilar or generic medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

### Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court of before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business. The following examples are illustrative:

- others may be able to make compounds, or linzagolix, ebopiprant and nolasiban formulations that are similar to our linzagolix, ebopiprant and nolasiban formulations but that are not covered by the claims of the patents that we own or control;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;

- third parties performing manufacturing or testing for us using our product candidates or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

### Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or the AIA, was signed into law on September 16, 2011, and many of the substantive changes became effective on March 16, 2013.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U.S. Patent and Trademark Office, or USPTO, after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The USPTO has developed, in the last few years, regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA, and, in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaboration partners' patent applications and the enforcement or defense of our or our licensors' or collaboration partners' issued patents, all of which could have an adverse effect on our business and financial condition.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, such as *Association for Molecular Pathology v. Myriad Genetics*, *Inc.* (Myriad I), *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. For example, the April 2010 amendment of the European Patent Convention, which limited the time permitted for filing divisional applications, was subsequently abrogated. This amendment and subsequent abrogation illustrates the uncertainty involved in the prosecution of European patent laws. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution. These changes could limit our ability to obtain new patents in the future that may be important for our business.

# Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability, and the ability of our future collaborators, to develop, manufacture, market and sell linzagolix, ebopiprant and nolasiban and any future product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and re-examination proceedings before the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the intellectual property rights of third parties.

We may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to linzagolix, ebopiprant and nolasiban and any future product candidates and technology, including interference or derivation proceedings, post grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Similarly, we or our licensors or collaborators may initiate such proceedings or litigation against third parties, including to challenge the validity or scope of intellectual property rights controlled by third parties. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our compositions, formulations, or methods of treatment, prevention or use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such an event, we would be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could harm our business significantly.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

# We may become involved in lawsuits to protect or enforce our patents, the patents of our licensors or our other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe or otherwise violate our or our licensors' patents or misappropriate or otherwise violate our or our licensor's other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. Our agreements with Merck Serono give Merck Serono the first right to control such claims. Therefore, these patents and applications may not be enforced in a manner consistent with the best interests of our business. Our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result

in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that our patents are invalid or unenforceable or claims challenging the scope of the intellectual property rights we own or control. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte re-examinations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we, our licensors and the patent examiner were unaware during prosecution. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. Our agreements with Kissei and Merck Serono give our licensors the first right to defend such validity challenges. Therefore, these patents and applications may not be defended in a manner consistent with the best interests of our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on our current or future product candidates. Such a loss of patent protection could harm our business. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may not be able to prevent, alone or with our licensors, infringement or misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Our business could be harmed if in litigation the prevailing party does not offer us a license on commercially reasonable terms. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares.

#### We may not be able to protect our intellectual property rights throughout the world, which could negatively impact our business.

Filing, prosecuting and defending patents covering linzagolix, ebopiprant, nolasiban and any future product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Further, licensing partners may not prosecute patents in certain jurisdictions in which we may obtain commercial rights, thereby precluding the possibility of later obtaining patent protection in these countries. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may also export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies

awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

Additionally, the requirements for patentability may differ in certain countries, particularly developing countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In India, unlike the United States, there is no link between regulatory approval of a drug and its patent status. Furthermore, generic or biosimilar drug manufacturers or other competitors may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us or our licensors to engage in complex, lengthy and costly litigation or other proceedings. Generic or biosimilar drug manufacturers may develop, seek approval for, and launch biosimilar versions of our products. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our and our licensors' efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

# We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We may employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, and we are not currently subject to any claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties, we may in the future be subject to such claims. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

#### We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. For example, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, or we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

#### Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our

confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace.

### Our inability to protect our confidential information and trade secrets would harm our business and competitive position.

In addition to seeking patents for some of our technology and products, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business, results of operations and financial condition. Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us.

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common shares.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our products, our competitors might be able to enter the market, which would harm our business.

### Risks Related to Our Business Operations, Employee Matters and Managing Growth

#### Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

We are highly dependent on the management, development, clinical, financial and business development experience of Brian O'Callaghan, our Chief Executive Officer, David Renas, our Chief Financial Officer, Jean-Pierre Gotteland, our Chief Scientific Officer and Head of R&D, Wim Souverijns, our Chief Commercial Officer, Fabien de Ladonchamps, our Chief Administrative Officer and Elizabeth Garner, our Chief Medical Officer. Each of these officers may currently terminate their employment with us on short notice. We do not maintain "key person" insurance for any of our executives or employees.

Laws and regulations on executive compensation, including legislation in our home country, Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel. In Switzerland, legislation affecting public companies has been passed that, among other things, (1) imposes an annual binding shareholders' "say on pay" vote with respect to the compensation of executive management, including executive officers and the board of directors, (2) generally prohibits severance, advances, transaction premiums and similar payments to members of our executive management and board of directors, (3) imposes other restrictive compensation practices and (4) requires companies to specify various compensation-related matters in their articles of association, thus requiring them to be approved by a shareholders' vote. In addition, the competition for qualified personnel in the biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. Because the Swiss legislation affecting public companies will apply to operations in the United States and are more onerous and restrictive than comparable laws and regulations applying to U.S. domiciled companies, recruiting and retaining employees in the United States will be even more difficult as compared to companies in the United States. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could harm our business.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in markets outside of the United States and the European Union. If we commercialize our product candidates in foreign markets, we will be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;

- tariffs and trade barriers:
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or foreign governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- · uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 pandemic, which has significantly impacted the global economy, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of clinical trial sites or other business operations, or materially affect our operations globally, including at our headquarters in Geneva, Switzerland, which might be subject to government restrictions in response to the COVID-19 pandemic, and at our clinical trial sites, as well as the business or operations of our manufacturers, clinical research organizations or other third parties with whom we conduct business.

Our business could be materially adversely affected by the effects of health pandemics or epidemics, including the ongoing COVID-19 global pandemic, which has resulted in travel and other restrictions to reduce the spread of the disease, including government restrictions in Europe, the United States and other countries, which, among other things, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings, and ordered cessation of non-essential travel. Some of these government restrictions have been lifted, including in Switzerland and in Massachusetts, where our U.S. subsidiary is located, however many countries and regions in which we operate or where are employees are located are experiencing continued outbreaks, and new restrictions are being implemented. The extent of and timing of government restrictions remains uncertain as the COVID-19 pandemic continues to evolve. Although we implemented work-from-home policies for most of our employees in March 2020, in light of phased reopenings, we reopened 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. Given the continued outbreaks and reimposition of restrictions in many jurisdictions, there is no guarantee that we will not need to further adapt our operations to the continued spread of COVID-19. The effects of the government restrictions and our evolving work-from-home policies may negatively impact productivity, disrupt our business and continue to delay certain of our clinical programs and timelines, the magnitude of which will depend, in part, on the continued length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our bus

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, be further extended or be reinstated, related to COVID-19 or other infectious diseases, could impact personnel at third-party manufacturing facilities in Europe, the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Further, Kissei has the exclusive right to supply us with the active pharmaceutical ingredient for linzagolix for our clinical trials and commercial supplies, if approved, subject to limited specified exceptions within the control of Kissei. While many of these materials may be obtained by more than one supplier, restrictions resulting from the COVID-19 pandemic in the regions our third-party suppliers and

Kissei operate may disrupt our supply chain or limit our ability to obtain sufficient materials for our product candidates, which might impact and delay certain of our clinical programs and timelines.

In addition, our clinical trials have been affected by the ongoing COVID-19 pandemic. Site initiation and patient enrollment has been and may be further delayed due to continued prioritization of hospital resources toward the COVID-19 pandemic, and some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, has been delayed or disrupted, which has adversely impacted our clinical trial operations. For example, 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. During the second quarter of 2020, new patient enrollment was resumed for EDELWEISS 2 and EDELWEISS 3 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.

In January 2021, we announced our decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing pandemic.

The spread of COVID-19, which has resulted in significant impacts globally, may materially affect us economically. While the full extent of the economic impact brought by, and the duration and scope of, the COVID-19 pandemic, may be difficult to assess or predict, it has caused, and may continue to cause, significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction in various economies resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the ongoing COVID-19 pandemic or a similar health pandemic or epidemic is highly uncertain and subject to change. While the COVID-19 pandemic has had significant impacts on global economies and has resulted in challenging operating environments, we do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. These effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2020, we had 45 employees. As our clinical development progresses, we may experience growth in the number of our employees and the scope of our operations, particularly in the areas of clinical operations, regulatory affairs and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or unauthorized activities that violates (1) the laws and regulations of the FDA, the EMA and other similar regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (4) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-

dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product candidates, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including damages, fines, disgorgement, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional integrity oversight and reporting obligations, contractual damages, reputational harm and the curtailment or restructuring of our operations.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the European Union may be a source of instability and uncertainty and pose additional risks to our business operations and financial condition.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the E.U., the U.K. was subject to a transition period until December 31, 2020, during which E.U. rules continued to apply. A trade and cooperation agreement that outlines the future trading relationship between the United Kingdom and the European Union was agreed in December 2020. Given the level of uncertainty caused by Brexit, and the perception as to its potential impact, business activity and economic conditions in the United Kingdom, Europe and globally may be adversely affected, and Brexit could continue to contribute to instability in global financial and foreign exchange markets, asset valuations and credit ratings. The United Kingdom's withdrawal from the EU, the Single Market and the Customs Union will create barriers to trade and cross-border exchanges that did not exist prior to 1 January 2021. As a consequence, Brexit will also have the effect of ending the free movement of goods, services and people between the United Kingdom and the EU. As a result of these and other factors, Brexit may negatively affect our operations or access to capital, or may have a limited detrimental effect on the timing of our research and development activities, which may, in turn, adversely affect our development and commercialization of certain product candidates.

#### **Risks Related to Our Common Shares**

#### The price of our common shares may be volatile and may fluctuate due to factors beyond our control.

The share price of our common shares has fluctuated, and is likely to continue to fluctuate substantially. The market price of our securities depends on a number of factors, including those described in this "Risk Factors" section, many of which are beyond our control and may not be related to our operating performance.

The market price of our securities may fluctuate significantly in response to numerous factors, many of which are beyond our control, including

- positive or negative results of preclinical studies and clinical trials reported by us, strategic partners or competitors;
- any delay in the commencement, enrollment and the ultimate completion of clinical trials;
- technological innovations or commercial product introductions by us or competitors;
- failure to successfully develop and commercialize any of our product candidates;
- developments, announcements or changes in government regulations relating to drug products, including related to drug pricing, reimbursement and healthcare coverage;
- delays in in-licensing or acquiring additional complementary product candidates;
- developments concerning proprietary rights, including patents and litigation matters;

- public concern relating to the commercial value or safety of any of our product candidates or reproductive therapy generally;
- financing or other corporate transactions, or inability to obtain additional funding;
- failure to meet or exceed expectations of the investment community;
- announcements by therapeutic drug product providers related to pricing of therapeutics;
- announcements of significant licenses, acquisitions, strategic partnerships or joint ventures by us or our competitors;
- publication of research reports or comments by securities or industry analysts;
- changes in the structure of healthcare payment systems;
- general market or regulatory conditions in the pharmaceutical industry or in the economy as a whole; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their common shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our common shares.

# Concentration of ownership of our common shares among our existing executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions.

Based upon our common shares outstanding as of December 31, 2020, our executive officers, directors and shareholders who owned more than 5% of our outstanding common shares beneficially own, in the aggregate, approximately 30% of our outstanding common shares. These shareholders, acting together, will be able to significantly influence all matters requiring shareholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

Some of these persons or entities may have interests different than our other shareholders. For example, because many of these shareholders purchased their shares at prices substantially below the price at which shares were sold in our initial public offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders.

### Future sales, or the possibility of future sales, of a substantial number of our common shares could adversely affect the price of our common shares.

As of December 31, 2020, 57,552,578 common shares were issued and outstanding. If a substantial number of these shares were sold in the public market, or the market perceives that such sales may occur, the market price of our common shares could be adversely affected. We have entered into a registration rights agreement pursuant to which we have agreed under certain circumstances to file a registration statement to register the resale of the common shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such common shares.

In addition, we have adopted an omnibus equity incentive plan, under which we have the discretion to grant a broad range of equity-based awards to eligible participants. We have filed a registration statement with the SEC to register the common shares that may be issued under our equity incentive plan. The common shares subject to outstanding options under our

equity incentive plan, common shares reserved for future issuance under our equity incentive plan and common shares subject to outstanding warrants will become eligible for sale in the public market in the future, subject to certain legal and contractual limitations. Sales of a large number of the shares issued under these plans in the public market could have an adverse effect on the market price of our securities.

### We do not expect to pay dividends in the foreseeable future.

We have not paid any dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. The proposal to pay future dividends to shareholders will in addition effectively be at the discretion of our board of directors and shareholders after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitations pursuant to Swiss law or by our articles of association. See "Item 10.B—Memorandum and Articles of Association." Accordingly, investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares.

# We are a Swiss stock corporation. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are a Swiss stock corporation. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in Switzerland. The rights of our shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and directors of companies governed by the U.S. laws. In the performance of its duties, our board of directors is required by Swiss law to consider the interests of our company, our shareholders, our employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder. Swiss corporate law limits the ability of our shareholders to challenge resolutions made or other actions taken by our board of directors in court. Our shareholders generally are not permitted to file a suit to reverse a decision or an action taken by our board of directors but are instead only permitted to seek damages for breaches of fiduciary duty. As a matter of Swiss law, shareholder claims against a member of our board of directors for breach of fiduciary duty would have to be brought in Geneva, Switzerland, or where the relevant member of our board of directors is domiciled. In addition, under Swiss law, any claims by our shareholders against us must be brought exclusively in Geneva, Switzerland. Class actions and derivative actions as such are not available under Swiss law. In addition, Swiss corporation law restricts our ability to implement rights plans or U.S.-style "poison pills." Also, there can be no assurance that Swiss law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

## Our common shares are traded on more than one market and this may result in price variations and adversely affect the liquidity and value of our common shares.

Our common shares are listed on the Nasdaq Global Select Market and the SIX Swiss Exchange. Trading in our common shares on these markets takes place in different currencies (U.S. dollars on the Nasdaq Global Select Market and Swiss Francs on the SIX Swiss Exchange), and at different times (resulting from different time zones, different trading days and different public holidays in the United States and Switzerland). The trading prices of our common shares on these two markets may differ due to these and other factors. Any decrease in the price of our common shares on the SIX Swiss Exchange could cause a decrease in the trading price of our common shares on the Nasdaq Global Select Market. Investors could seek to sell or buy our common shares to take advantage of any price differences between the markets through a practice referred to as arbitrage. Any arbitrage activity could create unexpected volatility in both our share prices on one exchange and the common shares available for trading on the other exchange.

### U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against us or our executive officers or members of our board of directors.

We are a Swiss stock corporation, and our jurisdiction of incorporation is Geneva, Switzerland. Moreover, a number of our directors and executive officers are not residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States.

We have been advised by our Swiss counsel that there is doubt as to the enforceability in Switzerland of original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent predicated upon the federal and state securities laws of the United States. Original actions against persons in Switzerland based solely upon the U.S. federal or state securities laws are governed, among other things, by the principles set forth in the Swiss Federal Act on International Private Law. This statute provides that the application of provisions of non-Swiss law by the courts in Switzerland shall be precluded if the result is incompatible with Swiss public policy. Also, mandatory provisions of Swiss law may be applicable regardless of any other law that would otherwise apply.

Switzerland and the United States do not have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters. The recognition and enforcement of a judgment of the courts of the United States in Switzerland is governed by the principles set forth in the Swiss Federal Act on Private International Law. This statute provides in principle that a judgment rendered by a non-Swiss court may be enforced in Switzerland only if:

- the non-Swiss court had jurisdiction pursuant to the Swiss Federal Act on Private International Law;
- the judgment of such non-Swiss court has become final and non-appealable;
- the judgment does not contravene Swiss public policy;
- the court procedures and the service of documents leading to the judgment were in accordance with the due process of law; and
- no proceeding involving the same position and the same subject matter was first brought in Switzerland, or adjudicated in Switzerland, or was earlier adjudicated in a third state and this decision is recognizable in Switzerland.

Our status as a Swiss stock corporation means that our shareholders enjoy certain rights and we are subject to certain corporate limitations that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs.

Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, the payment of dividends and cancellation of treasury shares must be approved by shareholders. Swiss law also requires that our shareholders themselves resolve to, or authorize our board of directors to, increase our share capital. While our shareholders may authorize share capital that can be issued by our board of directors without additional shareholder approval, Swiss law limits this authorization to 50% of the issued share capital at the time of the authorization. The authorization, furthermore, has a limited duration of up to two years and must be renewed by the shareholders from time to time thereafter in order to be available for raising capital. Additionally, subject to specified exceptions, including exceptions explicitly described in our articles of association, Swiss law grants pre-emptive rights to existing shareholders to subscribe for new issuances of shares. Swiss law also does not provide as much flexibility in the various rights and regulations that can attach to different classes of shares as do the laws of some other jurisdictions. Further, the constraints relating to our capital increase process deriving from Swiss corporate law may limit our flexibility to raise capital. These Swiss law requirements relating to our capital management may limit our flexibility, including with respect to our ability to raise funds under our "at the market", or ATM, program, and situations may arise where greater flexibility would have provided benefits to our shareholders. See "Item 10.B—Memorandum and Articles of Association."

We are a foreign private issuer and, as a result, are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Swiss laws and regulations with regard to such matters and intend to furnish quarterly financial information to the SEC, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including: (1) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (2) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (3) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each financial year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair

Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

# As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we will have the option to follow certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are a foreign private issuer. As a result, in accordance with Nasdaq Listing Rule 5615(a)(3), we may choose to comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of Nasdaq.

Swiss law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors regularly have scheduled meetings at which only independent directors are present.

Although Swiss law also requires that we set up a compensation committee, we may follow home country requirements with respect to such committee.

Our articles of association provide for an independent proxy elected by our shareholders, who may represent our shareholders at a general meeting of shareholders, and we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders. However, Swiss law does not have a regulatory regime for the solicitation of proxies and company solicitation of proxies is prohibited for public companies in Switzerland, thus our practice may vary from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies. Furthermore, in accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. Our practice thus varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

For an overview of our corporate governance principles, see "Item 10.B—Memorandum and Articles of Association." As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

# We may lose our foreign private issuer status, which would then require us to comply with the domestic reporting requirements of the Exchange Act and cause us to incur significant legal, accounting and other expenses.

We are currently a foreign private issuer and therefore, are not be required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (1) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (2)(a) a majority of our executive officers or directors may not be United States citizens or residents, (b) more than 50% of our assets cannot be located in the United States and (c) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time-consuming and costly. If we lose our foreign private issuer status and are unable to devote adequate funding and the resources needed to maintain compliance with U.S. securities laws, while continuing our operations, we could be forced to deregister with the SEC. A deregistration would substantially reduce or effectively terminate the trading of our securities in the United States. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director a

### If we are a "passive foreign investment company," or PFIC, there could be adverse U.S. federal income tax consequences to U.S. Holders.

Based on our analysis of our income, assets, activities and market capitalization for our taxable year ending December 31, 2020, we do not believe that we were a PFIC for our taxable year ending December 31, 2020. However, our operations generate very limited amounts of non-passive income. Until we generate sufficient revenue from active licensing and other non-passive sources, there is a risk that we will be a PFIC under the PFIC income test. Moreover, we hold a substantial amount of cash and cash equivalents. Because the calculation of the value of our assets may be based in part on the value of our common shares, the value of which may fluctuate considerably, our PFIC status may change from year to year and it is difficult to predict whether we will be a PFIC under the PFIC asset test for the current year or any future year. Therefore, we have not yet made any determination as to our expected PFIC status for the current year. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the Internal Revenue Service, or IRS, will agree with our conclusion. Because PFIC status is a fact specific determination, and generally cannot be made until the close of the taxable year in question, no assurance can be given that we will not be a PFIC for our current taxable year and that we will not be a PFIC in future taxable years. Furthermore, because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification of certain income and assets as non-passive or our valuation of our tangible and intangible assets, each of which may result in us being treated as a PFIC for our taxable year ending December 31, 2020 or us becoming a PFIC for the current taxable year or any future taxable years. Our United States counsel expresses no opinion with respect to our PFIC status for prior years, the current taxable year or any future years.

Under the Internal Revenue Code of 1986, as amended, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. Passive income generally includes dividends, interest, certain rents and royalties, and capital gains.

If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Item 10.E—Taxation") holds our shares, the U.S. Holder may be subject to adverse tax consequences, including (1) the treatment of all or a portion of any gain on the disposition of our common shares as ordinary income, (2) the addition of an interest charge to the tax on such gain and (3) the obligation to comply with certain reporting requirements.

Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues. For further discussion of the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see "Item 10.E—Taxation."

# If a United States person is treated as owning at least 10% of our common shares, such holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our common shares, such U.S. Holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes at least one U.S. subsidiary (ObsEva USA Inc.), our Irish subsidiary (ObsEva Ireland Limited) and any other non-U.S. subsidiaries we form or acquire in the future, may be treated as controlled foreign corporations (regardless of whether ObsEva SA is treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject you to significant monetary penalties and may prevent the statute of limitations from starting with respect to your U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholders information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares.

As a result of changes in tax laws, treaties, rulings, regulations or agreements, or their interpretation, of Switzerland or any other country in which we operate, the loss of a major tax dispute or a successful challenge to our operating structure, intercompany pricing policies or the taxable presence of our key subsidiaries in certain countries, or other factors, our effective income tax rates may increase in the future, which could adversely affect our net income and cash flows.

We operate in multiple jurisdictions and our profits are taxed pursuant to the tax laws of these jurisdictions. Our effective income tax rate may be affected by changes in or interpretations of tax laws, treaties, rulings, regulations or agreements in any given jurisdiction, utilization of net operating loss and tax credit carryforwards, changes in geographical allocation of income and expense, and changes in management's assessment of matters such as the realizability of deferred tax assets. In the past, we have experienced fluctuations in our effective income tax rate. Our effective income tax rate in a given fiscal year reflects a variety of factors that may not be present in the succeeding fiscal year or years. There is no assurance that our effective income tax rate will not change in future periods.

We file Swiss and non-Swiss tax returns. We are frequently subject to tax audits, examinations and assessments in various jurisdictions. If any tax authority successfully challenges our operational structure, intercompany pricing policies or the taxable presence of our key subsidiaries in certain countries, if the terms of certain income tax treaties are interpreted in a manner that is adverse to our structure, or if we lose a material tax dispute in any country, our effective income tax rate could increase. A material assessment by a governing tax authority could adversely affect our profitability. If our effective income tax rate increases in future periods, our net income and cash flows could be adversely affected.

### Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, legislation enacted in 2017 informally titled the Tax Cuts and Jobs Act or (the "Tax Act") enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Act may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

On May 19, 2019, the Swiss Federal Act on Tax Reform and AHV Financing, or TRAF, was approved by a public vote. The main part of the TRAF provisions entered into force, at the Swiss federal level and Geneva cantonal level, on January 1, 2020. The TRAF, among other things, contains significant changes to corporate taxation, including (i) the elimination of certain preferential tax regimes at both the federal and cantonal levels with certain transitional rules, (ii) the introduction of a mandatory cantonal patent box in line with the standards of the OECD, (iii) the introduction of R&D super deductions for R&D costs incurred in Switzerland, (iv) the introduction of an optional notional interest deduction in cantons with higher tax rates, (v) the introduction of a maximum relief limitation and (vi) the introduction of a limitation of the ability of Swiss resident corporations listed on a Swiss stock exchange to distribute dividends out of capital contributions exempt from withholding tax (these companies can only pay 50% of their annual dividend distributions out of capital contribution reserves). In addition, the cantons have implemented new tax rates. The measures entered into force in 2020. As a result, the standard combined (federal, cantonal, communal) effective corporate income tax rate, except for dividend income for which we could claim a participation exemption, is approximately 14% as from 2020 in the canton of Geneva. However, the standard effective corporate income tax rate in the canton of Geneva can change from time to time.

Our ability to use our net operating loss carryforwards, or NOL, to offset future taxable income may be subject to certain limitations.

Under the Tax Act, as modified by legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), U.S. federal NOLs generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change U.S. federal NOL carryforwards and other pre-change U.S. tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership.

As a result, our pre-2018 U.S. federal NOL carryforwards may expire prior to being used, and our U.S. federal NOL carryforwards generated in 2018 and thereafter may be subject to a percentage limitation. In addition, it is possible that we have in the past undergone, and in the future may undergo, additional ownership changes that could limit our ability to use all of our pre-change U.S. federal NOLs and other pre-change tax attributes to offset our post-change income or taxes. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of U.S. state NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our U.S. federal and state NOLs and other tax attributes, which could adversely affect our future cash flows.

Our Swiss NOL carryforwards are only permitted to be carried forward for seven years under applicable Swiss tax law. As a result, such NOL carryforwards may expire prior to being used and we may be unable to use all or a material portion of our NOLs, which could adversely affect our future cash flows.

We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to "emerging growth companies" will make our common shares less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an "emerging growth company," we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years from the date we completed our initial public offering, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common shares held by non-affiliates exceeds \$700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an "emerging growth company" as of the following December 31 (our fiscal year end). We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years from the date we completed our initial public offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our share price and trading volume could decline.

The trading market for our common shares is influenced by the research and reports that equity research analysts publish about us or our business, our market and our competitors. We have limited research coverage by equity research analysts. Equity research analysts may elect not to initiate or continue to provide research coverage of our common shares, and such lack of research coverage may adversely affect the market price of our common shares. Even if we have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our shares could decline if one or more equity research analysts downgrade our shares or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our shares could decrease, which in turn could cause our share price or trading volume to decline.

### Item 4. Information on the Company.

### A. History and Development of the Company

Our legal and commercial name is ObsEva SA. We are a Swiss stock corporation (*société anonyme*) organized under the laws of Switzerland. We were formed in 2012 with an indefinite duration. We are currently registered in Plan-les-Ouates, Geneva, Switzerland. Our principal executive offices are located at Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland. Our telephone number is +41 22 552 38 40. Investors should contact us for any inquiries through the address and telephone number of our principal executive office, or via our U.S. office at 1 Financial Center in Boston, MA, telephone number +1 (857) 972-9366. We maintain a website at *www.obseva.com*. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our web site is not a part of this Annual Report on Form 20-F. The SEC maintains a website at *www.sec.gov* that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

Our actual capital expenditures for the years ended December 31, 2020, 2019 and 2018 amounted to \$5.0 thousand, \$5.0 million and \$105.0 thousand respectively. These capital expenditures primarily consisted of purchase of furniture and office equipment, and payment of \$5.0 million to Kissei in 2019 upon execution of the linzagolix licensing agreement. We expect our capital expenditures to increase in absolute terms in the near term in line with our previous expenditures, as we continue to advance our drug development programs and grow our operations. We anticipate our capital expenditures in 2021 to be financed from our existing cash and cash equivalents.

#### **B.** Business Overview

We are a 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 advancing a pipeline of orally-administered innovative new chemical entities, or NCEs, for the treatment of symptoms associated with uterine fibroids and endometriosis, treatment of preterm labor and improvement of clinical pregnancy and live birth rates in women undergoing IVF. We have assembled a strong management team with extensive experience in successfully developing and commercializing therapeutics in our target market. 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.

Our portfolio currently consists of three in-licensed NCEs in clinical development for four indications intended to address areas that we believe present significant unmet medical needs:

Linzagolix for the treatment of HMB associated with uterine fibroids and pain associated with endometriosis. We are developing linzagolix as a novel, oral GnRH receptor antagonist, for the treatment of HMB associated with uterine fibroids and pain associated with endometriosis in pre-menopausal women.

In previous Phase 1 and Phase 2 clinical trials, linzagolix was observed to have a linear PK profile, a predictable dose-dependent suppression of estradiol and a dose range that was well-tolerated and provided symptom relief. 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 low dose of linzagolix without hormonal add-back therapy and (ii) a high dose of linzagolix with hormonal add-back therapy. Add-back therapy (ABT) consists of co-administering estrogen and progestin with a high dose of GnRH receptor antagonist to compensate for the severe depletion of estrogen levels and thus prevent the side effects of full estrogen suppression such as hot flushes, vaginal dryness, and loss of bone mineral density (BMD).

Uterine fibroids are common non-cancerous tumors that develop in the muscular wall of the uterus and have disabling symptoms such as HMB and pain. According to a study published in the American Journal of Obstetrics & Gynecology in 2003, uterine fibroids affect an estimated 20 to 40% of women over the age of 30 in the United States based on clinical cases and women who undergo treatment.

For the uterine fibroids indication, we have completed a Phase 1 PK/PD clinical trial to assess two different doses of ABT in patients receiving 100 mg and 200 mg doses of linzagolix over six weeks. The results of this clinical trial, which were announced in June 2017, support the ABT dose (1mg E2 /0.5mg NETA) being utilized in the two randomized, placebo-controlled Phase 3 clinical trials that commenced in the first half of 2017.

We refer to these two Phase 3 clinical trials of linzagolix in patients with HMB associated with uterine fibroids as 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  $\leq$  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, or Hb, pain, and quality of life. Safety endpoints included bone mineral density, or BMD, and adverse events. Calcium/vitamin D were not provided. BMD was measured centrally via Dual Energy X-ray Absorptiometry scan at baseline, 24 weeks, 52 weeks and 76 weeks (6-month post treatment assessment).

As further discussed below, the primary endpoint recorded at week 24 was successfully met in both the PRIMROSE 1 and PRIMROSE 2 clinical trials. We believe that based on pooled week 52 clinical data from these two Phase 3 trials linzagolix has the potential for a best-inclass profile, with a pooled responder rate of 89.3% in women receiving linzagolix 200 mg with ABT, and 56.4% in women receiving linzagolix 100 mg without ABT.

In December 2020, we reported additional results for PRIMROSE 2 Phase 3 trial at week 76 (6 months after stopping linzagolix treatment). These results show continued pain reduction and demonstrate evidence of BMD recovery after treatment end at 52 weeks.

In November 2020, we submitted a MAA to the EMA for YSELTY® (linzagolix 100mg and linzagolix 200mg) for the treatment of women with uterine fibroids. Our application has been validated by the EMA, as announced in January 2021, and we expect to receive approval for YSELTY® in the fourth quarter of 2021. If approved, linzagolix will be the only GnRH antagonist with flexible dose regimen options for the management of uterine fibroids consisting in (i) 100 mg once daily for women with a contraindication to or who prefer to avoid hormonal ABT or, (ii) 200 mg once daily with concomitant ABT for long-term use (beyond 6 months) or, (iii) 200 mg once daily for short-term use, in particular when rapid reduction in fibroid volume is desired.

Based on the positive PRIMROSE 1 and PRIMROSE 2 full data package including week 52 data and post treatment follow-up data up to week 76 for both trials, we intend to proceed with an NDA submission to the FDA in the second quarter of 2021.

Endometriosis is a painful disorder in which the tissue that normally lines the inside of the uterus, called the endometrium, grows outside of the uterus, causing monthly bleeding and chronic inflammatory reactions inside the abdomen that may result in ovarian cyst formation, scar tissue and adhesions. The symptoms of endometriosis include significant pain during menstrual periods (dysmenorrhea), chronic nonmenstrual pelvic pain (NMPP), pain during intercourse (dyspareunia), pain during defecation (dyschezia), excessive menstrual bleeding and infertility. These symptoms can impact general physical, mental and social well-being. Approximately 5 million women in the United States are diagnosed and treated annually for endometriosis and that the majority of those women experience significant pain during menstrual periods as well as non-menstrual pelvic pain that is not associated with their menstrual periods.

We have completed a placebo-controlled Phase 2b clinical trial of linzagolix in approximately 330 patients with endometriosis, the EDELWEISS 1 trial, which met its primary endpoint at Month 3 and showed maintenance or increase of the effect of linzagolix on endometriosis-associated pain and favorable safety up to 52 weeks of

treatment and up to 24 weeks after end of treatment. The results were presented at the 75th American Society of Reproductive Medicine (ASRM) Scientific Congress & Expo in October 2019. The efficacy and BMD results from EDELWEISS 1 supported Phase 3 development of two doses of linzagolix for the treatment of endometriosis, including a 75 mg once daily dose without ABT, and a 200 mg once daily dose in combination with ABT (1mg E2 / 0.5mg NETA, or Activella). Based on the results of our EDELWEISS 1 trial, we believe nearly three out of four patients with moderate to severe endometriosis-associated pain may achieve significant symptom relief with linzagolix 75 mg once daily with no need for ABT to mitigate BMD loss. Following the positive results of EDELWEISS 1 and the End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in December 2018, the EDELWEISS 2 and EDELWEISS 3 Phase 3 clinical trials were initiated in May 2019. These Phase 3 trials were designed to each enroll approximately 450 patients with endometriosis associated pain, with a co-primary endpoint of response on both dysmenorrhea (menstrual pain) and NMPP. 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 January 2021, we announced our decision to discontinue the EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing pandemic. We are planning to conduct, as soon as is feasible, a new Phase 3 clinical trial for endometriosis with a number of design and operational changes to facilitate faster enrollment, with a goal to maintain the original MAA and NDA filing timelines for this indication. Our EDELWEISS 3 clinical trial is progressing as planned, with primary endpoint data at 24 weeks expected in the fourth quarter of 2021.

We believe linzagolix, if approved in either or both indications, has the potential to be a best-in-class oral GnRH receptor antagonist based on its favorable PK and PD profiles, and its expected favorable benefit/risk profile. We expect linzagolix to potentially reduce heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain symptoms while mitigating bone mineral density loss and other adverse effects associated with full estradiol suppression. Further, we believe that linzagolix has the potential to offer flexible dosing alternatives to achieve either partial or full estrogen suppression that can be administered with or without hormonal add-back therapy. Our intent is to demonstrate that the majority of endometriosis patients may be able to experience significant symptomatic relief by utilizing our partial estrogen suppression linzagolix dose of 75 mg with no ABT. For uterine fibroids, we believe our 100 mg linzagolix dose without ABT is the only oral GnRH dosing regimen being developed for this indication without the use of ABT. Finally, we believe linzagolix has certain advantageous characteristics including the absence of food effect, high bioavailability, low volume of distribution, no induction of liver enzymes known as cytochrome P450 3A4, or CYP3A4, no active transport into the liver by organic-anion-transporting polypeptide 1B1 and 1B3 or OATP1B1/1B3, and low PK and PD variability. We believe these characteristics could be key product differentiators compared to other oral GnRH receptor antagonists in clinical development. We are also exploring various alternatives for the future potential commercialization of linzagolix, including through a collaboration with a third party.

• **Ebopiprant for the treatment of preterm labor** (GA 24-34 weeks). We are developing ebopiprant (formerly OBE022), a selective oral selective prostaglandin  $F_{2\alpha}$ , or  $PGF_{2\alpha}$ , receptor antagonist, as a once daily (7-day) treatment for preterm labor from 24 to 34 weeks gestational age, or GA.  $PGF_{2\alpha}$  is a naturally occurring prostaglandin, or active lipid compound, that acts to induce labor. Preterm labor, defined as the body commencing the birthing process prior to 37 weeks, is characterized by uterine contractions, cervical dilation and potential rupture of the fetal membranes that surround and protect the fetus during pregnancy. Preterm labor can lead to preterm birth, which is currently the leading worldwide cause of death of newborn babies. According to the National Center for Health Statistics, approximately 9.6% of babies in the United States were born preterm in 2014. Over 1 million children under the age of five died in 2013 worldwide due to preterm birth complications, and many infants who survive preterm birth are at greater risk for cerebral palsy, delays in development, hearing and vision issues, and often face a lifetime of disability. Rates of preterm birth are rising in almost all countries with reliable data, and are associated with an immense financial impact to the global healthcare system.

To date, only treatments with limited efficacy and/or restrictive safety issues are available to treat preterm labor. In the United States, only one drug (Ritodrine, a beta-agonist) has ever been approved for acute treatment of preterm labor and is no longer available in the US. Therefore, treatment of preterm labor comprises off-label use of tocolytic treatments (medications that inhibit labor) including beta-adrenergic receptor agonists, calcium channel blockers, or NSAIDs, which are used for short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal steroids (e.g., betamethasone). Magnesium sulfate, used for fetal

neuroprotection is also used (up to 48 hours) to treat acute preterm labor, but has limited efficacy. Approved tocolytic treatments in Europe include beta-adrenergic agonists, which carry severe maternal cardiovascular risks, and intravenous infusions of atosiban (an oxytocin receptor antagonist).

While prostaglandin synthesis inhibitors, a sub-group of NSAIDs, have been shown to be effective for inhibiting preterm labor, use of such drugs is limited, due to the threat of serious and sometimes life-threatening side effects in the fetus. As a result, indomethacin is not recommended after 32 weeks of gestation due to the potential for these serious side effects. In nonclinical studies, ObsEva has observed that ebopiprant markedly reduces spontaneous and induced uterine contractions in pregnant rats without causing the fetal side effects seen with NSAIDS, such as indomethacin.

Through specific antagonism of the  $PGF_{2\alpha}$  receptor, ebopiprant is designed to control preterm labor by reducing inflammation, decreasing uterine contractions and preventing cervical change and fetal membrane rupture (known in lay terms as "water breaking" of the amniotic sac). Based on its PK profile and efficacy observed in animal models, we believe ebopiprant has the potential to become a first-in-class therapy to suppress preterm labor and delay or avoid preterm birth, without significant safety concerns for the fetus.

In February 2017, we completed a Phase 1 clinical trial assessing the safety, tolerability and PK profile of ebopiprant in healthy postmenopausal female volunteers after single doses of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day over 7 consecutive days. In this trial, ebopiprant was observed to have a favorable PK profile, no clinically significant food effect, a favorable safety profile and to be well-tolerated at doses up to 1,300 mg after single dose administration and up to 1,000 mg per day after multiple dose administration over 7 days, each of which are above the estimated clinical effective dose. In March 2017, we completed a set of drug-drug interaction, or DDI, Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of ebopiprant when combined with magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in pre-menopausal female volunteers. Ebopiprant in combination with those drugs was observed to have a favorable safety profile and to be well-tolerated up to 1,100 mg per day, which was the highest tested dose.

In December 2017, we announced the initiation of our Phase 2a proof-of-concept clinical trial of ebopiprant known as PROLONG, which was conducted in two parts: Part A and Part B. In this trial, ebopiprant was orally administered daily for 7 days to pregnant women, who were already receiving standard of care therapy for preterm labor with atosiban infusion for 48 hours. Part A was an open-label trial assessing the safety and pharmacokinetics of ebopiprant. Part B is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of ebopiprant. In November 2020, we announced positive results from Part B of the trial. The efficacy endpoints were delivery within 48 hours of treatment initiation, delivery within 7 days of starting treatment, delivery before 37 weeks of gestation, and time to delivery. Safety assessments included maternal, fetal and neonatal safety. Infants are being followed-up at 6, 12 and 24 months.

In this study, 113 women with spontaneous preterm labor (gestational age between 24 and 34 weeks) were randomized and treated with atosiban for 48 hours (ex-U.S. standard of care) plus ebopiprant or atosiban plus placebo for 7 days. There were 83 (73%) women with singleton pregnancies and 30 (27%) with twin pregnancies. One hundred and forty-one neonates were born. In the PROLONG study, atosiban plus ebopiprant reduced delivery in singleton pregnancies at 48 hours after the start of dosing by 55% compared to atosiban alone. Overall, 7/56 (12.5%) of women receiving ebopiprant delivered within 48 hours of starting treatment compared to 12/55 (21.8%) receiving placebo (OR 90% CI: 0.52 (0.22, 1.23)). In singleton pregnancies, 5/40 (12.5%) of women receiving ebopiprant delivered within 48 hours compared to 11/41 (26.8%) receiving placebo (OR 90% CI: 0.39 (0.15, 1.04)). A modest effect on delivery at 7 days was seen in the singletons.

The incidence of maternal, fetal and neonatal adverse events was comparable between subjects in the ebopiprant group and the placebo group. Follow-up of infants at 6, 12 and 24 months after birth is continuing and results will be available in 2021 and 2022. These data results support advancement of ebopiprant to a Phase 2b dose range finding study, that we plan to initiate in Europe and Asia in the fourth quarter of 2021, including testing of higher doses, which will allow us to more fully define ebopiprant's potential to treat preterm labor, and its potential for longer-term benefits for babies.

• *Nolasiban to improve embryo transfer outcomes after IVF*. We have been developing nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing embryo transfer (ET) following an IVF cycle. 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. Patients receiving nolasiban prior to either Day 3 or Day 5 ET experienced an approximate 7% absolute or 25% relative increase in live birth rate over placebo. The Day 5 ET only population experienced an approximate 12% absolute or 35% relative increase in live birth rate over placebo.

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 have discontinued our previously ongoing development of nolasiban for IVF, and are exploring potential repositioning of the compound, such as through higher dose levels and earlier and longer exposure of nolasiban, as well as focusing on subjects with a high uterus contraction rate at the time of ET. In connection with this potential repositioning, 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. They will fund all development and registration activities in the PRC, starting with the obligation to fund and conduct a Phase 1 trial and a Phase 2 proof-of-concept trial in China. We retain all rights to the product outside of PRC, and have agreed to collaborate with YuYuan on its global development. Our development and commercialization partnership with YuYuan proceeded during the 2020 with steering committee meetings to define the development plan for nolasiban in China for women undergoing ET following IVF.

The following table summarizes key information regarding our current product candidates:

	Phase 1	Phase 2	Phase 3	Next Milestones
YSELTY® (LINZAGOLIX) Oral GnRH receptor antagonist	Uterine Fibroids – Ph3 PRIMROSE 2 (EU & US)  Uterine Fibroids – Ph3 PRIMROSE 1 (US)			NDA submission (Q2:21) MAA for uterine fibroids expected approval (Q4:21)
	Endometriosis – Ph3 6	EDELWEISS 3 (EU & US	)	EDELWEISS 3: Primary endpoint readout expected (Q4:21)
$\begin{array}{c} \textbf{EBOPIPRANT} \\ \textbf{Oral PGF}_{2\alpha} \\ \textbf{receptor antagonist} \end{array}$	Preterm Labor – Ph2b	(EU & Asia)		Initiation of Phase 2b dose ranging study (Q4:21)
NOLASIBAN Oral oxytocin receptor antagonist	IVF – Ph1/2 (China)			In development, partnership with Yuyuan BioScience Technology (PRC)

We are also evaluating additional indications for our current product candidates as well as opportunities to in-license or acquire additional product candidates in our therapeutic field.

Our executive team has substantial experience in developing and commercializing pharmaceutical products in this field. For example, Brian O'Callaghan, our Chief Executive Officer, is a life science executive with extensive experience within biotech, large pharmaceutical companies and the contract research organization, or CRO, sector, as well as extensive global experience, having lived and worked in five different countries and both coasts of the U.S. Prior to joining ObsEva, Mr. O'Callaghan has held CEO positions at Petra Pharma, Acucela, Sangart and BioPartners, as well as senior management positions at Pfizer. Merck Serono and Novartis.

Elizabeth Garner has served as our Chief Medical Officer since 2019 and has spent many years in the women's health industry at Agile Therapeutics Inc., Myriad Genetics Laboratories, Abbott Laboratories, and Merck. She has extensive experience with clinical trial design, NDA submissions and regulatory interactions and designed and conducted the trial that led to the 2020 approval of the Twirla® contraceptive patch. Dr. Garner has several years of experience in academic clinical practice, research and teaching at Harvard Medical School. Dr. Garner holds M.D. and M.P.H. degrees from the Harvard Medical School and Harvard School of Public Health, Boston, and received board certification in both general Obstetrics and Gynecology and Gynecologic Oncology.

In addition, Jean-Pierre Gotteland, Ph.D., our Chief Scientific Officer and Head of R&D, brings extensive experience in research and development, clinical trial design as well as chemistry, manufacturing and controls. He held the same roles at PregLem where he worked with our co-founder, Dr. Loumaye, for six years and successfully in-licensed, developed and registered a first-in-class product, Esmya (ulipristal acetate), for the treatment of uterine fibroids.

Wim Souverijns, our Chief Commercial Officer is responsible for leading our transition from a development company to a commercial company. Mr. Souverijns brings nearly 20 years of experience in the pharmaceutical industry and recently served as Corporate Vice President, Global Marketing, Hematology & Oncology within Celgene out of Summit, New Jersey. Previously, Mr. Souverijns developed his pharmaceutical experience through various international assignments at PwC Consulting and in different market access leadership roles at Amgen, both in Europe and the U.S.

Collectively, our management team has led the clinical development or contributed to the worldwide registration of market-leading products including Esmya and Evamist. In addition, members of our management team bring pharmaceutical development, regulatory approval, manufacturing, reimbursement and commercialization experience from other pharmaceutical and biotechnology companies, including Merck Serono, Celgene, Novartis, Pfizer, Abbott Laboratories, PregLem, Allergan, Pierre Fabre, SmithKline Beecham, Shire, Galderma and Acrux.

We have demonstrated an ability to successfully execute on the first part of our strategy by leveraging our extensive network in the field of women's reproductive health and pregnancy to in-license linzagolix from Kissei and ebopiprant and nolasiban from Merck Serono. Additionally, we have raised \$369.1 million in equity financing from inception to December 31, 2020 from leading healthcare investors, as well as \$25.0 million from the issuance of a debt instrument.

#### **Our Strengths**

We believe our clinical and product development experience in the field of women's reproductive health and pregnancy provides us with the following strengths:

- Strategic focus on diseases in women's reproductive health and pregnancy that affect growing female populations with high unmet medical needs and significant commercial potential;
- Product candidates with clear mechanisms of action and early evidence of efficacy that have the potential to progress into and through latestage clinical trials and potentially commercial stage;
- Management with substantial experience working together and developing and commercializing pharmaceutical products in the field of women's reproductive health and pregnancy;
- Strong industry and key opinion leader relationships in the field of women's reproductive health and pregnancy that provide access to potential product in-licensing opportunities and product development experience; and
- Support from leading healthcare-focused investors and board members with experience in building and operating life science companies.

### **Our Strategy**

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. The key elements of our strategy include the following:

- Continue to advance each of our current product candidates in their respective indications.
- Develop a targeted commercialization strategy for any approved product candidates. We have obtained worldwide commercial rights to
  our lead product candidates, except for certain countries in Asia with respect to linzagolix and for the PRC with respect to nolasiban. As we
  move our product candidates through development toward regulatory approval, we will evaluate several options for each product candidate's
  commercialization

strategy. These options include building our own internal sales force, entering into a joint marketing partnership with another pharmaceutical or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company. We are also exploring various alternatives for the future potential commercialization of linzagolix, including through collaboration with a third party.

- Pursue additional indications for our current product candidates. We believe each of our current product candidates have potential for
  application outside the indications we are currently developing, and we plan to pursue additional indications for our existing product
  candidates in the near future.
- Leverage our international product development experience and extensive network of clinical experts and pharmaceutical industry executives within women's reproductive health and pregnancy to in-license or acquire novel product candidates. We are focused on identifying, and in-licensing or acquiring, additional clinical-stage product candidates that we believe have the potential to become best-in-class or first-in-class products for the treatment of serious conditions in women's reproductive health and pregnancy, if approved. We intend to focus on product candidates that we believe will be efficient from a capital-management standpoint, and we are exploring additional needs in our therapeutic field, such as premenstrual syndrome, fibrocystic breast disease, post-menopausal hot flashes, preeclampsia, dysmenorrhea, and menopause-related auto-immune diseases.

#### Linzagolix: Investigational GnRH Receptor Antagonist for Symptoms Associated with Uterine Fibroids and Endometriosis

We are developing linzagolix as an oral GnRH receptor antagonist, which we have observed in our clinical trials to induce a dose-dependent reduction of estradiol levels. Through that mechanism, we expect linzagolix to be indicated for the treatment of heavy menstrual bleeding associated with uterine fibroids and endometriosis-associated pain. We believe linzagolix, if approved, has the potential to be a best-in-class oral GnRH receptor antagonist based on its favorable PK and PD profiles, and its potential to provide targeted estradiol suppression to reduce HMB associated with uterine fibroids and pain symptoms associated with endometriosis, while mitigating bone mineral density loss and other adverse effects that are typically associated with full estradiol suppression. We believe that linzagolix has the potential to offer flexible dosing alternatives to address symptoms in broad patient populations, supported by key differentiating product characteristics, including absence of food effect, high bioavailability, low volume of distribution, no CYP3A4 induction or OATP1B1/B3 interaction, and low PK and PD variability. We believe these characteristics are key product differentiators compared to other GnRH receptor antagonists in development.

In 2015, we in-licensed linzagolix from Kissei. Kissei completed three Phase 2a clinical trials in Japan of linzagolix in patients with endometriosis, including one double blind placebo-controlled trial with a subgroup of patients diagnosed with both uterine fibroids and endometriosis.

Aimed at addressing the needs 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 low dose of linzagolix without hormonal ABT 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 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  $\leq 80$  mL and a 50 percent or greater reduction from baseline in MBL, volume, measured using the alkaline hematin method. Secondary endpoints included amenorrhea, time to reduced MBL, hemoglobin, pain, and quality of life. Safety endpoints included BMD, and adverse events. Calcium/vitamin D were not provided. BMD was measured centrally via Dual Energy X-ray Absorptiometry scan at baseline, 24 weeks, 52 weeks and 76 weeks (6-month post treatment assessment).

In December 2019, we announced positive Phase 3 trial results from the PRIMROSE 2 trial of linzagolix at 24 weeks. 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.

In July 2020, we announced positive Phase 3 trial results from the PRIMROSE 1 trial of linzagolix at 24 weeks. 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 100 mg), 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 p > 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 July 2020, we also 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. The above results were presented 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). In December 2020, we announced positive 52-week treatment results from the PRIMROSE 1 trial, showing that continued treatment with linzagolix led to sustained efficacy for the primary endpoint of reduced heavy menstrual bleeding (defined as menstrual blood loss of at least 50% less than baseline and at or below 80 mL). This was seen across all doses of linzagolix and was in line with the earlier findings in PRIMROSE 2.

We believe that based on pooled week 52 clinical data from these two Phase 3 trials linzagolix has the potential for a best-in-class profile, with a pooled responder rate of 89.3% in women receiving linzagolix 200 mg with ABT, and 56.4% in women receiving linzagolix 100 mg without ABT. In December 2020, we reported additional results for PRIMROSE 2 Phase 3 trial at week 76 These results show continued pain reduction and demonstrate evidence of bone mineral density (BMD) recovery after treatment end at 52 weeks. Of note, at the request of FDA, PRIMROSE trial participants were not provided with Vitamin D or calcium, co-administration of which is expected in clinical practice to lead to even smaller changes in BMD. In November 2020, we submitted a MAA to the EMA for YSELTY® (linzagolix 100mg and linzagolix 200mg) for the treatment of women with uterine fibroids. Our application has been validated by the EMA, as announced in January 2021, and we expect to receive approval for YSELTY® in the fourth quarter of 2021. If approved, linzagolix will be the only GnRH antagonist with flexible dose regimen options for the management of uterine fibroids comprising (i) 100 mg once daily for women with a contraindication to or who prefer to avoid hormonal add-back therapy (ABT) or, (ii) 200 mg once daily with concomitant ABT for long-term use (beyond 6 months) and (iii) 200 mg once daily for short-term use, in particular when rapid reduction in fibroid volume is desired.

Based on the positive PRIMROSE 1 and PRIMROSE 2 full data package including week 52 data and post treatment follow-up data up to week 76 for both trials, we intend to proceed with an NDA submission to the FDA in the second quarter of 2021.

In addition, we have completed a 330-patient multiple-dose, placebo-controlled Phase 2b clinical trial of linzagolix (EDELWEISS 1) in endometriosis patients across 70 sites in the United States and 15 sites in Central and Eastern Europe. This prospective, dose finding, randomized, parallel-group, double-blind, placebo-controlled Phase 2b study was designed to investigate the efficacy and safety of a range of doses of linzagolix in the treatment of women with endometriosis associated pain. The 24-week treatment period (primary endpoint after 12 weeks of treatment) was followed either by a 24-week post treatment follow-up (PTFU) or an optional treatment extension phase with a 24-week PTFU.

The EDELWEISS 1 clinical trial successfully met its primary endpoint of a statistically significant patient response rate vs. placebo following 12 weeks of treatment. Patient response was measured by a reduction of at least 30% in combined menstrual and non-menstrual pelvic pain on a verbal rating scale (VRS) of 0 (no pain) through 3 (severe pain). Observed response rates were 34.5% for placebo, 61.5% for 75mg linzagolix, and 56.3% for 200mg linzagolix. Respective p values were 0.003 and 0.034. The efficacy in reducing pelvic pain, including dysmenorrhea and non-menstrual pelvic pain, as well as improvements in dyspareunia, dyschezia, and quality of life measures observed after 12 weeks of treatment were further improved or maintained up to Week 52, with the greatest treatment benefit observed at dose levels of 75 mg and above. The EDELWEISS 1 trial also demonstrated that linzagolix is well tolerated and has clinical benefits when administered continuously for up to 52 weeks.

After an End of Phase 2 meeting with the FDA in December 2018, we announced the initiation of the EDELWEISS 2 and EDELWEISS 3 Phase 3 clinical trials in May 2019. The target enrollment for both trials was approximately 450 patients with endometriosis associated pain, with a co-primary endpoint of patients' response on both dysmenorrhea (menstrual pain) and non-menstrual pain. Both trials include a 75 mg once daily dose without hormonal ABT option, and a 200 mg once daily dose in combination with ABT (1mg E2 / 0.5mg NETA) option. Subjects who have completed the initial six-month treatment period were to 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 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.

In January 2021, we announced our decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing pandemic. We are planning to conduct, as soon as is feasible, a new Phase 3 clinical trial for endometriosis with a number of design and operational changes to facilitate faster enrollment, with a goal to maintain the original MAA and NDA filing timelines for this indication. Our EDELWEISS 3 clinical trial is progressing and continuing as planned, with primary endpoint data at 24 weeks expected in the fourth quarter of 2021.

### Background on Uterine Fibroids and Endometriosis

Uterine fibroids are common non-cancerous tumors that develop in the muscular wall of the uterus. Uterine fibroids can vary in size from a few millimeters to more than 20 centimeters, and in number from a single fibroid to several dozen fibroids. The main symptoms of uterine fibroids are heavy menstrual bleeding, anemia, abdominal pain and pressure, bloating, and increased urinary frequency. Heavy menstrual bleeding is a frequent disabling symptom of uterine fibroids which often leads to anemia, which can be severe and potentially life threatening. Uterine fibroids also carry an increased risk of pregnancy complications such as miscarriage, placental abruption and premature onset of labor.

According to a study published in the American Journal of Obstetrics & Gynecology in 2003, uterine fibroids affect an estimated 20 to 40% of women over the age of 30 in the United States based on clinical cases and women who undergo treatment. We believe that approximately four million women in the United States are diagnosed and being treated for uterine fibroids.

Endometriosis is a painful disorder in which endometrial tissue grows outside of the uterus, typically on the lining of the pelvis, on the ovaries, in the rectovaginal septum, on the bladder, and on the bowels. Endometriosis causes pain with monthly bleeding and chronic inflammatory reactions in the abdomen that may result in ovarian cyst formation, scar tissue and adhesions. The symptoms of endometriosis include significant pain during menstrual periods, chronic non-menstrual pelvic pain, pain during intercourse, excessive menstrual bleeding and infertility, which in turn can impact general physical, mental and social well-being. Often the pain associated with endometriosis is cyclical in nature and reflects the response to circulation of reproductive hormones, particularly estrogen. Endometriosis is also one of the leading causes of infertility and is often diagnosed when women seek treatment for such infertility.

According to the World Endometriosis Research Foundation, as of 2014, endometriosis affects an estimated one in ten women during their reproductive years, totaling approximately 176 million women globally between the ages of 15 and 49. We believe that approximately 5 million women in the United States are diagnosed and treated annually for endometriosis, and the majority of those women experience significant pain during menstrual periods.

### The Role of GnRH

The exact causes of uterine fibroids and endometriosis are not currently understood. However, several factors can contribute to their development and progression, including the rise and fall of hormones, particularly estrogen, mainly in the form of estradiol. The production of estrogen in the body is regulated by GnRH. GnRH is responsible for stimulating the synthesis and release of luteinizing hormone, or LH, and follicle stimulating hormone, or FSH, by the pituitary gland. LH and FSH in turn drive estrogen production through stimulation of the ovaries. Estradiol is the hormone that, among other effects, causes the endometrium inside the uterus to thicken during the menstrual cycle. Similarly, estradiol has been determined to promote the growth of endometriosis lesions and uterine fibroids. Various pharmacological treatments directed at addressing uterine fibroids and endometriosis attempt to regulate the production of estrogen, particularly estradiol, by controlling the activity of GnRH.

### Limitations of Current Therapies for Uterine Fibroids and Endometriosis

Current treatment options for uterine fibroids and endometriosis are either pharmacological or surgical.

#### **Uterine Fibroids**

Current medical treatment options for heavy menstrual bleeding associated with uterine fibroids are limited and generally consist of oral contraceptives and GnRH agonist injections. Oral contraceptives are generally used as first-line therapy, but are often not effective in reducing heavy bleeding. Upon failure of a first-line therapy or contraindication to oral contraceptives, surgical intervention is generally the next treatment option. Hysterectomy is the most commonly performed surgical treatment. Other procedures include (1) myomectomy, which is selective removal of fibroids, typically performed by laparoscopy; this usually preserves fertility, (2) uterine artery embolization, which is a procedure to obstruct the arteries feeding the fibroid, performed by arterial catheterization, and (3) MRI-guided focused ultrasound ablation.

According to a study published in the American Journal of Obstetrics & Gynecology in 2012, approximately 300,000 hysterectomies and 30,000 myomectomies are performed annually for the treatment of uterine fibroids in the United States as of 2003. According to the National Uterine Fibroids Foundation, approximately 660 women die each year in the United States from complications following hysterectomy. Hysterectomies can be both physically and psychologically damaging, not only resulting in loss of fertility, but they also can be perceived by some women as a loss of femininity. Surgery also carries a risk of scar tissue and adhesions, which can lead to infertility, worsening of pain, damage to other pelvic structures, and may require additional surgical management.

Treating uterine fibroids is expensive, as surgery constitutes a significant cost burden. Patients who do not undergo surgery often require medical management, hospitalization and additional outpatient physician visits, which further increase the annual costs of the disease. According to a systematic review of literature published in the American Journal of Obstetrics &Gynecology in 2012, direct and indirect costs associated with uterine fibroids were estimated in 2010 to be up to \$34.4 billion annually in the United States.

### Endometriosis

For endometriosis, the treatment selected as standard of care is based on the severity of pain and the extent of the disease. Endometriosis treatments aim first to alleviate pain, then to remove or decrease the size and number of endometrial lesions, and possibly improve fertility. Oral contraceptives, progestins and NSAIDs are generally first-line treatments for women experiencing pain. Following the failure of first-line therapies, which is common, current treatment options are limited to intra-muscular or subcutaneous GnRH agonist injections and GnRH agonist nasal sprays. In July 2018, AbbVie Inc announced that their GnRH antagonist elagolix (Orilissa) received regulatory approval in the U.S. for the treatment of moderate-to-severe endometriosis-associated pain.

Surgery may be performed for the most symptomatic cases. However, in most cases conservative surgery can provide short-term relief by excising and/or ablating endometrial lesions, but does not prevent the endometrial lesions and associated symptoms from recurring. Surgery requires general anesthesia and has a risk of scar tissue and adhesion formation in the pelvis, which can lead to infertility, worsened pain, requirement for additional surgeries, and damage to other pelvic structures. Surgical treatments for endometriosis range from laparoscopy to more complex open abdominal surgery. If a woman has not responded to other medical or surgical treatments, a hysterectomy, which is the removal of all or part of the uterus, may be performed. Depending on the woman, removal of the ovaries may also be required, resulting in definitive infertility and immediate menopause.

The World Endometriosis Research Foundation through its EndoCost study estimated the aggregate annual cost of endometriosis to be approximately \$80 billion in the United States and approximately \$60 billion in Germany, the UK, France and Italy in 2012 based on then current exchange rates.

### Mechanism of Action and Limitations of GnRH Agonists

GnRH agonists are a standard pharmaceutical therapy for estrogen dependent conditions such as uterine fibroids and endometriosis as they have been demonstrated to reduce estradiol levels. GnRH agonists act by first overstimulating the GnRH receptors which initially may worsen the symptoms for several weeks (the flare effect) and subsequently desensitizing the receptors, resulting in reduced secretion of LH and FSH, and severely reduced production of estrogen. This leads to a state referred to as pseudo-menopause, in which patients experience menopausal symptoms before ultimately experiencing symptom relief. While GnRH agonists may be effective at treating the symptoms of uterine fibroids and endometriosis, they can be accompanied with serious drawbacks and limitations including:

- Full suppression of estradiol and related unfavorable side effect profile. Because GnRH agonists cannot be titrated, they act by fully suppressing estradiol to a post-menopausal level of less than 20 picogram/milliliter, or pg/ml. Excessive suppression of estrogen can result in multiple side effects before the patient experiences any relief, including hot flashes, vaginal dryness, and bone mineral density loss. Clinical trials of an approved GnRH agonist demonstrated that patients lose an average of up to 6% of their bone mineral density after 12 months of GnRH agonist treatment.
- **Delayed therapeutic effect and initial worsening of symptoms**. Since GnRH agonists act by initially overstimulating the GnRH receptors (the flare effect), they can cause an initial worsening of symptoms that can last for several weeks.
- Administration by injection. Many GnRH agonists such as Lupron (leuprolide acetate) must be injected on a monthly basis or a tri-monthly basis, which generally requires the assistance of a doctor or nurse.
- **Required add-back therapy**. To counteract the side effects of the full estrogen suppression, additional administration of estrogen, referred to as "add-back therapy," may be recommended after three months of treatment and is required after six months of treatment. ABT is standard hormone replacement therapy, or HRT and is most commonly used in post-menopausal women. For some women, ABT is contraindicated due to related and potentially serious adverse effects, including venous and arterial thromboembolism.
- *Variable and unpredictable reversibility of treatment*. After stopping treatment with injectable GnRH agonists, ovarian function can take weeks or months to return to normal. This is particularly relevant and problematic if a woman wishes to conceive after treatment or if treatment is interrupted for lack of tolerability.

#### Linzagolix Mechanism of Action and Solution to GnRH Agonist Drawbacks and Limitations

Linzagolix is an orally administered GnRH receptor antagonist with low PK/PD variability. Linzagolix binds to and blocks the GnRH receptor in the pituitary gland, which results in dose-dependent reduction of LH and FSH production. This reduction in LH and FSH production in turn leads to dose-dependent reduction of estrogen levels.

At selected doses, linzagolix has been observed to maintain estradiol levels in the target range of 20 to 60 pg/ml, which we believe is the optimal range to relieve symptoms associated with uterine fibroids and endometriosis while mitigating bone mineral density loss or other adverse effects that can be associated with full estradiol suppression. Higher doses of linzagolix drive estradiol below 20 pg/ml, considered full suppression.

We believe linzagolix has the potential to overcome certain drawbacks and limitations of GnRH agonists. The potential advantages of linzagolix compared to GnRH agonists include:

- **Rapid onset of therapeutic effect**. By blocking, as opposed to initially stimulating the GnRH receptor, linzagolix has the potential to suppress LH and FSH within hours, lowering estradiol levels and reducing pain within days while potentially avoiding the initial flare effect which is often associated with GnRH agonist treatments.
- *Ease of administration*. Linzagolix has the potential to be administered orally once daily, and regardless of food intake timing. This potential dosing regime is a more convenient and less invasive treatment option than GnRH agonist intramuscular or subcutaneous injections.

- Optionality for uterine fibroids and endometriosis treatment: stand alone or in combination with ABT. In contrast to GnRH agonists, for which hormonal ABT is required when treatment exceeds six months, we believe that the 75mg once daily dose tested in our EDELWEISS 1 Phase 2b trial and the 100mg once daily dose tested in our PRIMROSE trials, have the potential to be utilized as a stand-alone treatment for a substantial proportion of patients with endometriosis-associated pain and heavy menstrual bleeding associated with uterine fibroids by maintaining estradiol levels between 20 and 60 pg/ml.
  - The once daily 200 mg dose of linzagolix will require the addition of ABT if used long-term to counteract the side effects associated with full suppression of estradiol, i.e. below 20 pg/ml.
  - These doses of 75 mg or 100mg without ABT, 200 mg with ABT, and 200 mg without ABT (for short-term use in uterine fibroids) are being tested in the confirmatory Phase 3 trials.
- *Rapid reversibility of effect.* As a result of the observed linzagolix half-life of approximately 15 hours, we believe there is the potential for ovarian function to resume within days following the end of treatment. In contrast, a patient's ovarian function can take weeks or months to return to normal after stopping treatment with injectable GnRH agonists.

### Potential Clinical Profile of linzagolix

In July 2018, AbbVie Inc. announced that their oral GnRH antagonist elagolix (Orilissa®) received regulatory approval in the U.S. for the treatment of women with moderate to severe endometriosis-associated pain (150mg QD up to 2-year and 400mg (200mg BID) up to 6 months). Abbvie also obtained approval for Oriahnn® in May 2020 for the indication of heavy menstrual bleeding associated with uterine fibroids. Oriahnn® is given as a high dose of elagolix (300mg BID) with ABT AbbVie Inc is now conducting Phase 3b trials with elagolix 600mg daily dose (300mg BID) in combination with ABT to assess long-term impact (48 months) of treatment on BMD.

In addition, Myovant Sciences, Inc. conducted Phase 3 trials with the oral GnRH receptor antagonist relugolix 40mg daily in combination with ABT for the treatment of symptoms associated with endometriosis and uterine fibroids. This is the only dose level being studied for both indications. In 2019, Myovant reported positive 6-month results for the two Phase 3 trials in the fibroid indication (LIBERTY 1 and 2) and filed a MAA and a NDA on the basis of 52-week treatment data in March 2020 and in June 2020 (with a PDUFA set to June 2021), respectively. In 2020, Myovant also reported positive 6-month results for the two Phase 3 trials in the endometriosis indication (SPIRIT 1 and 2). In January 2021, Myovant reported positive 1-year results from the SPIRIT trials, and announced the intention to file an NDA for this indication in the first half of 2021.

We believe that linzagolix has a best-in-class clinical profile as assessed by:

- **Optimal characteristics for consistent PK.** Linzagolix has been observed to have a consistent PK profile and low variability, due to high bioavailability and low volume of distribution. In addition, its half-life allows for once daily dosing for across indications. We believe these characteristics are important for optimizing patient compliance and drug exposure.
- Three dosing options. Based on its consistent PK and PD profile observed in preclinical studies and clinical trials, we are currently pursuing the development of linzagolix doses both with and without hormonal ABT, which is related to partial or full suppression of estrogen. We believe that various levels of estrogen suppression may be required to successfully treat symptoms in different patients in different indications to account for patient characteristics, individual response or patient preference, but that the option of partial suppression, with no need for ABT has the potential to be a first line therapy for many patients.
- **Potential to avoid hormonal ABT**. For symptoms associated with both uterine fibroids and endometriosis, we are developing linzagolix as a stand-alone treatment (without need for ABT) and in association with ABT to fulfill the needs of a broad patient population with uterine fibroids and endometriosis. We do not believe that all patients will have the desire or need for hormonal ABT, some of whom may have a contraindication or tolerability issue (as per boxed warning on ABT), or simply prefer the management of endogenous estrogen levels in the clinical setting where bone mineral density loss is not reduced to the degree that would require hormone replacement.
- *Compliance benefit.* Linzagolix may have an advantage in patient compliance due to the lack of observed interactions with food, CYP3A4 or OATP1B1/B3 enzyme pathways, and the ability to be taken once anytime throughout the day, without the risk of reduced and/or variable exposure to active drug.

### Linzagolix Clinical Development for Heavy Menstrual Bleeding Associated with Uterine Fibroids

We are also developing linzagolix for reduction of heavy menstrual bleeding associated with uterine fibroids in adult women of reproductive age. We believe linzagolix has the potential to provide an alternative to surgery, which is the most common treatment for uterine fibroids.

#### Completed Phase 2a Trial in Japanese Patients

In a Phase 2a double-blind clinical trial in Japanese patients with endometriosis (Study KLH1202), 50, 100, or 200 mg linzagolix or placebo was orally administered once daily after breakfast for 12 weeks. 57 patients presented with uterine fibroids in addition to endometriosis, which allowed assessment of endpoints relevant to fibroids. In subjects with endometriosis and concomitant uterine fibroids, the 50 mg dose suppressed menstrual bleeding in only 8.3%, the 100 mg dose led to absence of menstrual bleeding in 66.7% of subjects, and in the 200 mg group all subjects reported suppressed menstrual bleeding. Amenorrhea was quickly achieved with patients being most frequently amenorrhoeic in the 200 mg arm and less frequently in the 50 mg arm. However, presence of uterine fibroids impacted the bleeding control and the rapidity of onset; for example, at the 50 mg dose, only roughly 25% of patients were in amenorrhea after approximately 1 month of treatment when concomitant fibroids were present. The 50 mg dose suppressed bleeding in approximately 55% of patients, whereas the 200 mg daily dose of linzagolix suppressed bleeding in approximately 95% of patients. In addition, most patients in the 100 mg and 200 mg groups stopped bleeding within a few weeks of treatment initiation. A dose-dependent reduction in uterine volume was observed in the active treatment arms.

#### Ongoing Phase 3 Clinical Trials PRIMROSE 1 and PRIMROSE 2 for Heavy Menstrual Bleeding Associated with Uterine Fibroids

Based on the above Phase 2 results and the feedback we received from the FDA in November 2016, we commenced the two PRIMROSE Phase 3 clinical trials in patients with heavy menstrual bleeding associated with uterine fibroids in the first half of 2017. As part of these trials, we have been assessing the efficacy of both a 100 mg once daily dose and a 200 mg once daily dose of linzagolix both with and without ABT. We believe that the 200 mg dose may be used alone for short-term treatment and will require ABT for longer term treatment to prevent excessive bone mineral density loss, while the 100mg dose may not necessitate the use of ABT.

Figure 1 below depicts the trial design of the Phase 3 PRIMROSE clinical trials:

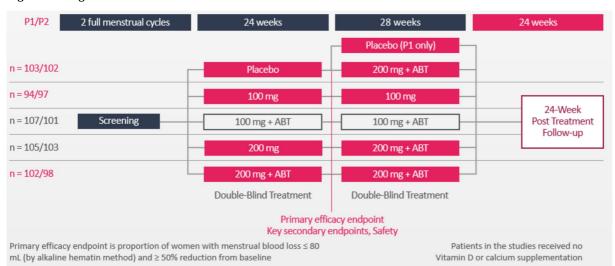


Figure 1: Design of Phase 3 PRIMROSE Clinical Trials

The primary endpoint of heavy menstrual bleeding was measured via two approaches. Patients collected and delivered their used sanitary protection to a central laboratory analysis using a validated alkaline hematin method; this provided an objective measure of bleeding. In addition, patients report their bleeding status on a daily basis with an electronic diary.

The PRIMROSE 1 clinical trial was conducted in the United States, and enrolled 526 women with uterine fibroids, while the PRIMROSE 2 clinical trial was conducted both in Europe and in the United States and enrolled 535 women with uterine fibroids. 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  $\leq 80$  mL and a 50 percent or greater reduction from baseline in MBL, volume, measured using the alkaline hematin method. Secondary endpoints included amenorrhea, time to reduced MBL, hemoglobin, pain, and quality of life. Safety endpoints included BMD, and adverse events. BMD was measured centrally via Dual Energy X-ray Absorptiometry scan at baseline, 24 weeks, 52 weeks and 76 weeks (6-month post treatment assessment). Calcium/vitamin D were not provided.

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 p > 0.008) were headache, hot flushes, and anemia. Mean percentage change from baseline in BMD was consistent with previous clinical data.

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 p < 0.001) 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 July 2020, we also 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. 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). In December 2020, we announced positive 52-week treatment results from the PRIMROSE 1 trial, showing that continued treatment with YSELTY® led to sustained efficacy for the primary endpoint of reduced heavy menstrual bleeding (defined as menstrual blood loss of at least 50% less than baseline and at or below 80 mL). This was seen across all doses of YSELTY® and was in line with the earlier findings in PRIMROSE 2.

We believe that based on pooled week 52 clinical data from these two Phase 3 trials linzagolix has the potential for a best-in-class profile, with a pooled responder rate of 89.3% in women receiving linzagolix 200 mg with ABT, and 56.4% in women receiving linzagolix 100 mg without ABT. In December 2020, we reported additional results for PRIMROSE 2 Phase 3 trial at week 76 These results show continued pain reduction and demonstrate evidence of bone mineral density (BMD) recovery after treatment end at 52 weeks.

In November 2020, we submitted a MAA to the EMA for YSELTY® (linzagolix 100mg and linzagolix 200mg) for the treatment of women with uterine fibroids. Our application has been validated by the EMA, as announced in January 2021, and we expect to receive approval for YSELTY® in the fourth quarter of 2021. If approved, linzagolix will be the only GnRH antagonist with flexible dose regimen options for the management of uterine fibroids consisting of (i) 100 mg once daily for women with a contraindication to or who prefer to avoid hormonal add-back therapy (ABT) or, (ii) 200 mg once daily with concomitant ABT for long-term use (beyond 6 months) or, (iii) 200 mg once daily for short-term use, in particular when rapid reduction in fibroid volume is desired.

Based on the positive PRIMROSE 1 and PRIMROSE 2 full data package including week 52 data and post treatment follow-up data up to week 76 for both trials, we intend to proceed with an NDA submission to the FDA in the second quarter of 2021.

#### Linzagolix Preclinical and Clinical Development for Pain Associated with Endometriosis

Prior to in-licensing linzagolix, Kissei completed a preclinical program, a Phase 1 clinical trial in healthy female volunteers of Japanese and European descent and three Phase 2a clinical trials in patients of Japanese descent with endometriosis, including one trial that included a subgroup of patients with both endometriosis and uterine fibroids. In these trials, linzagolix was observed to have a linear PK profile, a predictable dose-dependent suppression of estradiol and a dose range that was well-tolerated and provided symptom relief. Following our in-license of linzagolix from Kissei, we submitted an IND for linzagolix in May 2016, which was accepted by the FDA. In 2019, we completed the EDELWEISS 1 Phase 2b clinical trial and initiated our two pivotal Phase 3 clinical trials (EDELWEISS 2 and EDELWEISS 3).

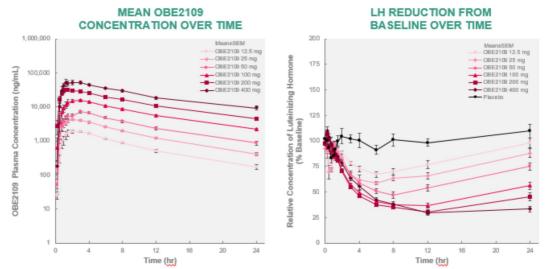
#### Preclinical Studies and Phase 1 Clinical Trial

In preclinical studies, linzagolix was observed to be a highly potent and selective antagonist of the GnRH receptor. The preclinical toxicology and safety pharmacology studies did not raise tolerance or safety concerns or potential for DDIs. In the Phase 1 clinical trial, linzagolix was observed to have a favorable safety profile and to be well-tolerated up to 400 mg once daily for seven days. Additionally, linzagolix had a linear PK profile, a half-life of approximately 15 hours and no significant differences between women of Japanese and European descent. Moreover, linzagolix was observed to have a low volume of distribution, meaning the drug remained in the blood and did not accumulate in fatty tissue (Figure 2). Furthermore, in the Phase 1 clinical trial, there was no food effect observed.

Linzagolix was observed to induce a dose-dependent decrease in LH and FSH over time (Figure 3), which we believe correlates with its ability to control estradiol levels in a dose-dependent manner. Based on the low PK variability and lack of dose overlap observed in the Phase 1 clinical trial, we believe we will be able to more tightly control biological response with personalized doses of linzagolix. In addition, in 2016 we completed a Phase 1 trial to assess the impact of linzagolix on the potential induction of CYP3A4, which is responsible for most of the metabolism of ABT. In this trial, we observed no relevant CYP3A4 induction, which we believe indicates that linzagolix will not interfere with ABT and has low risk of drug-drug interactions.

Figure 2: Mean linzagolix Concentration Over Time

Figure 3: LH Reduction from Baseline Over Time



In 2017, we conducted a Phase 1 PK and PD clinical trial to assess two different doses of add-back therapy in patients receiving 100 mg and 200 mg doses of linzagolix over six weeks. The results of this clinical trial, which we announced in June 2017, supported our add-back therapy dose (1mg E2 / 0.5mg NETA) and linzagolix doses being utilized our clinical trials. We are planning to utilize solely the 200 mg dose in our Phase 3 endometriosis clinical trials that we started in May 2019.

In 2018, we completed a drug-drug interaction study for the organic anion-transporting polypeptide (OATP) 1B1 and OATP1B3, which demonstrated that clinically relevant drug interactions between linzagolix and OATP1B1 / OATP1B3 inhibitors are not to be expected.

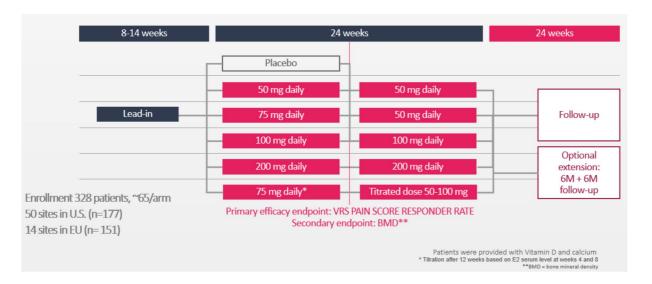
#### Completed Phase 2a Clinical Trials

Kissei completed three Phase 2a clinical trials of linzagolix in patients of Japanese descent with endometriosis in 2013 and 2014. In these studies (KLH1201, KLH1202, and KLH1202), which evaluated doses of 50, 75, 100, or 200 mg of linzagolix or placebo, linzagolix demonstrated improvement in endometriosis-associated pain and showed dose-dependent E2 suppression. These studies supported the design and dose selection for the EDELWEISS 1 Phase 2b trial.

#### Completed Phase 2b Clinical trial EDELWEISS 1 —Endometriosis-Associated Pain

In 2019, we completed our Phase 2b EDELWEISS 1 clinical trial in patients with endometriosis. In this trial, women with moderate-to-severe endometriosis-associated pain were recruited from 64 gynecological clinics across the U.S. and Europe. The trial included a screening period, two consecutive 12-week treatment periods (Part A and Part B) followed by an optional 28 week treatment extension phase or, for those who did not enter the optional treatment extension phase, a 24-week PTFU. In total, 328 subjects were randomized to 1 of 6 treatment groups: placebo, fixed dose groups at 50 mg, 75 mg, 100 mg and 200 mg daily and a 75 mg titrated dose group. In the placebo group, the placebo was provided for 12 weeks (Part A) after which all placebo subjects were crossed over on to active treatment (100 mg daily) for a further 12 weeks (Part B). In the titrated dose arm, all subjects started on 75 mg daily for 12 weeks (Part A) after which the dose was titrated up to 100 mg or down to 50 mg or remained the same (75 mg) for the next 12 weeks (Part B), based on the mean of serum E2 results collected at Weeks 4 and 8. The majority (71%) of subjects who completed the 24-week treatment entered the optional treatment extension, where they received linzagolix for an additional 28 weeks. Subjects randomized to the 200 mg group, received 100 mg daily dose of linzagolix during the extension treatment, while subjects in all other groups continued the treatment they were receiving at the end of Part B. The trial design is provided in Figure 4 below.

Figure 4: Design of Phase 2b EDELWEISS Clinical Trial



Menstrual (dysmenorrhea) and non-menstrual pelvic pain (NMPP) were assessed with a 4-point Verbal Rating Scale, or VRS, and an 11-point Numeric Rating Scale, or NRS. The primary endpoint of the EDELWEISS clinical trial was a responder analysis, with responses defined as a reduction of at least 30% in combined menstrual and non-menstrual pelvic pain, recorded daily and assessed via electronic diary over the last 28 days of treatment on a verbal rating scale (VRS) of 0 (no pain) through 3 (severe pain). The key secondary safety endpoint was the bone mineral density after 24 weeks of treatment assessed with a dual-energy x-ray absorptiometry scan (DXA).

In June 2018, we announced that the EDELWEISS clinical trial successfully met its primary endpoint, a statistically significant difference in patient response rate vs. placebo following 12 weeks of treatment. Observed response rates were 34.5% for placebo, 61.5% for 75mg linzagolix and 56.3% for 200mg linzagolix.

With respect to the dysmenorrhea (DYS), VRS scale, patients receiving a 200 mg dose reported the highest responder rate at 78.9%, compared to a placebo responder rate of 28.5%. Response to doses from 75 mg and above were highly statistically significant. Responder rates for the non-menstrual pelvic pain (NMPP) VRS scale endpoint were statistically significant for the 75 mg dose and the 100 mg dose, and both doses showed comparable responder rates at 58.5% and 61.5% respectively.

In addition, the 75, 100 and 200 mg doses of linzagolix were observed to improve dyschezia and patient well-being as assessed by Endometriosis Health Profile-30 score (EHP- 30), Patient Global Impression of Change (PGIC) scale, Patient Global Impression of Severity (PGIS), the activity impairment score and the modified Biberoglu & Behrman score. Dyspareunia was also improved for all doses and reached statistical significance at the 200 mg dose.

In general, treatment effects observed at Week 12 at all linzagolix doses were maintained or further improved at Week 24, and generally maintained until Week 52. Treatment with linzagolix demonstrated clinical benefit over a 52-week continuous daily administration in alleviating endometriosis-associated pain symptoms. The greatest benefits were derived by subjects treated at doses of 75 mg and above. Significant reductions in pelvic pain were observed at Week 12 and maintained or increased at Weeks 24 and 52. This long-term treatment with linzagolix showed sustained reductions in dysmenorrhea, non-menstrual pelvic pain, dyspareunia and dyschezia, as well as improvements in quality of life and subject assessment of endometriosis severity.

The key safety endpoint for linzagolix is BMD loss due to suppression of estradiol. In the 75 mg treatment group, the mean BMD loss for lumbar spine at 6 months was -0.798% with the lower boundary of the 95% confidence interval of BMD reduction from baseline to week 24 at -1.57%; therefore, we believe that this dose could be given chronically with an appropriate benefit/risk ratio without the need for ABT. By contrast, in the linzagolix 200 mg group, the mean BMD at lumbar spine decreased by more than -2.5% after 6 months of treatment, which indicates the need for combining the high dose of linzagolix with ABT.

Linzagolix was well-tolerated during long-term administration of up to a year. In line with the therapeutic class and mechanism of action, the most frequently reported related treatment-emergent adverse event (TEAE) was hot flush, which was more frequently reported at the higher doses. Changes in BMD between baseline and Week 52, measured by DXA scan, were consistent with the values observed after 24 weeks of treatment. BMD loss for the linzagolix 75 mg dose was within an acceptable range, whereas the decrease with linzagolix 200/100 mg dose was clinically relevant. Consequently, for confirmatory testing, we are combining the 200 mg dose with estrogen/progestin add-back therapy (E2 1 mg/NETA 0.5 mg) to avoid significant BMD loss during chronic administration.

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 ABT, and a 200 mg once daily dose in combination with ABT. With regards to the titration scheme, although there were some numerical differences between treatment groups, we did not conclude there was sufficient benefit to continue further development, and are instead focused upon fixed dosing of linzagolix.

### Ongoing Phase 3 Clinical trial EDELWEISS 3 —Endometriosis-Associated Pain

After discussion of the planned Phase 3 trial design with the FDA during an End of Phase 2 meeting in December 2018, we initiated the Phase 3 program in 2019. Our Phase 3 program initially consisted of two clinical trials: EDELWEISS 2, designed to enroll approximately 450 patients (150 per arm) in the United States and Puerto Rico, and EDELWEISS 3 designed to enroll approximately 450 patients (150 per arm) across sites in the U.S., as well as Canada, Europe and CIS countries. In these two double-blind, placebo-controlled trials, we will evaluate two once daily doses of linzagolix, the 75 mg without ABT and 200 mg with ABT. Patients report their pain on a daily basis with an electronic diary.

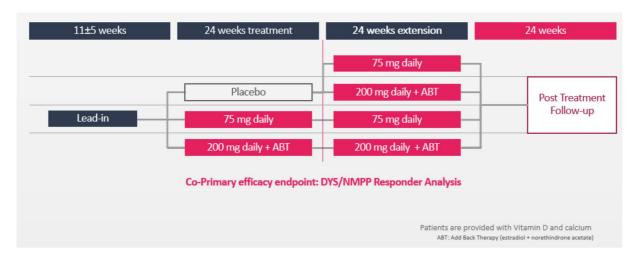
The data will be analyzed at 24 weeks after initial treatment. After the initial 24-week evaluation period, an optional extension study will be proposed to patients. In this extension study, patients receiving placebo will be randomly allocated to either 75 mg without ABT or 200 mg with ABT, whereas patients on active doses of linzagolix will continue on their respective dose. The co-primary endpoint will be a responder analysis of Dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) performed after 12-weeks of treatment. After treatment, all patients will be followed for at least an additional 24-week treatment-free period.

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.

In January 2021, we announced our decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing pandemic. We are planning to conduct, as soon as is feasible, a new Phase 3 clinical trial for endometriosis with a number of design and operational changes to facilitate faster enrollment, with a goal to maintain the original MAA and NDA filing timelines for this indication. Our EDELWEISS 3 clinical trial is progressing and continuing as planned, with primary endpoint data at 24 weeks expected in the fourth quarter of 2021.

Figure 5 below depicts the trial design of the Phase 3 EDELWEISS 3 clinical trial:

Figure 5: Design of Phase 3 EDELWEISS 3 Clinical Trial



## Safety Results of Phase 1, Phase 2a and Ongoing Phase 2b and Phase 3 Clinical Trials

As of February 2021, more than 2,160 subjects have been exposed to linzagolix in completed studies and more than 450 subjects in ongoing clinical studies and linzagolix has been generally well tolerated.

In the three completed Phase 1 clinical trials (n=177), adverse events were reported with similar frequency in all groups, including the placebo group. No serious adverse events were reported.

In the three completed Phase 2a clinical trials (n=128), almost all of the adverse events were mild. The most common adverse events were abnormal bleeding from the uterus, upper respiratory tract infection, headaches and hot flushes. Most hot flushes were mild, three were moderate in severity and none were severe. No serious adverse events were reported in the KLH1203 trial. A single serious adverse event was observed in each of the KLH1201 and KLH1202 trials and both were determined by the principal investigators to be unrelated to linzagolix.

In the PRIMROSE trials in European and US subjects (n=1037), a BMD decrease in line with previous studies was observed. The most frequently observed adverse events (occurring in > 5% of patients in any active treatment group) were headache, hot flushes, anemia and nausea. Headache was reported with a higher incidence in the 200 mg group (11.9%) compared to placebo (5.7%) and other linzagolix groups ( $\le 7.2\%$ ). The incidence of hot flushes during the first 24 weeks of treatment was dose-dependent. The highest incidence of hot flushes was observed in the linzagolix 200 mg group (33.3%), which is consistent with the mechanism of action of linzagolix. Rates of hot flushes were similar in the 100 mg (10.1%) and

200 mg+ABT groups (9.6%), compared with 5.3% in the placebo arm, which demonstrates that the use of ABT combined with linzagolix 200 mg dose alleviates hormone-related TEAEs such as hot flushes. On-treatment anaemia was generally reported with a similar frequency between the placebo (6.7%) and linzagolix arms ( $\leq$ 10.1%). The rate of nausea was highest in the 200 mg group (5.2%); rates in all other arms were similar to placebo. As expected, a dose dependent BMD changes were observed in all active treatment arms and changes in BMD were mitigated by the concomitant use of hormonal ABT. Elevations in lipids and liver transaminases were observed with incidences generally consistent with those seen in other GnRH receptor antagonists, and appear to be a class effect.

In the EDELWEISS 1 Phase 2b clinical trial in European and U.S. subjects (n=327), headaches were the most frequently reported TEAE followed by hot flushes. The occurrence of headaches did not show any dose-dependent increase and ranged from 20.2% to 29.8%. The occurrence of hot flushes increased with increasing dose, but their intensity was most often mild to moderate. A dose-dependent decrease in BMD was observed.

## Ebopiprant (formerly OBE022): Our PGF<sub>2</sub>α Receptor Antagonist for the Treatment of Preterm Labor (GA 24-34 weeks)

We are developing ebopiprant (formerly OBE022) as a potential first-in-class, once daily, or all and selective  $PGF_{2\alpha}$ , receptor antagonist for the treatment of preterm labor in weeks 24 to 34 of pregnancy.  $PGF_{2\alpha}$  is a naturally occurring prostaglandin that acts to induce labor in pregnant women. Through specific antagonism of the  $PGF_{2\alpha}$  receptor, ebopiprant is designed to control preterm labor by reducing inflammation, decreasing uterine contractions and preventing cervical changes and membrane ruptures. Based on its PK profile and efficacy observed in animal models, we believe ebopiprant has the potential to become a first-in-class therapy to suppress premature labor and delay or avoid preterm birth while also being safe for the fetus. In February 2017, we completed a Phase 1 clinical trial assessing the safety, tolerability and PK profile of ebopiprant in healthy post-menopausal female volunteers after single doses of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day over 7 consecutive days. Ebopiprant was observed to have a favorable pharmacokinetic profile, no clinically significant food effect, a favorable safety profile and to be well-tolerated at doses up to 1,300 mg after single dose administration and up to 1,000 mg per day after multiple dose administration over 7 days, each of which are above the estimated clinical effective dose. In March 2017, we completed a set of drug-drug interaction, or DDI, Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of ebopiprant when combined with magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in pre-menopausal female volunteers. Ebopiprant in combination with those drugs was observed to have a favorable safety profile and to be well-tolerated up to 1,100 mg per day, which was the highest tested dose. In December 2017, we announced the initiation of our Phase 2a proof-of-concept clinical trial of ebopiprant known as PROLONG, which is being conducted in two parts: Part A and Part B. In this trial, ebopiprant is orally administered daily for 7 days to pregnant women, who are already receiving standard of care therapy for preterm labor, atosiban infusion for 48 hours. Part A is an open-label trial assessing the safety and pharmacokinetics of ebopiprant. Part B, is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of ebopiprant. In November 2020, we announced positive results for the PROLONG Proof-of-Concept Trial. The efficacy endpoints were delivery within 48 hours of starting treatment, delivery within 7 days of starting treatment, delivery before 37 weeks of gestation, and time to delivery. Safety assessments included maternal, fetal and neonatal safety. Infants are being followed-up at 6, 12

In this study, 113 women with spontaneous preterm labor (gestational age between 24 and 34 weeks) were randomized and treated with atosiban (ex-U.S. standard of care) plus ebopiprant or atosiban plus placebo for 7 days. There were 83 (73%) women with singleton pregnancies and 30 (27%) with twin pregnancies. One hundred and forty-one neonates were born. Overall, 7/56 (12.5%) of women receiving ebopiprant delivered within 48 hours of starting treatment compared to 12/55 (21.8%) receiving placebo (OR 90% CI: 0.52 (0.22, 1.23)). In singleton pregnancies, 5/40 (12.5%) of women receiving ebopiprant delivered within 48 hours compared to 11/41 (26.8%) receiving placebo (OR 90% CI: 0.39 (0.15, 1.04)) which is a reduction of delivery in singleton pregnancies at 48 hours 55% compared to atosiban alone. A modest effect on delivery at 7 days was seen in the singletons.

The incidence of maternal, fetal and neonatal adverse events were comparable between subjects in the ebopiprant group and the placebo group. Follow-up of infants at 6, 12 and 24 months after birth is continuing and results will be available in 2021 and 2022. These data results support advancement of ebopiprant to Phase 2b dose range finding, that we plan to initiate in Europe and Asia in the fourth quarter of 2021, including testing of higher doses, which will allow us to more fully define this product's potential and the longer-term benefits for babies.

### **Background and Impact of Preterm Labor**

Preterm labor, defined as the body commencing the birthing process prior to 37 weeks, is characterized by uterine contractions, cervical dilation and rupture of the fetal membranes that surround and protect the fetus during pregnancy. According to a study published in the Lancet in 2012, approximately 15 million babies were born preterm in 2010, accounting for 11.1% of all live births worldwide. In the 65 countries with reliable data for preterm birth, 62 countries had increasing rates of preterm birth over the period from 1990 to 2010. According to the National Center for Health Statistics, the United States' preterm birth rate was 9.6% in 2014, which, according to the March of Dimes Foundation, ranks among the worst of high-resource countries. In 2007, the Institute of Medicine reported that the cost associated with premature birth in the United States was approximately \$26.2 billion each year.

According to the World Health Organization, preterm birth is the leading worldwide cause of neonatal death, defined as death in the first 28 days of life. Preterm birth complications are also the leading cause of death in children under the age of five, having caused nearly one million deaths in 2013 worldwide. Infants who survive preterm birth may have lifelong health problems such as cerebral palsy, vision and hearing impairment and intellectual disabilities. Approximately one-third of children born prematurely need special school services, according to the March of Dimes Foundation.

## Role of Prostaglandins in Preterm Labor

Prostaglandins play a major role in the normal function of the female reproductive system. There are various prostaglandins at work in the human body with different functions, such as prostaglandin E2, or PGE2, and PGF $_{2\alpha}$ . PGE2 and PGF $_{2\alpha}$  have opposing effects on the female reproductive system. PGE2 causes the widening of blood vessels. PGE2 is produced by the fetus and is important in fetal physiology and development, and therefore, blocking its action has the potential to produce unwanted fetal effects. By contrast, PGF $_{2\alpha}$  is a constrictor of the myometrium and uterine blood vessels. PGF $_{2\alpha}$  is present in the uterus and plays a major role in the initiation and process of childbirth. PGF $_{2\alpha}$  modulates various functions leading to the progression of labor and is involved in all aspects of childbirth including ripening of the cervix, membrane rupture and induction of uterine contraction. PGF $_{2\alpha}$  promotes the establishment of a pro-inflammatory intra-uterine environment by stimulation of pro-inflammatory cytokine and chemokine production in the myometrium, leading to the initiation of labor.

# **Limitations of Current Treatment Options**

Various classes of pharmaceutical agents that decrease uterine contractions, also known as tocolytics, are used to treat preterm labor. These different classes act on the uterine muscle through various mechanisms of action but have limited efficacy, restrictive safety issues and are all used off-label in the United States. These different classes include nifedipine, a calcium channel blocker, magnesium sulfate, indomethacin (a NSAID) and glyceryl trinitrate, each of which have been observed to have limited efficacy and/or safety issues. Beta-adrenergic agonists have been largely discontinued because of severe maternal cardiovascular side effects. Atosiban, an oxytocin receptor antagonist, is approved in Europe and most of Asia, but not in the United States. It can treat preterm labor, but is administered through a bolus injection followed by an infusion and is not indicated for dosing beyond 48 hours.

Reviews of these different classes of tocolytic drugs concluded that prostaglandin synthesis inhibitors, such as NSAIDs, provided the best efficacy for delaying labor at 48 hours and seven days. According to a study published in Obstetrics & Gynecology in 2009, prostaglandin antagonists were most effective at delaying delivery at 48 hours and seven days among the class of drugs available in the United States. Delaying delivery as long as possible up to full term is ideal, but delaying delivery by at least 48 hours is significant because betamethasone (a corticosteroid) can be administered to the mother to mature the baby's lungs so the baby can potentially breathe on its own. The table below, which shows the results of that study, displays the percentage of patients that did not deliver a baby at various time points following treatment.

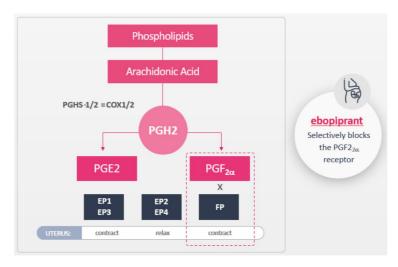
Figure 6: Weighted Percentages of Tocolytic Agents for Efficacy

Delay	of	De	livery
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	48 Hours	7 Days
Placebo/Control	53 (45-61) [9]	39 (28-49) [8]
Betamimetics	75 (65-85) [29]	65 (59-71) [26]
Calcium-Channel Blocker	76 (57-95) [17]	62 (56-69) [10]
Magnesium Sulfate	89 (85-93) [11]	61 (39-84) [5]
Oxytocin Receptor Antagonists	86 (80-91) [8]	78 (68-88) [6]
Prostaglandin Inhibitors	93 (90-95) [8]	76 (67-85) [3]

- · Data presented as percentage of women experiencing delay
- () = 95% confidence interval
- . [] = number of studies

Figure 7: Mode of action of ebopiprant



Currently available prostaglandin inhibitors, such as the NSAID indomethacin, act by non-selective inhibition of prostaglandin-forming enzymes, thus blocking the generation and signaling of many prostaglandin sub-types, including both PGE2 and PGF $_{2\alpha}$ . Because they potentially adversely affect fetal physiology, use of NSAIDs is restricted to 48 hours in women at gestational age below 32 weeks, due to these unwanted side effects. According to a publication in 2015 in the American Journal of Obstetrics and Gynecology, the most concerning side effects associated with the non-selective prostaglandin inhibitors include severe conditions in newborn babies, such as renal function impairment, premature closure of the ductus arteriosus (i.e., constriction of the blood vessel connecting the pulmonary artery to the aorta), bleeding in the area surrounding the fluid-filled areas of the brain, necrotizing enterocolitis, which is a serious condition that occurs when the intestinal tissue blood flow is damaged and causes tissue death, and periventricular leukomalacia, which is a form of brain injury that can lead to serious disabilities.

As a result of the limited efficacy and unfavorable safety profile of many current therapies used off-label to treat preterm labor, we believe there remains a significant unmet need for a selective prostaglandin inhibitor focused on the specific inhibition of  $PGF_{2\alpha}$  to delay preterm labor and provide a safe treatment option for both mother and child.

### **Ebopiprant Preclinical and Clinical Development**

Ebopiprant was discovered and initially developed by Merck Serono as a selective inhibitor of  $PGF_{2\alpha}$ . We in-licensed ebopiprant from Merck Serono in 2015. In preclinical studies, ebopiprant was observed to reduce uterine contractions and to exert a synergistic effect in combination with nifedipine to delay delivery. We advanced ebopiprant into a Phase 2a proof-of-concept clinical trial in December 2017 to assess its safety and efficacy to delay birth in women 24 to 34 weeks pregnant in preterm labor with threatened preterm delivery. In February 2017, we completed a Phase 1 clinical trial assessing the safety,

tolerability and PK profile of ebopiprant in healthy post-menopausal female volunteers after single doses of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day over 7 consecutive days. Ebopiprant was observed to have a favorable PK profile, no clinically significant food effect, a favorable safety profile and to be well-tolerated at doses up to 1,300 mg after single dose administration and up to 1,000 mg per day after multiple dose administration over 7 days. In March 2017, we completed a set of DDI Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of ebopiprant when combined with magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in pre-menopausal female volunteers. Ebopiprant in combination with those drugs was observed to have a favorable safety profile and to be well-tolerated up to 1,100 mg per day, which was the highest tested dose.

### Preclinical Development

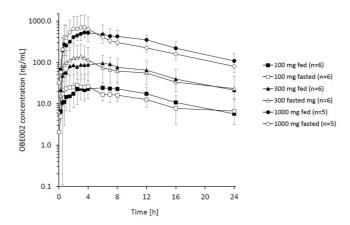
In the preclinical pharmacology, PK and toxicology studies conducted by Merck Serono, ebopiprant was observed to be a highly selective, competitive and reversible  $PGF_{2\alpha}$  receptor antagonist with over 100 times the affinity for it compared to other prostaglandin receptor subtypes. Ebopiprant has been observed to have tocolytic effects in vitro and in vivo by markedly reducing spontaneous uterine contractions in a preterm labor animal model. At the Society for Reproductive Investigations'  $64^{th}$  Annual Scientific Meeting in March 2017, we presented results of a non-clinical study in which we observed that ebopiprant exerted a synergistic effect in combination with nifedipine on the delay of delivery in an animal model for preterm labor. The study evaluated the effect of ebopiprant and nifedipine, alone and in combination with each other, on an animal model of RU486-induced birth in pregnant mice. The induction of labor by the antiprogestin RU486 results from inhibition of progesterone activation leading to the up-regulation of labor-associated proteins as seen in the case of idiopathic preterm labor. Compared to the vehicle control, we observed nifedipine (5mg/kg, taken orally), as well as ebopiprant (100mg/kg, taken orally), alone resulted in statistically significant delays in RU486-induced preterm labor. We also observed a synergistic effect of combination treatment with ebopiprant and nifedipine on the delay of delivery when compared to vehicle, nifedipine or ebopiprant alone (p<0.001, p<0.001 and p<0.001, respectively).

Preclinical studies have also been conducted to support oral administration of ebopiprant in humans. Overall, the toxicological profile of ebopiprant observed in repeated-dose toxicity studies in rats and dogs as well as reprotoxicity in rabbits and rats appeared to be benign. We also conducted safety studies to evaluate ebopiprant compared to NSAIDs in pregnant rats prior to delivery. In these studies, we observed that the NSAID indomethacin induced, as expected, constriction of the blood vessel connecting the pulmonary artery to the aorta and impaired the renal function in the newborn rats, while ebopiprant did not. In addition, we have observed that ebopiprant does not inhibit platelet aggregation whereas the NSAIDs were confirmed to significantly inhibit it, which is considered to be a potential risk factor for neonatal tissue hemorrhage, e.g. periventricular brain hemorrhage. Based on the results of these preclinical studies, we believe that ebopiprant has the potential to be an effective, safer tocolytic agent for the treatment of preterm labor.

#### Phase 1 Clinical Trials

We completed a Phase 1 clinical trial assessing the safety, tolerability and PK profile of ebopiprant when administered in approximately 70 healthy post-menopausal female volunteers as single and multiple ascending doses at one site in the United Kingdom. As  $PGF_{2\alpha}$  is also involved in uterine contractions and the related pain that can occur during normal menstruation in non-pregnant women, we are assessing the feasibility of measuring the ability of ebopiprant to reduce the intra-uterine pressure and the pelvic pain scores in healthy female volunteers of child bearing age during menstruation. From the single doses administered of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day administered over 7 consecutive days in the completed Phase 1 clinical trial, we observed that pro-drug ebopiprant was readily absorbed and rapidly converted into its equally active stable metabolite ebopiprant. The plasma level of ebopiprant increased with increasing doses of ebopiprant, reaching exposure levels that were anticipated to be clinically relevant within an hour following administration. There was no clinically significant food interaction with peak exposures reduced to 80% and AUC staying bioequivalent. The mean half-life of ebopiprant ranged between 8 and 11 hours following administration of a single dose and between 22 to 29 hours after multiple doses (figure 8). Single and multiple administrations of ebopiprant were well tolerated at all doses. There have been no serious adverse events and no clinically relevant changes in safety parameters.

Figure 8:



We also completed a set of DDI Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of ebopiprant when combined with therapeutic doses of magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in premenopausal female volunteers. We performed an open-label, randomized, three-period crossover trial assessing co-administration of single doses of ebopiprant (1100 mg) and MgSO4 (15.5g) and also performed an open-label, single-sequence crossover trial assessing the interactions of ebopiprant (1000 mg/d) at steady-state co-administered with single doses of atosiban (60.75 mg), nifedipine (20 mg) and betamethasone (12 mg). Both trials enrolled 12 healthy non-pregnant women of reproductive age at one clinical center in the United Kingdom. There were no clinically relevant pharmacokinetic interactions between ebopiprant and MgSO4, betamethasone or atosiban; however, nifedipine exposure increased notably. Co-administration of ebopiprant with MgSO4, betamethasone, atosiban and nifedipine was generally well tolerated.

### Phase 2a Clinical Trial (PROLONG) - Acute Preterm Labor

Based on these Phase 1 clinical trial results, we initiated the PROLONG Phase 2a proof-of-concept clinical trial. The trial objectives are to assess the pharmacokinetic, the safety and efficacy of ebopiprant when co-administered with atosiban, to delay birth after oral administration in pregnant women in active preterm labor and threatened preterm delivery. The study population included women who were at least 24 weeks and less than 34 weeks pregnant, with intact amniotic membranes, presenting with spontaneous preterm labor for which they received atosiban for 48 hours and had no contraindications to a prolongation of pregnancy.

The PROLONG Phase 2a trial was conducted in two parts: Part A and Part B. Part A was an open-label trial of ebopiprant administered orally, with a loading dose of 1000 mg, then 500 mg twice a day for 7 days to pregnant women with threatened preterm labor. Ebopiprant pharmacokinetics and maternal, fetal and infant safety were assessed. Fetal cardiac safety was monitored using Doppler ultrasound. Time to delivery was also measured. Nine patients were included in this part. Eight of the nine patients did not deliver within the 7 days of ebopiprant treatment and one patient delivered the day after starting ebopiprant. Ebopiprant was observed to be well absorbed from Day 1 to Day 7 and steady-state serum concentrations and pharmacokinetics were comparable to those observed previously in non-pregnant women. Ebopiprant administration was observed to be well tolerated by the mother and there were no fetal adverse events reported. There were also no clinically significant abnormal findings on Doppler ultrasound including no constrictive effect on the ductus arteriosus. The results were presented at the 66th Annual Scientific Meeting of the Society for Reproductive Investigation from 12th to 16th of March 2019.

In January 2019, based on the favorable safety and pharmacokinetic results we observed in Part A, we announced the initiation of Part B of the PROLONG trial, which is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of ebopiprant. We enrolled 113 patients with preterm labor at a gestational age of 24 to 34 weeks. As in Part A, ebopiprant or placebo has been administered orally, with 1,000 mg as a starting dose, then 500 mg twice a day for 7 days to women already receiving atosiban infusion for 48 hours.

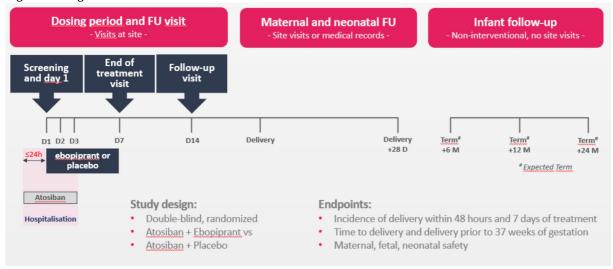
In November 2020, we announced positive results for the PROLONG proof-of-concept trial. The efficacy endpoints were delivery within 48 hours of starting treatment, delivery within 7 days of starting treatment, delivery before 37 weeks of gestation, and time to delivery. Safety assessments included maternal, fetal and neonatal safety. Infants are being followed-up at 6, 12 and 24 months.

In this study, 113 women with spontaneous preterm labor (gestational age between 24 and 34 weeks) were randomized and treated with atosiban (ex-U.S. standard of care) plus ebopiprant or atosiban plus placebo for 7 days. There were 83 (73%) women with singleton pregnancies and 30 (27%) with twin pregnancies. One hundred and forty-one neonates were born. Overall, 7/56 (12.5%) of women receiving ebopiprant delivered within 48 hours of starting treatment compared to 12/55 (21.8%) receiving placebo (OR 90% CI: 0.52 (0.22, 1.23)). In singleton pregnancies, 5/40 (12.5%) of women receiving ebopiprant delivered within 48 hours compared to 11/41 (26.8%) receiving placebo (OR 90% CI: 0.39 (0.15, 1.04)), a reduction of delivery in singleton pregnancies at 48 hours of 53% compared to atosiban alone. The treatment effect was greater in the earlier gestational age group compared to the later gestational age group. Overall, a modest effect on delivery at 7 days was seen in singletons; however, a marked effect was observed in the 24-30 week singleton pregnancies, with 23.8% vs 14.3% (OR 90% CI: 0.53 (0.14, 2.01) of women delivering within 7 days in the placebo versus ebopiprant arms, respectively, a 40% reduction. No effect was seen in twin pregnancies, consistent with a different mechanism of action for preterm labor in singletons versus twins.

The incidence of maternal, fetal and neonatal adverse events was comparable between subjects in the ebopiprant and placebo groups. Follow-up of infants at 6, 12 and 24 months after birth is continuing and results will be available in 2021 and 2022. These results support advancement of ebopiprant to Phase 2b dose range finding, that we plan to initiate in Europe and Asia in the fourth quarter of 2021, including testing of higher doses, which will allow us to more fully define this product's potential to treat preterm labor and the longer-term benefits for babies.

Figure 9 below depicts the trial design of the Phase 2 PROLONG clinical trial:

Figure 9: Design of Phase 2 PROLONG clinical trial



# Nolasiban in IVF

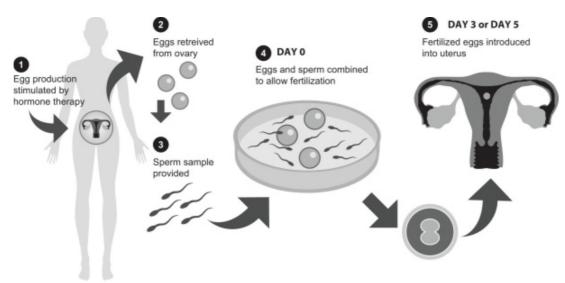
Nolasiban is an oral oxytocin receptor antagonist that is being developed to improve clinical pregnancy and live birth rates in women undergoing embryo transfer following IVF, including intracytoplasmic sperm injection, or ICSI. The mechanism of action of nolasiban supports its potential to improve uterine receptivity by decreasing uterine contractions, improve uterine blood flow and enhance the receptivity of the endometrium to embryo implantation. We inlicensed nolasiban from Merck Serono, which had previously completed preclinical studies and Phase 1 clinical trials in 103 healthy female volunteers that evaluated the safety and PK profile of nolasiban.

### Background on Assisted Reproductive Technology (IVF/ICSI)

Infertility is a condition of the reproductive system that impairs the body's ability to reproduce. From 2006 to 2010, the inability to have a child affected approximately 6.7 million women in the United States, which represented approximately 11% of the reproductive-age population. An increasing number of women in developed countries are delaying having children until their mid-thirties, which has resulted in decreased fertility rates and increased demand for reproductive therapies.

ART is used primarily for infertility treatments. According to the Centers for Disease Control and the European Society of Human Reproduction and Embryology, IVF represents the vast majority of ART treatments or procedures. IVF helps women achieve pregnancy by the collection of mature eggs in the ovaries, followed by fertilization and early embryo development in the laboratory before transfer of the embryos into the womb. According to the European Society of Human Reproduction and Embryology, more than 2.0 million ART cycles are performed worldwide. In Europe, ART treatments doubled from 2000 to 2010, and nearly 800,000 IVF cycles were performed in 2014. In the United States, IVF treatments increased by 41.7% from 2010 to 2014. Approximately 230,000 IVF treatments were performed in the United States in 2015. In Japan, approximately 400,000 IVF treatments were performed in 2015. In China, more than 700,000 ART cycles were performed in 2017, and year over year growth is double digit supported by government policies related to childbirth. We are currently assessing the regulatory development pathway in China, as well as various alternatives for future potential commercialization.

The first step in IVF is stimulation of egg production. Approximately ten days later, the eggs are harvested from the ovaries, otherwise known as ovum pick-up, or OPU, and co-incubated with sperm cells, with this day being referred to as Day 0. The resulting embryos are either used for fresh transfer to the uterus over the next three to five days or frozen for future use. In Europe in 2012, we estimate that approximately 39% of all embryo transfers occur three days after Day 0 and an additional 36% occur five days after Day 0, with the remaining 25% frozen for future transfer. In the United States in 2015, we estimate that the respective percentages were 19% (Day 3, or D3), 38% (Day 5, or D5) and 43% (frozen-thawed embryo transfers). The figure below depicts the IVF procedure:

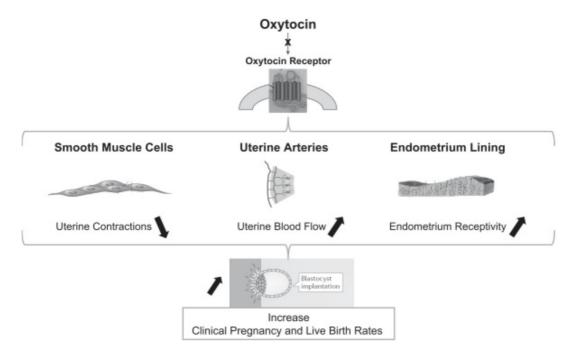


The cost of one IVF cycle varies between \$8,000 to \$15,000 in the United States, EUR 2,000 to EUR 10,000 in Europe and \$3,000 to \$6,000 in Japan. As of 2006, fertility drugs account for more than \$2,000 of the cost of a treatment cycle. Most patients require multiple fertility treatment cycles. Data from IQVIA estimates that global sales of fertility drugs approximated \$2.7 billion in 2017.

The success of IVF depends on the quality of the embryo, the transfer procedure and ultimately the receptivity of the uterus. In order for the embryo transfer to be successful, it is important for the uterus to be receptive to embryo implantation, which includes a proper hormonal environment, appropriate blood flow within the uterus, and minimal uterine contractions at the time of embryo transfer. The endometrium is the inner layer of the uterus that is in direct contact with the implanting embryo.

#### Role of Oxytocin in Embryo Implantation

Oxytocin is a hormone that is secreted by the pituitary gland. Oxytocin receptors are present in uterine smooth muscle cells, the endometrium and the uterine arteries. The release of oxytocin by the pituitary gland activates oxytocin receptors, which results in uterine contractions. As shown in the graphic below, blocking the activation of uterine oxytocin receptors at the time of embryo transfer may enhance uterine receptivity by decreasing uterine contractions, improving uterine blood flow and enhancing the receptivity of the endometrium to embryo implantation, which can lead to increased clinical pregnancy and live birth rates.



A systematic review and meta-analysis of investigator-sponsored trials conducted in 2014 and published in Fertility & Sterility concluded that pregnancy rates doubled with the infusion of an oxytocin receptor antagonist at the time of embryo transfer. As part of this analysis, it was observed that improvement in pregnancy rates was not restricted to women with a high rate of uterine contractions. According to this analysis, additional mechanisms, such as endometrium receptivity and uterine blood flow, may also contribute to improving pregnancy rates. A systematic review and meta-analysis of investigator-sponsored trials conducted in 2017 and published in PLOS/one by Qian-Yi Huang also concluded that clinical pregnancy rate was significantly increased with the infusion of an oxytocin receptor antagonist at the time of embryo transfer (OR = 1.84, 95% CI: 1.31±2.57; P < 0.001), but not the live birth rate (P=0.083). Moreover, in a recent trial published in 2016 involving patients with endometriosis undergoing frozen-thawed embryo transfer, clinical pregnancy rates were approximately 20% higher after treatment with an oxytocin receptor antagonist, representing a 51% increase relative to the placebo. In addition, according to studies published in Archives of Gynecology and Obstetrics in 2011, women who received an oxytocin receptor antagonist after embryo transfer, were observed, based on three-dimensional power Doppler ultrasound, to have improved characteristics for uterine receptivity, including enhanced endometrial blood flow.

# The nolasiban clinical development program

We previously conducted a Phase 3 clinical development program for nolasiban to evaluate its potential to improve clinical pregnancy and live birth rates for women undergoing IVF. In 2018, we completed a Phase 3 clinical trial in Europe, which we refer to as IMPLANT 2. This was a Phase 3 trial in women undergoing Day 3 (D3, n=388) and Day 5 (D5, n=390) fresh single embryo transfer (SET) following IVF. 778 subjects were randomized from 41 fertility clinics in Europe. 900 mg of nolasiban or placebo was administered as a single dose 4 hours before ET. The primary endpoint was ongoing pregnancy rate (confirmed by ultrasound observation of one gestational sac and at least one positive fetal heartbeat) at 10 weeks after ET. Results from this trial demonstrated the efficacy of 900 mg dose on ongoing pregnancy and live birth rate as well as its similar safety profile to placebo.

There was a statistically significant 25% relative increase in ongoing pregnancy rate in the nolasiban 900 mg group compared to placebo (nolasiban 900 mg 35.6%, placebo 28.5%; p=0.031) in the pooled D3/D5 group. There was also a statistically significant 32% relative increase in the ongoing pregnancy rate in the D5 sub-group (placebo 34.7%, nolasiban 900 mg 45.9%; p=0.034). There was no significant increase in the D3 sub-group (placebo 22.2%, nolasiban 900 mg 25.3%; p=0.477). However, the interaction term between the factors treatment and day of ET was not significant (p=0.518), and therefore, there is no conclusive evidence that the nolasiban treatment effect was different following D3 or D5 SET. Relative increases in live birth rates with nolasiban were 26% in the pooled D3/D5 group. The live birth rate in women undergoing Day 5 ET was 44.8% for those receiving nolasiban vs. 33.2% for those receiving placebo (p value = 0.025), a 35% relative increase. Serum pregnancy and clinical pregnancy rates at 6 weeks post-ET followed a similar pattern to the ongoing pregnancy rates. Miscarriage rates (any pregnancy loss up to Week 10 post-ET after a positive serum pregnancy test at Week 2) were numerically higher in the placebo group compared to the nolasiban group (no significance testing was performed for this endpoint). In the pooled D3/D5 population, there were 37 (21%) pregnancy losses in the nolasiban group compared to 44 (28%) in the placebo group.

Furthermore, the safety profile was similar to placebo, and the multiple pregnancy rate was less than 5%. At the 6-month infant follow-up, developmental outcomes showed no notable differences between the nolasiban and placebo groups in terms of ASQ-3 domain scores.

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 have discontinued our previously ongoing development of nolasiban for IVF, and are exploring potential repositioning of the compound, such as through higher dose levels and earlier and longer exposure of nolasiban, as well as focusing on subjects with a high uterus contraction rate at the time of ET. In addition, we performed an individual patient level meta-analysis of the IMPLANT 1, 2, and 4 studies and showed an overall 5% absolute increase in ongoing pregnancy rate which was statistically significant (p=0.029). Furthermore, population PK analyses indicated that higher exposures of nolasiban were associated with a higher probability of pregnancy. These results have been accepted for publication in the peer-reviewed journal, Human Reproduction. A mechanism of study in health volunteers showed evidence that treatment with nolasiban reduces uterine contractions, increases uterine blood flow, and induces changes in genes reported to be associated with endometrial receptivity. The results also suggested the potential for larger effects with higher doses of nolasiban. This study was published in the peer-reviewed journal RBM online. In connection with this potential repositioning, 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. They will fund all development and registration activities in the PRC, starting with the obligation to fund and conduct a Phase 1 trial and a Phase 2 proof-of-concept trial in China. We retain all rights to the product outside of PRC, and have agreed to collaborate with Yuyuan on its global development. Our development and commercialization partnership with Yuyuan proceeded during the 2020 with steering committee meetings to define the development plan for nolasiban in China for women undergoing ET following IVF.

#### Commercialization

We have not yet established a sales, marketing or product distribution infrastructure. In order to commercialize any of our product candidates if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third-parties that have sales and marketing experience. For example, in January 2020, we announced our entrance into a sublicense agreement with Yuyuan to develop and commercialize nolasiban for improving clinical pregnancy and live birth rates in women undergoing embryo transfer following IVF in the PRC. Under the terms of the sublicense agreement, Yuyuan has the exclusive rights to develop and commercialize nolasiban in the PRC. We are also exploring various alternatives for the future potential commercialization of linzagolix, including through a collaboration with a third party. As we move our product candidates through development toward regulatory approval we will evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force, entering into a joint marketing partnership with another pharmaceutical

or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company. We are currently evaluating such options for YSELTY® in anticipation of commencing commercialization activities if and when YSELTY® receives marketing approval.

#### **Manufacturing**

We rely on CMOs to produce our product candidates in accordance with the FDA's cGMP regulations for use in our clinical trials. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control. Replacement of any of our CMOs would require us to qualify new manufacturers and negotiate and execute contractual agreements with them. If any of our supply or service agreements with our CMOs are terminated, we will experience delays and additional expenses in the completion of the development of and obtaining regulatory approval for linzagolix, ebopiprant and nolasiban.

To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase scale of production or we will need to secure alternate suppliers. Pursuant to the Kissei license and supply agreement, we have agreed to exclusively purchase the active pharmaceutical ingredient for linzagolix from Kissei who is now obtaining linzagolix cGMP supply from two suppliers, both of which are different from the supplier who received the warning letter from the FDA in November 2016. If we are unable to obtain sufficient quantities of our products candidates or receive raw materials in a timely manner, we could be required to delay our ongoing clinical trials and seek alternative manufacturers, which would be costly and time-consuming.

The CMOs with whom we currently work will also need to ensure and maintain quality (cGMP compliance, specifications, shelf-life, expiry, in-process-control) throughout the production process of our clinical and commercial supplies. If we are unable to ensure and maintain quality of our products candidates, we could be required to delay our ongoing clinical trials which would be costly and time-consuming.

To mitigate the risks above, our relationships with CMOs are managed by internal personnel with extensive experience in NCE pharmaceutical development and chemistry, manufacturing and controls, or CMC.

#### Competition

Biopharmaceutical product development is highly competitive and subject to rapid and significant technological advancements. Our success is highly dependent upon our ability to in-license, acquire, develop and obtain regulatory approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated, well-established pharmaceutical companies who already possess a large share of the market, specialty pharmaceutical and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the European Union, United States and other jurisdictions.

With respect to linzagolix, in 2018 the first compound in the oral gonadotropin-releasing hormone, or GnRH, receptor antagonist class received regulatory approval in the United States for the treatment of pain associated with endometriosis. AbbVie Inc. has been commercializing elagolix, brand named Orilissa, in the United States since August 2018, and submitted a regulatory application for its uterine fibroids indication in August 2019, for which approval was obtained in May 2020, and now marketed under the brand name Oriahnn (300mg BID + E2 1mg/NETA 0.5 mg QD). We are aware of relugolix (Myovant Sciences, Inc.), another oral GnRH receptor antagonist product candidate being developed in Phase 3 clinical trials for the endometriosis and uterine fibroids indications. In 2019, Myovant reported positive 6-month results for the two Phase 3 trials in the fibroid indication (LIBERTY 1 and 2) and filed a MAA and an NDA on the basis of 52-week treatment data in March 2020 and in June 2020 (with a PDUFA set to June 2021), respectively. In January 2021, Myovant reported positive 1-year results from the SPIRIT trials, and announced the intention to file an NDA for this indication in the first half of 2021. We also anticipate competing with GnRH receptor agonists, including Lupron (leuprolide acetate), marketed by AbbVie Inc. and Takeda Pharmaceuticals, Visanne (dienogest), which is approved for the treatment of endometriosis outside the United States and is marketed by Bayer. Ulipristal acetate, a Selective Progesterone Receptor Modulator (or SPRM) which is approved for the treatment of moderate-to-severe symptoms of uterine fibroids outside the United States and is marketed by Gedeon Richter in Europe and other regions, and by Allergan in Canada. Severe label restrictions regarding usage of ulipristal acetate were added in 2018 which were further restricted in early 2021, due to post marketing liver safety issues. Allergan had submitted an NDA for ulipristal acetate but disclosed receipt of a complete response letter (CRL) from the FDA in August 2018 indicating that the NDA was not approvable in its current form and requesting additional information. Bayer Schering which was conducting an exhaustive clinical development program for Vilaprisan for the treatment of uterine

fibroids and endometriosis, announced that it would be stopping its development activities. In addition, oral contraceptives and nonsteroidal antiinflammatory drugs, or NSAIDs, are routinely used as a first-line therapy for the treatment of symptoms associated with endometriosis and uterine fibroids and have a meaningful success rate at mitigating the symptoms associated with these conditions.

With respect to ebopiprant, Tractotile (atosiban) is approved to delay preterm birth outside of the United States, and we anticipate potential competition as a single agent, if not used in combination with ebopiprant, given their different mechanisms of action. In terms of clinical development, it is our understanding that GlaxoSmithKline terminated the in-house development of retosiban, an oxytocin receptor antagonist, designed to delay preterm birth. Currently available prostaglandin synthesis inhibitors, such as NSAIDs may also represent competitive therapies, some of which may be used off-label as standard of care, despite risk of serious side effects for the neonates.

Makena, which is registered in the USA for preventing preterm labor in high-risk patients is seen as a complement rather than a competitor for ebopiprant, due to its mechanism of action as a preventive measure rather than a treatment for preterm labor. In October 2019, an FDA Advisory Committee voted 9 to 7 for withdrawal of the approval of Makena, given negative results from a required post-approval study. Seven committee members voted to keep Makena on the market with requirement for an additional trial. Subsequently in October 2020, the FDA proposed that Makena be withdrawn from the market based on its conclusion that the available evidence does not show Makena is effective for its approved use.

With respect to nolasiban, there are no other oxytocin receptor antagonists approved either for oral administration or for use in connection with IVF. However, it is our understanding that Ferring Pharmaceuticals Inc. has barusiban in its development pipeline, an oxytocin receptor antagonist, to be administered subcutaneously, that may be developed for use in connection with IVF. Nevertheless, to our knowledge, no new clinical trial activity has been publicly announced since completion of a Phase 2 in 2015. Ferring Pharmaceuticals' atosiban, an oxytocin receptor antagonist, to be administered by continuous infusion, has been used off-label in investigator-initiated trials in connection with IVF outside the United States.

We may also compete with other companies acquiring and developing or marketing drug therapies or products for women's reproductive health diseases.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the biopharmaceutical industry could result in even more resources being concentrated among a small number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than linzagolix, ebopiprant, nolasiban or any other product candidate that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful.

In addition, established biopharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make linzagolix, ebopiprant, nolasiban or any of our future product candidates less competitive.

## **Intellectual Property**

We have filed numerous patent applications and have licensed numerous issued patents and patent applications pertaining to our product candidates and methods of manufacture and clinical use. We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining and defending our intellectual property, whether developed internally or licensed from third parties. For additional information regarding the license agreements to which we are a party, see the sections entitled "2013 License Agreement with Merck Serono," "2015 License Agreement with Merck Serono" and "License and Supply Agreement with

Kissei." We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of reproductive healthcare. Additionally, we intend to rely on regulatory protection afforded through data exclusivity and market exclusivity, as well as patent term extensions, where available.

As of December 31, 2020, our patent portfolio as it pertains to certain of our product candidates included:

- seven United States (U.S.) patents, projected to expire between 2034 and 2035, four U.S. patent applications, which, if granted, project to expire between 2034 and 2041, as well as corresponding patents and patent applications internationally, directed to nolasiban as a composition of matter and uses of nolasiban in assisted reproductive technology;
- one PCT application, which, if granted in the U.S., projects to expire in 2040, directed to compositions of matter containing nolasiban and uses of nolasiban in assisted reproductive technology;
- one U.S. patent, projected to expire in 2037, three U.S. patent applications, which, if granted, project to expire between 2037 and 2041, as well as corresponding patent applications internationally, directed to compositions of matter containing ebopiprant and uses of ebopiprant for the treatment of preterm labor;
- two U.S. patent applications, which, if granted, project to expire in 2038, as well as corresponding patent applications internationally, directed to uses of linzagolix for the treatment of sex hormone-dependent diseases; and
- four PCT applications, which, if granted in the U.S., project to expire between 2039 and 2040, directed to uses of linzagolix for the treatment of sex hormone-dependent diseases.

As of December 31, 2020, our in-licensed patent portfolio as it pertains to certain of our product candidates included:

- one U.S. patent, projected to expire in 2023, as well as corresponding patents and patent applications internationally, directed to nolasiban as a composition of matter;
- four U.S. patents, projected to expire between 2024 and 2036, one U.S. patent application, which, if granted, projects to expire in 2036, as well as corresponding patents and patent applications internationally, directed to ebopiprant as a composition of matter and uses of ebopiprant for the treatment of preterm labor; and
- four U.S. patents, projected to expire between 2030 and 2032, two U.S. patent applications, which, if granted, project to expire between 2031 and 2037, as well as corresponding patents and patent applications internationally outside of specified Asian countries, directed to linzagolix as a composition of matter and uses of linzagolix for the treatment of sex hormone-dependent diseases.

The terms of individual patents may vary based on the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest effective non-provisional filing date in the absence, for example, of a terminal disclaimer shortening the term of the patent or patent term adjustment increasing the term of the patent. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of FDA regulatory review periods. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date.

In addition to the U.S. patents and U.S. patent applications described above, our patent portfolio and our in-licensed patent portfolio include issued patents and pending patent applications in various other jurisdictions. For example, we have obtained, or we license from third parties, issued patents in Europe that pertain to certain aspects of our product candidates described above.

In addition to patents and patent applications that we own and license, we rely on trade secrets and know-how to develop and maintain our competitive position. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, and obtain and maintain ownership of certain technologies, in part, through confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors, and commercial partners.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents; preserve the confidentiality of our trade secrets; and operate without infringing valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to our owned and licensed intellectual property, we cannot be sure that patents will issue from any of the pending patent applications to which we own or license rights or from any patent applications that we or our licensors may file in the future, nor can we be sure that any of our licensed patents or any patents that may be issued in the future to us or to our licensors will be commercially useful in protecting our product candidates and methods of using or manufacturing the same. Moreover, we may be unable to obtain patent protection for certain aspects of our product candidates generally, as well as with respect to certain indications. See the section entitled "Risk Factors—Risks Related to Our Intellectual Property" for a more comprehensive description of risks related to our intellectual property.

## 2013 License Agreement with Merck Serono

In August 2013, we entered into a license agreement, or the 2013 license agreement, with 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, which we are developing for the treatment of conditions associated with ART. 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. With respect to any products we commercialize under the 2013 license agreement, we have agreed to pay Merck Serono quarterly royalties based on our annual net sales of each product at a high-single-digit percentage of annual net sales, subject to specified reductions, until the later of 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 ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

We are solely responsible for the development and commercialization of the product candidates licensed under the 2013 license agreement. Merck Serono has the first right to maintain, prosecute, and even enforce the licensed patent rights. The 2013 license agreement expires on the date of expiration of all royalty obligations, at which time our license becomes fully paid-up, irrevocable, and perpetual. Either party may terminate the 2013 license agreement earlier for an uncured material breach, subject to notice requirements and specified exceptions. Merck may terminate the 2013 license agreement if we or any of our affiliates or sublicensees challenge the licensed patent rights or in the event of our bankruptcy if we do not obtain a sublicensee within two years thereafter. We may also terminate the 2013 license agreement without cause at any time upon advance written notice to Merck Serono. Upon any termination, all license granted to us under the 2013 license agreement terminate.

# 2015 License Agreement with Merck Serono

In June 2015, we entered into a second license agreement with Merck Serono, or the 2015 license agreement, 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 ebopiprant, which we are developing for the treatment of preterm labor in weeks 24 to 34 of pregnancy. In consideration for the license, we agreed to issue 325,000 Series A preferred shares to Merck Serono 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 have agreed to pay Merck Serono quarterly royalties based on our annual net sales of each product at a mid-single-digit percentage of annual net sales, subject to specified reductions, until the later of 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 ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

We are solely responsible for the development and commercialization of the product candidates licensed under the 2015 license agreement. Merck Serono has the first right to maintain, prosecute, and even enforce the licensed patent rights. The 2015 license agreement expires on the date of expiration of all royalty obligations, at which time our license becomes fully paid-up, irrevocable and perpetual. Either party may terminate the 2015 license agreement earlier for an uncured material breach, subject to notice requirements and specified exceptions. Merck may terminate the 2015 license agreement if we or any of our affiliates or sublicensees challenge the licensed patent rights or in the event of our bankruptcy if we do not obtain a sublicensee within two years thereafter. We may also terminate the agreement without cause at any time upon advance written notice to Merck Serono. Upon any termination, all license granted to us under the 2015 license agreement terminate.

## License and Supply Agreement with Kissei

In November 2015, we entered into a license and supply agreement, or the Kissei license and supply agreement, with 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 and we arranged to exclusively acquire from Kissei the material necessary to produce linzagolix. Under the Kissei license and supply agreement, we are developing linzagolix for the treatment of HMB associated with uterine fibroids and pain associated with endometriosis. The agreement also establishes a joint development committee, and upon the filing of regulatory approval, a joint marketing committee, each of which shall be composed of an equal number of representatives for each party, which will exchange information and monitor progress in the development and marketing of the Product, respectively. We must use commercially reasonable efforts to develop, manufacture and commercialize the Compound and the Product. We and Kissei will share development data and regulatory filings from our respective territories with one another. Further, we granted Kissei an exclusive license under any of our know-how and patents related to inventions or improvements resulting from our activities under the Kissei license and supply agreement, for Kissei to use in exploiting the Compound and the Product in their retained territory.

In consideration for the license, we made an initial \$10.0 million upfront payment. We also made two payments of \$5.0 million each to Kissei in 2017 and 2019 related to our commencement of the PRIMROSE and EDELWEISS Phase 3 clinical trials in the uterine fibroid and endometriosis indications, respectively. In addition, we have agreed to make additional aggregate milestone payments of up to \$53.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. 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.

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 payment in the low twenty percent range as a percentage of net sales, which includes payment for Kissei's supply of the active pharmaceutical ingredient until the latest of the date that the valid claim of a patent for the Product has expired, the expiration of our regulatory exclusivity period or 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.

We are solely responsible, at our expense, for the development and commercialization of the Product candidates licensed under the Kissei license and supply agreement in the licensed territory. Kissei has the responsibility to maintain and prosecute the licensed patent rights in the licensed territory and we have the right to enforce any of them in the event that Kissei abandons it. The Kissei license and supply agreement terminates on the date of expiration of all royalty obligations, unless we elect to continue to purchase the Compound from Kissei after the expiration of all royalty obligations. Either party may terminate the Kissei license and supply agreement earlier for an uncured breach, subject to notice requirements and specified exceptions, including that Kissei has the option to convert the exclusive licenses granted to us to non-exclusive if we breach the agreement and fail to cure within a specified time period. We may also terminate the agreement for scientific, commercial, strategic or intellectual property reasons at any time upon advance written notice to Kissei. Kissei may also terminate the agreement if we do not fulfill certain development-related obligations for a specified period of time, or if, in connection with a change of control by us, we do not fulfill certain diligence obligations for a specified period of time. Further, under the terms of the Kissei license and supply agreement, Kissei is obligated to have a backup supplier based on the pharmaceutical industry standard. We may only gain the right to obtain an alternative source of the supply of linzagolix upon Kissei failing to deliver a substantial percentage of the requested supply, delivering the supply late or delivering the supply of linzagolix in nonconforming manner; provided that Kissei has a specified period of time to cure any of these defects. In the event that Kissei failed to deliver a substantial percentage of requested supply in excess of the estimate for yearly requirements that we submit to Kissei.

# **Sublicense Agreement with Yuyuan**

In January 2020, we entered into a sublicense agreement, or the 2020 sublicense agreement, with Hangzhou Yuyuan BioScience Technology Co., Ltd., or 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 People's Republic of China, including Hong Kong and Macau. Yuyuan will be responsible for the continued development of nolasiban in China at its sole cost, and is required to use commercially reasonable efforts to develop the product in accordance with certain development milestones. Yuyuan will be responsible for commercialization of nolasiban in China at its sole cost. We are obligated to supply Yuyuan with its clinical and commercial requirements of the product at cost. Yuyuan has agreed to not develop, market or sell any oxytocin receptor antagonist other than nolasiban during the term of the 2020 sublicense agreement. The development and commercialization activities for nolasiban will be governed by a joint development committee and joint commercialization committee, respectively, with each party having final decision-making authority for its territory. 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 \$15.0 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.

We have the first right to file, prosecute and maintain the licensed patents in China. In the event that we do not elect to file, prosecute or maintain a licensed patent in China, Yuyuan will have the right to request an assignment of such patent, in which event, Yuyuan would be responsible for further filing, prosecution and maintenance. We have the first right to enforce licensed patents in China. Subject to the consent of our licensor of the licensed patents, Yuyuan will have a back-up right to enforce licensed patents in China. The 2020 sublicense agreement expires on the date of expiration of all royalty obligations. The 2020 sublicense agreement is subject to earlier termination by either party upon an uncured material breach of the 2020 sublicense agreement by the other party or an unresolved force majeure event. Yuyuan may terminate the agreement upon specified written notice in the event that certain clinical results are negative. Additionally, we may terminate the agreement if Yuyuan fails to make certain payments in a timely manner, if Yuyuan is acquired by a party with a competing product, if Yuyuan fails to achieve first commercial sale within a specified timeframe after approval, and in the event that Yuyuan challenges the validity, enforceability or patentability of the licensed patents.

### **Government Regulation**

### FDA Drug Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. To obtain regulatory approvals in the United States and in foreign countries, and subsequently comply with applicable statutes and regulations, we will need to spend substantial time and financial resources.

### **Approval Process**

The FDA must approve any new drug or a drug with certain changes to a previously approved drug before a company can market it in the United States. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning or untitled letters, clinical holds, withdrawal of an approval, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, civil penalties or criminal prosecution.

The steps required before a drug may be marketed in the United States generally include the following:

- completion of extensive preclinical laboratory tests, animal studies and CMC studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin. The sponsor must update the IND annually;
- approval of the study by an IRB or ethics committee at each site before the study begins;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the drug for each proposed indication to the FDA's satisfaction;

- submission to the FDA of an NDA after completion of all clinical trials;
- potential review of the drug application by an FDA advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMP regulations and to assure that the facilities, methods and controls are adequate to preserve the drug's identity; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The company submits the results of the preclinical testing, together with manufacturing information, analytical data and any available clinical data or literature to the FDA as part of an IND along with other information, including information about product CMC and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after submitting the initial IND.

The FDA requires a 30-day waiting period after the submission of each IND before the company can begin clinical testing in humans. The FDA may, within the 30-day time period, raise concerns or questions relating to one or more proposed clinical trials and place the study on a clinical hold. In such a case, the company and the FDA must resolve any outstanding concerns before the company may begin the clinical trial. Accordingly, the submission of an IND may or may not be sufficient to permit the sponsor to start a clinical trial. If, following the 30-day period, the FDA does not raise any concerns regarding the IND submission, the company may begin clinical testing under the IND. The company must also make a separate submission to an existing IND for each successive clinical trial conducted during drug development.

#### Clinical Trials

Clinical trials involve administering the investigational new drug to healthy volunteers or patient trials under the supervision of a qualified investigator. The company must conduct clinical trials:

- in compliance with federal regulations
- in compliance with GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors
- under protocols detailing the objectives of the trial, the safety monitoring parameters, and the effectiveness criteria to be evaluated.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the sponsor is not conducting the clinical trial in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The sponsor must also submit the study protocol, any amendments to protocols and informed consent information for patients in clinical trials to an IRB for approval at each site at which the clinical trial will be conducted. An IRB may halt the clinical trial, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Information about certain clinical trials and their results must be also submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on their www.clinicaltrials.gov website.

Companies generally divide the clinical investigation of a drug into three or four phases. While companies usually conduct these phases sequentially, they are sometimes overlapped or combined.

• **Phase 1.** These trials typically evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, gain early evidence on effectiveness. Other Phase 1 or clinical pharmacology studies generally evaluate the drug for potential DDI, cardiovascular safety and special population interactions. These studies, if needed, are to be conducted prior to NDA submission but may be conducted in parallel to Phase 2 and Phase 3.

- *Phase 2.* The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy. Phase 2 trials may be denoted as Phase 2a, wherein initial dose-response relationship is explored, and Phase 2b, wherein dose-ranging and proof-of-concept is targeted.
- **Phase 3.** The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for labeling and product approval.
- *Phase 4.* In some cases, the FDA may condition approval of an NDA for a drug on the company's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Companies typically refer to such post-approval trials as Phase 4 clinical trials.

The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, may oversee some clinical trials. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives and the competitive climate.

### Submission of an NDA

After we complete the required preclinical, CMC and clinical testing, we can prepare and submit an NDA to the FDA, which must approve the NDA before we can start marketing the drug in the United States. An NDA must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the drug's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials on a drug, or from a number of alternative sources, including studies initiated by investigators. To support marketing authorization, the data we submit must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug to the FDA's satisfaction.

The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the sponsor under an approved NDA is also subject to annual program user fees. The FDA typically increases these fees annually.

The FDA has 60 days from its receipt of an NDA to determine whether it will accept the application for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Once the FDA accepts the filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to standard review NDAs within ten months after the 60-day filing review period and priority review drugs within six months after the filing review period. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy ovicts.

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee. This is typically a panel that includes clinicians and other experts that will review, evaluate, and recommend whether the FDA should approve the application. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP, and will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide evidence that the drug is safe and effective in the indication studied.

#### The FDA's Decision on an NDA

After the FDA evaluates the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, it issues either an approval letter or a complete response letter. A complete response letter indicates that the FDA has completed its review of the application, and the agency has determined that it will not approve the application in its present form. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional clinical data or other significant, expensive, and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. The FDA has committed to reviewing resubmissions of the NDA addressing such deficiencies in two or six months, depending on the type of information included. Even with the submission of this additional information, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The government may establish additional requirements, including those resulting from new legislation, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require an REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the drug. Moreover, the FDA may condition approval on substantial post-approval testing and surveillance to monitor the drug's safety or efficacy.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before we can implement the change. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing new NDAs. As with new NDAs, the FDA often significantly extends the review process with requests for additional information or clarification.

#### **Post-approval Requirements**

The FDA regulates products that are manufactured or distributed pursuant to FDA approvals and has specific requirements pertaining to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, the FDA must provide review and approval for most changes to the approved product, such as adding new indications or other labeling claims. There also are continuing, annual user fee requirements for any marketed products and the establishments who manufacture our products, as well as new application fees for supplemental applications with clinical data.

In some cases, the FDA may condition approval of an NDA for a product on the sponsor's agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the product. Such post-approval trials are typically referred to as Phase 4 clinical trials.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. There are strict regulations regarding changes to the manufacturing process, and, depending on the significance of the change, it may require prior FDA approval before we can implement it. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if a company does not comply with regulatory requirements and maintain standards or if problems occur after the product reaches the market. If a company or the FDA discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, issues with manufacturing processes, or the company's failure to comply with regulatory requirements, the FDA may revise the approved labeling to add new safety information; impose post-marketing trials or other clinical trials to assess new safety risks; or impose distribution or other restrictions under a REMS program. Other potential consequences may include:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- the FDA refusing to approve pending NDAs or supplements to approved NDAs, or suspending or revoking of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. We could be subject to significant liability if we violated these laws and regulations.

## Healthcare Reform

In the United States, the European Union and foreign jurisdictions, the legislative landscape continues to evolve. There have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, was enacted, which includes measures that have significantly changed health care financing by both governmental and private insurers. The provisions of the ACA of importance to the pharmaceutical and biotechnology industry are, among others, the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs agents and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts to
  negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's
  outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, unless the drug is subject to discounts under the 340B drug discount program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements under the federal Physician Payments Sunshine Act for drug manufacturers to report information related to payments and other transfers of value made to physicians, as defined by such law, and teaching hospitals as well as ownership or investment interests held by physicians and their immediate family members;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on highcost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unclear when a decision will be made. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is also unclear how the Supreme court ruling, other such litigation and the healthcare reform efforts of the Biden administration will impact the ACA.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which, due to subsequent legislation, including the BBA, will remain in effect through 2030, except for a temporary suspension from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic, unless additional Congressional action is taken.

Further, the American Taxpayer Relief Act of 2012 reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments from providers from three to five years. More recently, there has been heightened governmental scrutiny recently over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for products.

At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to drug pricing that seeks to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. At the state level, individual states in the United States have increasingly passed legislation and implemented regulat

pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

## Coverage, Reimbursement and Pricing

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and the adequacy of reimbursement from third-party payors. Third-party payors include government authorities, managed care organizations, private health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor's reimbursement payment rate may not be adequate or may require co-payments that patients find unacceptably high. Additionally, coverage and reimbursement for products can differ significantly from payor to payor. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's decision to cover a particular product does not ensure that other payors will also provide coverage for the product, or will provide coverage at an adequate reimbursement rate. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they provide reimbursement for use of such therapies.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of products and services, in addition to their safety and efficacy. To obtain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. Thus, obtaining and maintaining reimbursement status is time-consuming and costly.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription products. By way of example, the ACA contains provisions that may reduce the profitability of products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models, or APMs, and the Merit-based Incentive Payment System, or MIPS. In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it remains unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

In the European Community, governments influence the price of products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company

profits. The downward pressure on health care costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide coverage and adequate reimbursement. In addition, the focus on cost containment measures in the United States and other countries has increased and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if we attain favorable coverage and reimbursement status for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

## Sales and Marketing

Numerous regulatory authorities in addition to the FDA, including, in the United States, CMS, other divisions of HHS, the U.S. Department of Justice, and similar foreign, state, and local government authorities, regulate sales, promotion and other activities of prescription drug manufacturers. As described above, the FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. Only those claims relating to safety and efficacy that the FDA has approved may be used in labeling. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those we tested and the FDA approved. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for the patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. If we do not comply with applicable FDA requirements we may face adverse publicity, enforcement action by the FDA, corrective advertising, consent decrees and the full range of civil and criminal penalties available to the FDA. Promotion of off-label uses of products can also implicate the false claims laws described

In the United States, clinical research, sales, marketing and scientific/educational programs must also comply with various federal and state laws pertaining to healthcare "fraud and abuse," including anti-kickback laws and false claims laws. Anti-kickback laws including, without limitation, the federal Anti-Kickback Statute that applies to items and services reimbursable under governmental healthcare programs such as Medicare and Medicaid, makes it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular product. Due to the breadth of the statutory provisions and the narrowness of statutory exceptions and regulatory safe harbors available, it is possible that our practices might be challenged under the federal Anti-Kickback Statute or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA clarifies that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. In addition, the U.S. federal government and private individuals, on behalf of the U.S. federal government, can bring similar actions under the federal civil False Claims Act, False claims laws, including, without limitation, the federal civil False Claims Act, prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment, to third-party payors (including Medicare and Medicaid) claims for reimbursed products or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws, as well as civil monetary penalties laws and the criminal healthcare fraud provisions enacted as part of the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA. Violations of fraud and abuse laws may be punishable by criminal, civil and administrative sanctions, including significant fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement, imprisonment, and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees, including criminal sanctions against executive officers under the so-called "responsible corporate officer" doctrine, even in situations where the executive officer did not intend to violate the law and was unaware of any wrongdoing.

Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the

increasing attention being given to them by law enforcement authorities. Other healthcare laws that may affect our ability to operate include HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and the federal Physician Payments Sunshine Act, which requires certain manufacturers of products, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such obligations will include payments and other transfers of value provided in the previous year to certain other healthcare professionals, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, and certified nurse-midwives.

Further, there are an increasing number of state laws that affect our business operations. Some state and local laws require manufacturers to make reports to on pricing and marketing information and impose registration requirements on salespersons within the jurisdiction. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources. Some states maintain anti-kickback and false claims laws that apply to claims involving healthcare items or services reimbursed by any third-party payor, including private insurers. We may also be subject to state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Many of these state laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs.

Similar rigid restrictions are imposed on the promotion and marketing of products in the European Union and other countries. Even in those countries where we may not be directly responsible for the promotion and marketing of our products, if our potential international distribution partners engage in inappropriate activity it can have adverse implications for us.

### Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

### The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and debarment from government contracts.

#### European Union—EMA process

In the European Union, products follow a similar demanding process as that we described above for the United States and the ICH Common Technical Document is the basis for applications.

#### **Centralized Procedure**

Under the centralized procedure, after the EMA issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human products that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; and officially designated orphan drugs. For products that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA as long as the product concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

#### **National Authorization Procedures**

There are also two other possible routes to authorize medicinal products in several countries, which are available for products that fall outside the scope of the centralized procedure:

- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one European Union country of a medicinal product that has not yet been authorized in any European Union country and that does not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one European Union Member State, in accordance with the national procedures of that country. Thereafter, further marketing authorizations can be sought from other European Union countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

#### **Good Manufacturing Practices**

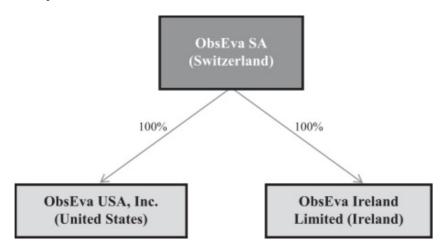
Like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of products prior to approving a product. If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. Once we or our partners commercialize products, we will be required to comply with cGMP, and product-specific regulations enforced by, the European Commission, the EMA and the competent authorities of European Union Member States following product approval. Also like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. If, as a result of these inspections, the regulatory agencies determine that our or our partners' equipment, facilities, or processes do not comply with applicable regulations and conditions of product approval, they may seek civil, criminal or administrative sanctions or remedies against us, including the suspension of our manufacturing operations or the withdrawal of our product from the market.

#### Data and Market Exclusivity

Similar to the United States, there is a process to authorize generic versions of innovative products in the European Union. Generic competitors can submit abridged applications to authorize generic versions of products authorized by EMA through a centralized procedure referencing the innovator's data and demonstrating bioequivalence to the reference product, among other things. New products in the European Union can receive eight years of data exclusivity coupled with two years of market exclusivity, and a potential one-year extension, if the marketing authorizations holder obtains an authorization for one or more new therapeutic indications that demonstrates "significant clinical benefit" in comparison with existing therapies. This system is usually referred to as "8+2". Abridged applications cannot rely on an innovator's data until after expiration of the eight year date exclusivity term, meaning that a competitor can file an application for a generic product but the product cannot be marketed until the end of the market exclusivity term.

## C. Organizational Structure.

The following diagram illustrates our corporate structure:



#### D. Property, Plants and Equipment.

Our principal executive offices are located at Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland, where we lease an approximately 1,000 square meter facility. We also have offices in Boston, Massachusetts, for our U.S. subsidiary, ObsEva USA Inc. We believe that our current facilities are suitable and adequate to meet our current needs. If we need to add new facilities or expand existing facilities as we add employees, we believe that suitable additional space will be available to accommodate any such expansion of our operations.

#### Item 4A. Unresolved Staff Comments.

Not applicable.

### Item 5. Operating and Financial Review and Prospects.

#### Overview

We are a 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 reproductive aged women 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.

We are developing linzagolix as a novel, oral gonadotropin releasing hormone, or GnRH, receptor antagonist, for the treatment of HMB associated with uterine fibroids and pain associated with endometriosis 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 low dose of linzagolix without hormonal ABT and (ii) a high dose of linzagolix with hormonal ABT.

In November 2020, we submitted a MAA to the EMA for YSELTY® (linzagolix 100mg and linzagolix 200mg) for the treatment of women with uterine fibroids. Our application has been validated by the EMA, as announced in January 2021, and we expect to receive approval for YSELTY® in the fourth quarter of 2021. If approved, linzagolix will be the only GnRH antagonist with flexible dose regimen options for the management of uterine fibroids consisting in (i) 100 mg once daily for women with a contraindication to or who prefer to avoid hormonal add-back therapy (ABT) or, (ii) 200 mg once daily with concomitant ABT for long-term use (beyond 6 months) or, (iii) 200 mg once daily for short-term use, in particular when rapid reduction in fibroid volume is desired.

Based on the positive PRIMROSE 1 and PRIMROSE 2 full data package including week 52 data and post treatment follow-up data up to week 76 for both trials, we intend to proceed with an NDA submission to the FDA in the second quarter of 2021.

With respect to the endometriosis indication, in January 2021, we announced our decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing pandemic. We are planning to conduct, as soon as is feasible, a new Phase 3 clinical trial for endometriosis with a number of design and operational changes to facilitate faster enrollment, with a goal to maintain the original MAA and NDA filing timelines for this indication. Our EDELWEISS 3 clinical trial is progressing and continuing as planned, with primary endpoint data at 24 weeks expected in the fourth quarter of 2021.

In addition, we are developing ebopiprant, an oral and selective prostaglandin  $F2\alpha$  receptor antagonist, for preterm labor in weeks 24 to 34 of pregnancy. In November 2020, we announced positive results for the PROLONG Proof-of-Concept Trial, with over 50% reduction of pre-term delivery within 48 hours of treatment in singleton pregnancy, as compared to atosiban alone. The efficacy endpoints were delivery within 48 hours of starting treatment, delivery within 7 days of starting treatment, delivery before 37 weeks of gestation, and time to delivery. Safety assessments included maternal, fetal and neonatal safety. Follow-up of infants at 6, 12 and 24 months after birth is continuing and results will be available in 2021 and 2022. These data results support advancement of ebopiprant to Phase 2b dose range finding, including testing of higher doses, which will allow us to more fully define this product's potential and the longer-term benefits for babies.

We are also developing nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing in-vitro fertilization, or IVF.

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 have discontinued our previously ongoing development of nolasiban for IVF, and are exploring potential repositioning of the compound, such as through higher dose levels and earlier and longer exposure of nolasiban, as well as focusing on subjects with a high uterus contraction rate at the time of ET. In connection with this potential repositioning, 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. They will fund all development and registration activities in the PRC, starting with the obligation to fund and conduct a Phase 1 trial and a Phase 2 proof-of-concept trial in China. We retain all rights to the product outside of PRC, and have agreed to collaborate with YuYuan on its global development. Our development and commercialization partnership with YuYuan proceeded during the 2020 with steering committee meetings to define the development plan for nolasiban in China for women undergoing ET following IVF.

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, ebopiprant 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. From inception through the date of this Annual Report on Form 20-F, we have raised an aggregate of \$424.7 million of net proceeds, including \$88.5 million of net proceeds from our initial public offering in January 2017, \$56.3 million of net proceeds from our private placement with institutional investors in October 2017, \$72.4 million in net proceeds from our underwritten public offering in June 2018 and \$20.0 million in net proceeds from our underwritten public offering and concurrent private placement in September 2020. In August 2019, we borrowed \$25.0 million under our \$75.0 million senior secured term loan credit facility with Oxford Finance LLC. In addition, between 2018 and 2020, we sold treasury shares from our "at the market" (ATM) program, generating net proceeds of \$39.3 million.

We have never been profitable and have incurred significant net losses in each period since our inception. Our net losses were \$83.0 million, \$108.8 million and \$76.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020, we had accumulated losses of \$410.0 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 \$70.8 million and \$90.6 million of cash in operations in 2020 and

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 EDELWEISS 3, PRIMROSE 1 and 2, 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 a collaboration with a third party.

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 yet have a commercialization organization. As we move our product candidates through development toward regulatory approval, we will evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force, entering into a joint marketing partnership with another pharmaceutical or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company. We are currently evaluating such options for YSELTY® in anticipation of commercialization activities if and when YSELTY® receives marketing approval.

#### **COVID-19 Business Update**

With the global spread of the ongoing COVID-19 pandemic which continues to date, we have 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. In January 2021, we announced our decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing pandemic. Enrollment delays may further occur in the coming months for ongoing trials, 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. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business and operations 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, such as when effective vaccines or other treatment would be made available to public.

## **Strategic Licensing Agreements**

#### Linzagolix

In November 2015, we entered into the Kissei license and supply agreement with 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 uterine fibroids in 2017 and endometriosis in 2019, two \$5.0 million milestones were 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.

# **Ebopiprant**

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 ebopiprant. 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 People's Republic of China, 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 do not expect to generate any revenue from product sales in the near term.

#### **Operating Expenses**

Research and Development Expenses

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

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

From inception through December 31, 2020, we have incurred \$328.1 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 years ended December 31, 2020, 2019 and 2018, respectively.

	Year Ended December 31,							
		2020	2019			2018		
Linzagolix	\$	(49,431)	\$	(51,489)	\$	(39,315)		
Nolasiban		(1,070)		(17,205)		(7,515)		
Ebopiprant		(1,662)		(2,434)		(2,502)		
Total outsourced research and development expenses	\$	(52,163)	\$	(71,128)	\$	(49,332)		

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

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

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

## General and Administrative Expenses

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

We anticipate that our general and administrative 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 foreign exchange loss and gain, as well as interest expense associated with our lease liabilities and debt instruments.

#### **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, 2020, we had tax loss carryforwards totaling \$392.5 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 2019 and 2020 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 for the year ended December 31, 2020.

#### A. Operating Results

### **Analysis of Results of Operations**

The following table sets forth our selected consolidated statements of operations data for the periods indicated:

	Year Ended December 31,					
		2020 2019				2018
Consolidated Statements of Operations Data:						
Operating income other than revenue	\$	17	\$	16	\$	15
Operating expenses:						
Research and development expenses		(67,536)		(88,053)		(62,872)
General and administrative expenses		(12,182)		(19,058)		(14,297)
Total operating expenses		(79,718)		(107,111)		(77,169)
Finance result, net		(3,231)		(1,628)		393
Income tax (expense) / benefit		(34)		(67)		45
Net loss	\$	(82,966)	\$	(108,790)	\$	(76,716)

The following discussion includes the changes in the results of our operations for the years ended December 31, 2020 and 2019. A discussion of the changes in our results of operations for the years ended December 31, 2019 and 2018 has been omitted from this Annual Report on Form 20-F but may be found in "Item 5.A. Operating Results—Years Ended December 31, 2019 and 2018" in our Annual Report on Form 20-F for the year ended December 31, 2019, filed with the U.S. Securities and Exchange Commission, or SEC, on March 5, 2020.

## Years Ended December 31, 2020 and 2019

## **Operating Expenses**

Research and Development Expenses

	Year Ended December 31,					
		2020		2019		Change
	(in thousands) (unaudited)					
Research and development expenses by product candidate						
Linzagolix	\$	(49,431)	\$	(51,489)	\$	2,058
Nolasiban		(1,070)		(17,205)		16,135
Ebopiprant		(1,662)		(2,434)		772
Unallocated expenses						
Staff costs		(12,930)		(13,817)		887
Other research and development costs		(2,443)		(3,108)		665
Total research and development expenses	\$	(67,536)	\$	(88,053)	\$	20,517

Research and development expenses decreased by \$20.5 million in 2020 compared to 2019 primarily due to our nolasiban program that we conducted until November 2019 and the adverse IMPLANT 4 clinical trial results. Staff costs and other research and development costs also contributed to the overall decrease, primarily due to lower share-based compensation expense.

# General and Administrative Expenses

	Year Ended December 31,					
		2020 2019			Change	
	(in thousands) (unaudited)					
Staff costs	\$	(6,714)	\$	(10,740)	\$	4,026
Professional fees		(2,911)		(5,734)		2,823
Other general and administrative costs		(2,557)		(2,584)		27
Total general and administrative expenses	\$	(12,182)	\$	(19,058)	\$	6,876

General and administrative expenses decreased by \$6.9 million in 2020 compared to 2019 primarily due to decreased staff costs of \$4.0 million associated with lower headcount and share-based compensation expense, as well as decreased professional fees of \$2.8 million mainly due to pre-commercial activities carried out in 2019.

# Finance Result, Net

		Year Ended Decen			
	2	2020 2019			Change
		(in thousand			
Foreign exchange loss, net	\$	(527) \$	(442)	\$	(85)
Interest expense		(2,704)	(1,186)		(1,518)
Finance result, net	\$	(3,231) \$	(1,628)	\$	(1,602)

Finance result, net, in 2020 and 2019 primarily consisted of foreign exchange losses, as well as interest expense associated with our lease liabilities and debt instruments.

#### Years ended December 31, 2019 and 2018

See our Annual Report on Form 20-F for the year ended December 31, 2019, filed with the SEC on March 5, 2020, "Item 5.A. Operating Results—Years Ended December 31, 2019 and 2018" for the comparison discussion between the years ended December 31, 2019 and 2018.

#### **B.** 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 December 31, 2020, we have raised an aggregate of \$369.1 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.

In January 2017, we completed our initial public offering of 6,450,000 common shares at a public offering price of \$15.00 per share. We received \$88.5 million in net proceeds after deducting \$8.3 million of underwriting discounts and commissions and other offering expenses. Additionally, in October 2017, we raised \$56.3 million of net proceeds after deducting \$3.7 million of placement expenses through the issuance of 7,500,000 shares at a price of \$8.00 per share in a private placement with institutional investors.

In May 2018, we sold 1,600,851 treasury shares at a price of \$12.50 per share as part of our ATM program, receiving net proceeds of \$19.4 million after deducting \$0.6 million of directly related issuance costs.

In June 2018, we completed an underwritten public offering of common shares and issued 4,750,000 shares at a price of \$15.39 per share, raising \$68.0 million in net proceeds after deducting \$5.1 million of underwriting discounts, commissions and other offering expenses. In July 2018, we raised additional funds for net proceeds of \$4.4 million from the exercise of the option available to the underwriters in connection with the June 2018 offering.

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 ATM program initiated in May 2018, and received net proceeds of \$3.5 million after deducting \$0.1 million of directly-related issuance costs.

On August 7, 2019, we entered into the Credit Facility Agreement with 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 have used 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. In April 2020, we entered into an amendment to the Credit Facility Agreement pursuant to which 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.

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 former Chief Executive Officer, Ernest Loumaye, purchased 516,352 units at an effective price of \$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 \$3.43 per share, in a concurrent private placement. The net proceeds from the offering (including exercise of pre-funded warrants) and the concurrent private placement were \$20.0 million, after deducting underwriting discounts, commissions and other offering expenses.

During the year ended December 31, 2020, we sold a total of 5,995,897 treasury shares at an average price of \$2.82 per share, as part of our ATM program. These multiple daily transactions generated total gross proceeds of \$16.9 million. Directly related share issuance costs of \$0.5 million were recorded as a deduction in equity.

As of December 31, 2020, we had \$31.2 million in cash and cash equivalents. Subsequent to December 31, 2020, we raised additional proceeds of \$55.6 million from the sale of additional treasury shares as part of our ATM program, and the exercise of the warrants included in the units sold in our underwritten public offering in September 2020.

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 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 current cash and cash equivalents will be sufficient to fund our operating expenses (without consideration of any commercialization expenses) into the second quarter of 2022. 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, ebopiprant and nolasiban;
- 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, ebopiprant 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 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. Even though we have submitted a Marketing Authorization Approval, or MAA, to the European Medicines Agency, or EMA, for YSELTY® (linzagolix 100mg and linzagolix 200mg) for the treatment of women with uterine fibroids and our application has been validated by the EMA, we cannot assure you that YSELTY® will receive regulatory approval or, if YSELTY® were to receive regulatory approval, that the commercialization of YSELTY® would be successful. We may be unable to commercialize our product candidates and derive revenue from sales of products, on a timely basis or 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 periods indicated:

	Year Ended December 31,							
(in thousands)		2020	2019			2018		
Cash and cash equivalents at beginning of period	\$	69,370	\$	138,640	\$	110,841		
Net cash used in operating activities		(70,766)		(90,611)		(63,941)		
Net cash used in investing activities		(5)		(5,046)		(271)		
Net cash from financing activities		32,249		26,627		91,652		
Effect of exchange rates		335		(240)		359		
Cash and cash equivalents at end of period	\$	31,183	\$	69,370	\$	138,640		

#### **Operating Activities**

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

During the year ended December 31, 2020, \$70.8 million of cash was used for operating activities, primarily as the result of our net loss before tax of \$83.0 million, as adjusted for non-cash items and changes in net working capital. Non-cash items amounted to \$10.9 million and mainly consisted of share-based payments. Changes in net working capital included primarily a \$2.1 million increase in payables and a \$1.0 million increase in prepaid expenses, mainly due to the progress made in our various ongoing Phase 3 clinical trials and the invoicing schedules of our main vendors.

During the year ended December 31, 2019, \$90.6 million of cash was used for operating activities, primarily as the result of our net loss before tax of \$108.7 million, as adjusted for non-cash items and changes in net working capital. Non-cash items amounted to \$13.7 million and mainly consisted of share-based payments. Changes in net working capital included primarily a \$5.5 million increase in payables and a \$2.6 million decrease in accrued expenses, mainly due to the progress made in our various ongoing Phase 3 clinical trials and the invoicing schedules of our main vendors.

See our Annual Report on Form 20-F for the year ended December 31, 2019, filed with the SEC on March 5, 2020, "Item 5.B. Liquidity and Capital Resources—Operating Activities" for a discussion of the operating activities for the year ended December 31, 2018.

# Investing Activities

Net cash used in investing activities consists primarily of investments in leasehold improvements and furniture and fixtures, as well as investments in intangible assets through the execution of in-licensing agreements or the payment of development-based milestones to our licensors.

During 2020, net cash used in investing activities consisted primarily of investments in information technology equipment.

During 2019, net cash used in investing activities consisted primarily of a \$5.0 million milestone payment to Kissei made in connection with the initiation of the Phase 3 clinical program for linzagolix in endometriosis, as well as purchases of furniture and fixtures for our offices in Switzerland and the United States.

See our Annual Report on Form 20-F for the year ended December 31, 2019, filed with the SEC on March 5, 2020, "Item 5.B. Liquidity and Capital Resources—Investing Activities" for a discussion of the investing activities for the year ended December 31, 2019.

## Financing Activities

Net cash from financing activities consists primarily of proceeds from the sale of equity securities and borrowings under our credit facility with Oxford.

Cash flows from financing activities in 2020 mainly consisted primarily of the net proceeds from our underwritten public offering and concurrent private placement completed in September 2020 and the sales of treasury shares under our ATM program, which were partially offset by the principal elements of lease payments as well as interest expense associated with our leases and debt instruments.

Cash flows from financing activities in 2019 mainly consisted primarily of the proceeds from the first tranche of the Credit Facility Agreement with Oxford, as well as from the sales of treasury shares under our "at the market" (ATM) program, which were partially offset by the principal elements of lease payments as well as interest expense associated with our leases and debt instruments.

See our Annual Report on Form 20-F for the year ended December 31, 2019, filed with the SEC on March 5, 2020, "Item 5.B. Liquidity and Capital Resources—Financing Activities" for a discussion of the financing activities for the year ended December 31, 2019.

### C. Research and Development

For a discussion of our research and development activities, see "Item 4.B—Business Overview" and "Item 5.A—Operating Results."

#### **D. Trend Information**

For a discussion of trends, see "Item 5.A—Operating Results" and "Item 5.B—Liquidity and Capital Resources."

### **E. Off-Balance Sheet Arrangements**

During the periods presented, we did not have, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the U.S. Securities and Exchange Commission.

# F. Tabular Disclosure of Contractual Obligations

The following table summarizes the contractual maturity profile of our on-balance sheet liabilities, including interest payments, as of December 31, 2020:

	L	ess than 1 Year	1 to 3 Years	3 to 5 Years		More than 5 Years			Total
				(in thousands)					
Trade and other payables	\$	(9,450)	\$ -	\$ -	\$	<b>.</b>	-	\$	(9,450)
Borrowings		(2,200)	(20,150)	(10,297	)		-	(32	2,646 )
Lease liabilities		(758)	(981)	-			-	(1,	,738 )
Total as of December 31, 2020	\$	(12,408)	\$ (21,129)	\$ (10,297	) \$		-	\$	(43,834)

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, of which we had paid \$10.0 million as of December 31, 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 have not included any contingent payment obligation, such as milestone payments and royalties, in the table above as the amount, timing and likelihood of such payments are not known.

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 therefore we believe that our non-cancelable obligations under these agreements are not material.

### G. Safe Harbor

This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See "Special Note Regarding Forward-Looking Statements."

### Item 6. Directors, Senior Management and Employees.

### A. Directors and Senior Management.

The following table sets forth information regarding our executive officers and directors, including their ages, as of February 28, 2021. Our directors are appointed for one-year terms, which expire on the occasion of each annual general meeting. Accordingly, the terms of the directors set forth below will expire on the date of our 2020 annual general meeting of shareholders.

Name	Age	Position(s)
Executive Officers:		
Brian O'Callaghan	51	Chief Executive Officer
David Renas	56	Chief Financial Officer
Elizabeth Garner	53	Chief Medical Officer
Jean-Pierre Gotteland	56	Chief Scientific Officer and Head of R&D
Wim Souverijns	50	Chief Commercial Officer
Fabien de Ladonchamps	42	Chief Administrative Officer
Non-Employee Directors:		
Frank Verwiel	58	Chairperson of the Board of Directors
Ernest Loumaye	68	Director
Annette Clancy	66	Director
Barbara Duncan	56	Director
James I. Healy	55	Director
Ed Mathers	60	Director
Rafaèle Tordjman	51	Director
Jacky Vonderscher	66	Director

Unless otherwise indicated, the current business addresses for our executive officers and directors is: Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland.

### **Executive Officers**

Brian O'Callaghan has served as our Chief Executive Officer since December 2020 to lead the Company through its future development, regulatory filings and product launches. He is a life science executive with extensive experience within biotech, large pharmaceutical companies and the CRO sector, as well as extensive global experience, having lived and worked in 5 different countries and both coasts of the US. Prior to joining ObsEva, Mr. O'Callaghan has held CEO positions at Petra Pharma (from 2017 to 2020), Acucela (from 2013 to 2015), Sangart (from 2008 to 2014) and BioPartners (from 2000 to 2004), as well as senior management positions at Pfizer (from 1992 to 1994), Merck Serono (from 1996 to 2000), Novartis (from 2004 to 2006), Covance (from 2006 to 2007) and NPS Pharmaceuticals (from 2007 to 2008). Mr. O'Callaghan has experience running both public and private companies, M&A's, IPO's, fundraising, divestments, spin-outs and strategic alliances. He also has extensive Board experience, having served on numerous biotech and 501c3 Boards. In particular, he is currently a member of the Board of Directors of Decoy Biosystems and Biocom, since 2018 and 2013, respectively, two companies based in California.

David Renas has served as our Chief Financial Officer since January 2021, bringing with him more than 30 years of financial and legal experience, including 15 years within the pharmaceutical and life science industry. Before joining ObsEva, Mr. Renas served as CFO at Petra Pharma Corporation (from 2017 to 2020) and Sangart, Inc. (from 2002 to 2014), and practiced corporate and securities law at Gray Cary Ware & Freidenrich (now DLA Piper), Foley & Lardner and Adkins Black LLP. Earlier in his career he worked as a Certified Public Accountant at Deloitte. Mr. Renas holds a Bachelor of Arts in Economics from Stanford University and a Juris Doctorate from the University of California at Davis.

Elizabeth Garner has served as our Chief Medical Officer since July 2019. From January 2014 to July 2019, Dr. Garner was Chief Medical Officer and SVP of Research and Development at Agile Therapeutics Inc., and prior to that was Senior Vice President, Medical Affairs, Women's Health and Preventive Care at Myriad Genetics Laboratories. From 2011 to 2012 she was Senior Medical Director, Women's Health at Abbott Laboratories, where she was the Clinical Lead of the endometriosis program for elagolix (Orilissa®), which is now FDA-approved. Before joining Abbott Laboratories, she served as Associate Director and then Director, Vaccines Clinical Research at Merck Research Laboratories from 2007 to 2011. Dr. Garner is a current member of the Boards of Directors of Kezar Life Sciences, Inc. (KZR; Audit and Clinical Strategy Committees), Sermonix Pharmaceuticals, and PharmOlam International. She is also on the Executive Committee of the American Medical Women's Association (AMWA) and a member of the board of the Drug Information Association (DIA). Dr. Garner received joint M.D. and M.P.H degrees from Harvard Medical School and Harvard School of Public Health. She was trained in obstetrics and gynecology at Brigham and Women's/Massachusetts General Hospitals and completed a fellowship in gynecologic oncology at Brigham and Women's Hospital and the Dana Farber Cancer Institute. Dr. Garner was a 2019 awardee of the PharmaVoice 100 most inspiring individuals in the life-sciences industry.

Jean-Pierre Gotteland has served as our Chief Scientific Officer and Head of Research and Development since April 2018 and served as Chief Scientific Officer from September 2015 to March 2018. From May 2007 to August 2015, Mr. Gotteland worked at PregLem SA, initially as the Vice President of Non-Clinical Development and CMC from 2007 to 2012 and as the Chief Development Officer from January 2012 to August 2015. From 1998 to 2007, Mr. Gotteland held several research and development positions at Serono (subsequently Merck Serono). From 1991 to 1998, Mr. Gotteland served as medicinal chemistry group leader at Pierre Fabre Medicament. Mr. Gotteland holds a Ph.D. in Organic Chemistry from the University Claude Bernard, Lyon, France, and an Engineering Diploma from Ecole Superieure de Chimie Industrielle of Lyon, France and did postdoctoral studies at the University of California, Berkeley (US).

Wim Souverijns has served as our Chief Commercial Officer since November 2018. Prior to joining ObsEva, Dr. Souverijns spent 11 years, from 2007 to 2018, at Celgene where he contributed to the successful built out of Celgene's product portfolio in diverse strategic (European & Global Marketing), as well as operational (General Manager for the Nordics and the UK & Ireland) roles. He developed a broad pharmaceutical background through various international assignments at PwC Consulting, from 1999 to 2003. and in different market access leadership roles at Amgen, from 2003 to 2007, both in the European headquarter in Luzern, Switzerland, as well as at the global level out of Thousand Oaks, California. He started of his career working for CTG, from 1997 to 1999, an IT services company, in Brussels, Belgium. Dr. Souverijns studied as a bio-engineer at the KU Leuven, Belgium, and obtained a PhD from the same institute.

Fabien de Ladonchamps has served as our Chief Administrative Officer since January 2021, and previously served as interim Chief Financial Officer from April 2020 to December 2020, Vice President Corporate Affairs and Finance from January 2019 to April 2020, Vice President of Finance from January 2016 to December 2018 and Finance Director from October 2013 to December 2015. Prior to joining our company, Mr. de Ladonchamps worked at Addex Therapeutics, initially as Chief Accountant from 2008 to 2009 and then as Group Financial Controller from 2010 to September 2013. Mr. de Ladonchamps holds a French degree in Finance and Accounting from the Lyon III University in Lyon, France.

## **Non-Employee Directors**

*Ernest Loumaye* is a co-founder and member of our board of directors since its inception in November 2012. He served as our Chief Executive Officer since our inception until December 2020. Since September 2019, he is a member of the board of directors at AVA, a Zurich-based company active in all areas of women's health. Previously, Dr. Loumaye co-founded PregLem, a Swiss specialty biopharmaceutical company sold to Gedeon Richter Plc., and served as its Chief Executive Officer and member of the board of directors from 2006 to October 2012. From 2011 to 2016, Dr. Loumaye served as chairperson and member of the board at Genkyotex, a public biopharmaceutical company developing treatments against various diseases based on enzyme inhibition. Dr. Loumaye holds an M.D. and a Ph.D. from University of Louvain, Belgium, with a specialization in Obstetrics and Gynaecology. Dr Loumaye was research fellow at the National Institute of Health (NIH, Bethesda, MD, USA).

Frank Verwiel has served as a member of our board of directors since March 2016 and has served as the chairperson of the board since December 2016. He currently serves as of the chairperson of the board of directors of Intellia Inc. (Nasdaq: NTLA) and is a member of the board of directors of Bavarian Nordic A/S, both public biotechnology companies. From 2005 to 2014, Dr. Verwiel was President, Chief Executive Officer and member of the board of directors of Aptalis Pharma Inc., a pharmaceutical company. Dr. Verwiel previously served on the board of directors of InterMune, Inc. from 2012 to 2014, on the board of Avexis, Inc., from 2016 to 2018, both biotechnology companies, and on the board of Achillion Pharmaceuticals, Inc., a pharmaceutical company, from 2015 to 2020. Dr. Verwiel received his M.D. from Erasmus University, Rotterdam,

The Netherlands, and his M.B.A. from INSEAD in Fontainebleau, France. Our board of directors believes that Dr. Verwiel's scientific acumen and his over 25 years of strategic, operational and international experience in the pharmaceutical industry provide him with the qualifications and skills to serve as a director.

Annette Clancy has served as a member of our board of directors since November 2013 and served as our chairperson from November 2013 to December 2016. Ms Clancy's other current positions include member of the board of directors of Swedish Orphan Biovitrum AB since May 2014, a public biopharmaceutical company, as well as Chairperson of the Board of Directors of ENYO Pharma SA since June 2016. Since 2019, Ms Clancy has acted as an Operational Investor at Jeito Capital, a French- based healthcare venture capital firm. In earlier years, Ms Clancy has held a number of Board and Chairperson positions with a range of European based biotechnology companies and acted as a senior advisor at Frazier Healthcare Ventures, a U.S.-based healthcare venture capital firm from 2009 to 2017. Ms. Clancy also held various senior positions at GlaxoSmithKline, a global healthcare company up until 2008. Ms. Clancy holds a B.Sc. in Pharmacology from Bath University and a series of American Management Association diplomas in finance and marketing. Our board of directors believes that Ms. Clancy's over 30 years of experience in the pharmaceutical and biopharmaceutical industries provide her with the qualifications and skills to serve as a director.

Barbara Duncan has served as a member of our board of directors since December 2016. Ms. Duncan serves on the board of directors of Adaptimmune Therapeutics plc (Nasdaq: ADAP) since June 2016, Atea Pharmaceuticals, Inc. (Nasdaq: AVIR) since November 2020, Fusion Pharmaceuticals Inc. (Nasdaq: FUSN) since November 2020, Jounce Therapeutics, Inc. (Nasdaq: JNCE) since May 2016, and Ovid Therapeutics Inc. (Nasdaq: OVID) since June 2017, publicly traded biopharmaceutical companies. Ms. Duncan also served as a member of the board of directors of Immunomedics, Inc. (from March 2019 to October 2020) and Innoviva Inc. (from November 2016 to April 2018) and as a member of the board of directors of Aevi Genomic Medicine, Inc. (from July 2015 to February 2020). From May 2009 through June 2016, Ms. Duncan served as the Chief Financial Officer of Intercept Pharmaceuticals, Inc., a biopharmaceutical company. Prior to joining Intercept Pharmaceuticals, Inc., Ms. Duncan served as the Chief Financial Officer and then Chief Executive Officer of DOV Pharmaceutical, Inc., or DOV, from 2001 to April 2009. Prior to joining DOV, Ms. Duncan served as a vice president of Lehman Brothers Inc. in its corporate finance division from August 1998 to August 2001. From September 1994 to August 1998, Ms. Duncan was an associate and director at SBC Warburg Dillon Read, Inc. in its corporate finance group. Ms. Duncan received her B.S. from Louisiana State University, Baton Rouge, in 1985 and her M.B.A. from the Wharton School, University of Pennsylvania, Philadelphia, in 1994. Our board of directors believes that Ms. Duncan's expertise with public and financial accounting matters, as well as her experience in the pharmaceutical industry, provide her with the qualifications and skills to serve as a director.

James I. Healy has served as a member of our board of directors since August 2013. Dr. Healy has been a general partner at Sofinnova Investments, Inc. (formerly, Sofinnova Ventures, Inc.) since 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals (as successor to Miles Laboratories) and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Ascendis Pharma A/S (Nasdaq: ASND), Coherus BioSciences, Inc. (Nasdaq: CHRS), Karuna Therapeutics, Inc. (Nasdaq: KRTX), Natera, Inc. (Nasdaq: NTRA), NuCana plc (Nasdaq: NCNA), Y-mAbs Therapeutics, Inc. (Nasdaq: YMAB) and several private companies. Previously, Dr. Healy served as a board member of Amarin Corporation plc, Anthera Pharmaceuticals, Inc., Auris Medical Holding AG, CoTherix, Inc., Durata Therapeutics, Inc., Edge Therapeutics, Inc., Hyperion Therapeutics, Inc., InterMune, Inc., Movetis NV, Iterum Therapeutics plc, and several private companies. In 2011, Dr. Healy won the IBF Risk Innovator Award and was named as one of the industry's top leading Life Science investors in 2013 by Forbes Magazine. Dr. Healy holds a B.A. in Molecular Biology and a B.A. in Scandinavian Studies from the University of California at Berkeley, and an M.D. and Ph.D. in Immunology from Stanford University School of Medicine. He was previously a Director on the Board of the National Venture Capital Association (NVCA) and the Board of the Biotechnology Industry Organization (BIO). Our board of directors believes that Dr. Healy's experience in the pharmaceutical industry and investing in life sciences companies, as well as his medical and scientific background, provide him with the qualifications and skills to serve as a director.

Ed Mathers has served as a member of our board of directors since February 2016. Mr. Mathers is a General Partner of NEA since August 2008 and is focused on biotechnology and specialty pharmaceuticals investments. He is a director of Rhythm Pharmaceuticals (Nasdaq: RYTM), Envisia Therapeutics, Synlogic (Nasdaq: SYBX), Amplyx Pharmaceuticals, Senti Biosciences, Inozyme (Nasdaq: INZY), Reneo Pharma, Akouos (Nasdaq: AKUS), Trevi Therapeutics (Nasdaq: TRVI), Mirium Pharmaceuticals (Nasdaq: MIRM), Shape Therapeutics, MBX Biosciences, and Affinia Therapeutics. Previously he was a board member of RA Pharmaceuticals (sold to UCB), Liquidia (Nasdaq: LQDA), Lumos Pharma (Nasdaq: LUMO), Curzion Pharmaceuticals (sold to Horizon), Lumena (sold to Shire), Ziarco (sold to Novartis), Motus Therapeutics (sold to Allergan), Plexxikon (sold to Daiichi Sankyo), Intarcia, Satori Pharmaceuticals, Southeast Bio, MedImmune, LLC, the Biotechnology Industry Organization (BIO), and a number of public biopharmaceutical boards. Prior to joining NEA, Mr.

Mathers most recently served as Executive Vice President, Corporate Development and Venture, at MedImmune, Inc. Before joining MedImmune in 2002, he was Vice President, Marketing and Corporate Licensing and Acquisitions at Inhale Therapeutic Systems. Mr. Mathers spent 15 years at Glaxo Wellcome, Inc. (GlaxoSmithKline), where he held sales and marketing positions of increasing responsibility. He earned his bachelor's degree in chemistry from North Carolina State University, Raleigh. Our board of directors believes that Mr. Mathers' experience with the healthcare and pharmaceutical industries and his broad management experience provide him with the qualifications and skills to serve as a director.

Rafaèle Tordjman has served as a member of our board of directors since August 2013. Since April 2018, Dr. Tordjman is founder and CEO of Jeito Capital, a biotech investment firm, that launched a €200M fund at the end of 2019. Moreover, Dr. Tordjman serves on the board of directors of the public company Nucana (Nasdaq: NCNA), a clinical-stage pharmaceutical company, and Innoskel, a pioneering platform biotechnology private company. Previously, Dr. Tordjman joined the French based venture capital firm Sofinnova Partners in 2001 until March 2017 where she served as Managing Partner specializing in life sciences investments. Dr. Tordjman has also served on the boards of directors at several life sciences companies including, DBV Technologies SA (from 2005 to 2013), a French publicly traded company specializing in allergy therapies, Ascendis Pharma A/S (from 2007 to 2017), Flexion Therapeutics, Inc. (from 2009 to 2014), publicly traded companies in clinical-stage pharmaceuticals, PregLem (from 2006 to 2010), a company specialized in reproductive female medicine, Lysogene (from 2017 to 2018), a public biopharmaceutical company developing treatments against central nervous system and genetic diseases, Medday Pharmaceuticals (from 2013 to 2017), a French company specializing in therapies against neurodegenerative diseases, and ENYO Pharma SA (from 2015 to 2017), a clinical stage biopharmaceutical company. Previously, Dr. Tordjman was a research scientist at the Institut National de la Santé et de la Recherche Médicale (INSERM) in Cochin Hospital, Paris, France. Dr. Tordjman has also practiced as a medical doctor, specializing in clinical hematology and internal medicine. Dr. Tordjman received an M.D. and completed a fellowship in hematology and internal medicine at the Paris University Hospitals, France. She received a Ph.D. in hematopoiesis and angiogenesis from and completed a post-doctoral fellowship in immunology at the University of Paris VII. Our board of directors believes that Dr. Tordjman's experience in the

Jacky Vonderscher has served as a member of our board of directors since October 2013. Since September 2013, Dr. Vonderscher has served as the Chief Executive Officer of Vonderscher & Co GmbH, a consultancy company. Dr. Vonderscher has also served as the Chief Executive Officer of ENYO Pharma SA, a biopharmaceutical company, since July 2016. Dr. Vonderscher serves as a member of the governing board of IMI (Innovative Medicines Initiative), a public-private partnership. He is also a member of the board of LyonBiopole, a business association and of several private companies. From January 2014 until June 2016, Dr. Vonderscher served as the President of ENYO Pharma SA. Prior to joining ENYO Pharma SA, Dr. Vonderscher served as a Senior Vice President of Hoffmann-La-Roche Ltd from 2008 to December 2013. From 1979 to 2008, Dr. Vonderscher held a variety of senior positions at Novartis Pharma AG. Dr. Vonderscher holds an engineering degree in Biological Chemistry from the National Institute of Applied Sciences (INSA), Lyon, France, and a Ph.D. in Biochemistry from the University of Geneva, Switzerland. Our board of directors believes that Dr. Vonderscher's experience in the pharmaceutical industry, as well as his scientific background, provide him with the qualifications and skills to serve as a director.

#### **Family Relationships**

There are no family relationships among any of our executive officers or directors.

### B. Compensation.

## **Compensation of Executive Officers and Directors**

For the year ended December 31, 2020, the aggregate compensation paid to the members of our board of directors and our executive officers for services in all capacities was \$10.7 million, including \$7.2 million of share-based compensation.

During the year ended December 31, 2020, other than the 2017 equity incentive plan outline below, we had no performance based compensation programs.

The amount set aside by us to provide pension, retirement or similar benefits to members of our board of directors or executive officers amounted to a total of \$0.2 million in the year ended December 31, 2020.

### **Director Compensation**

Each member of our board of directors who is not also serving as our employee and/or for an affiliate receives an annual fixed cash compensation, payable in quarterly installments, as determined under the review process of the compensation, nominating and corporate governance committee of our board of directors and approved by the board, as set forth below:

- Annual board service retainer
  - O Chairman of the board: \$70,000
  - O All other eligible members of the board: \$40,000
- Annual committee member service retainer
  - O Member of the audit committee: \$7,500
  - Member of the compensation, nominating and corporate governance committee: \$7,500
- Annual committee chair service retainer (in addition to committee member service retainer)
  - O Chair of the audit committee: \$7.500
  - O Chair of the compensation, nominating and corporate governance committee: \$7,500

Social contributions, to the extent required by Swiss law, are accrued on the annual cash compensation of the board and committee's members.

In addition, we reimburse the members of our board of directors for out-of-pocket expenses incurred in relation to their services on an ongoing basis upon presentation of the corresponding receipts. Expenses reimbursements are not part of the compensation.

The members of our board of directors are eligible to participate in our 2017 Equity Incentive Plan, as amended, or our 2017 Plan.

The aggregate compensation paid to the members of our board of directors from one annual general meeting of shareholders to the next annual general meeting of shareholders has to be within the maximum compensation approved for the board of directors by our shareholders at our general meeting of shareholders for each relevant period.

Pursuant to the organizational regulations of our board of directors, directors who are also serving as our employee and/or for an affiliate only receive compensation in their capacity as employees and do not receive additional compensation for their activities as members of our board of directors.

The following table sets forth the compensation received by our non-employee directors for the year ended December 31, 2020. Ernest Loumaye, member of our board of directors and who served as our Chief Executive Officer until December 2020, did not receive additional compensation for his services as a director.

		Social	
Name	Fees Earned	charges	Total
Frank Verwiel	\$ 78,000	\$ 7,000	\$ 85,000
Annette Clancy	\$ 55,000	\$ 3,000	\$ 58,000
Barbara Duncan	\$ 55,000	\$ 5,000	\$ 60,000
Ed Mathers	\$ 52,000	\$ 5,000	\$ 57,000
Jim Healy	\$ 48,000	\$ 4,000	\$ 52,000
Rafaèle Tordjman	\$ 48,000	\$ 4,000	\$ 52,000
Jacky Vonderscher	\$ 40,000	\$ 3,000	\$ 43,000

### **Executive Officer Compensation**

The annual cash compensation of our executive officers consists of fixed and variable compensation elements.

Fixed compensation comprises the base salary and other compensation elements, as determined under the review process of the compensation, nominating and corporate governance committee of our board of directors and approved by the board, and is based on the position and level of responsibility of the recipient.

Variable compensation comprises performance-related cash bonuses that are based on target bonuses which could be of 30%, 35%, 40% or 50% of the base salary before September 11, 2019 and of 40% or 50% of the base salary after the changes to the composition of our executive committee on September 11, 2019, depending on the executive officer's position and level of responsibility. The actual amount of cash bonus awarded for a specific year to an executive officer ranges from 50% to 150% of the target bonus for such executive officer. The adjustment rate applied to the target bonus of an executive officer is determined at the end of every year based on our general performance and the executive officer's individual performance for such fiscal year, which performance is assessed based on annual corporate and individual objectives. We do not use specific metrics to calculate the adjustment rates, which are determined at the sole and full discretion of the compensation, nominating and corporate governance committee of our board of directors and subject to approval by our board of directors. The average adjustment rate to target bonuses of executive officers was capped at 80% for the year ended December 31, 2020, as a result of our general performance. For 2020, on average, variable cash compensation represented approximately 24% of the total cash compensation of our executive officers, or 26% of their fixed cash compensation.

Social contributions, to the extent required by Swiss law, are accrued on the annual cash compensation of our executive officers.

Our executive officers are eligible to participate in our 2017 Plan.

The aggregate compensation paid to our executive officers with respect to each business year has to be within the maximum compensation approved for our executive officers by our shareholders at our general meeting of shareholders for each relevant period.

In addition, we reimburse our executive officers for out-of-pocket expenses incurred in relation to their services on an ongoing basis upon presentation of the corresponding receipts. Expenses reimbursements are not part of the compensation.

The following table sets forth the compensation received by our executive officers for the year ended December 31, 2020.

		Social	Equity	All Other	
Name	Salary	charges(1)	Awards(2)	Compensation(3)	Total
Brian O'Callaghan(4)	\$ 70,000	\$ 404,000	\$ 1,000	\$ 3,045,000	\$ 3,520,000
Ernest Loumaye(4)	\$ 753,000	\$ 183,000	\$ 37,000	\$ 1,656,000	\$ 2,629,000
Other executive officers(5)	\$ 1,999,000	\$ 383,000	\$ 122,000	\$ 2,457,000	\$ 4,961,000

- (1) Includes social charges on cash-based compensation and fair value of equity instruments granted.
- (2) Fair value of equity instruments granted during the period, as determined under IFRS.
- (3) Represents pension contributions.
- (4) On December 1, 2020, Brian O'Callaghan was appointed Chief Executive Officer to succeed to Ernest Loumaye who stepped down from the Executive Committee on the same date, while still remaining a Director of the Company.
- (5) Includes the compensation received by executive officers who left the Company during the year ended December 31, 2020 until their departure.

# **Non-Voting Share Incentive Plan**

On November 26, 2013, we adopted an incentive plan, or the Plan, under which, subject to the approval of our board of directors, we may grant awards of restricted non-voting shares to eligible participants. As of the date of our initial public offering, all non-voting shares issued under the Plan were immediately converted into common shares, with a par value of CHF 1/13 each. All converted common shares are still subject to all provisions provided under the Plan, or as otherwise set out in the participant's issuance agreement. The material terms of our Plan are set forth below.

All of our employees, advisors, including scientific consultants, agents and members of our board of directors are eligible to participate in our Plan. As of December 31, 2020, there were 1,854,502 issued and outstanding common shares awarded under our Plan. Under our Plan, common shares held by participants are subject to a four-year vesting period, or as otherwise set out in the participant's issuance agreement. Under the Plan, one-fourth of the common shares would vest upon the first anniversary of the issuance date, and one-36th of the remaining common shares would vest, starting from the first anniversary of the issuance date, over a total period of three years. Upon a termination of employment, certain forfeiture provisions may apply to a participant's vested or unvested common shares. As of December 31, 2020, all common shares awarded under our Plan are fully vested.

### 2017 Equity Incentive Plan

Following the completion of our initial public offering, we ceased issuing any new grants under our Plan, and began issuing new awards under our 2017 Equity Incentive Plan, as amended, or our 2017 Plan.Our 2017 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the Internal Revenue Code, or the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of non-statutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. Our 2017 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

### **Authorized Shares**

The maximum number of our common shares that may be issued under our 2017 Plan is 9,004,437 shares. The maximum number of common shares that may be issued pursuant to the exercise of incentive stock options under our 2017 Plan is 8,300,000 shares.

The maximum number of our common shares subject to stock awards granted under our 2017 Plan or otherwise during any one fiscal year to any non-employee director, taken together with any cash fees paid to the director during the fiscal year, will not exceed \$645,000 in total value.

Shares issued under our 2017 Plan may be authorized but unissued or reacquired shares. Shares subject to stock awards granted under our 2017 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2017 Plan. Additionally, shares issued pursuant to stock awards under our 2017 Plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under our 2017 Plan.

### Administration

Our board of directors, or a duly authorized committee thereof, has the authority to administer our 2017 Plan. Our board of directors has delegated its authority to administer our 2017 Plan to our compensation, nominating and corporate governance committee under the terms of the compensation, nominating and corporate governance committee's charter. Subject to the terms of our 2017 Plan, our board of directors may also delegate to one or more of our officers the authority to (1) designate employees other than officers to receive specified stock awards and (2) determine the number of common shares to be subject to such stock awards. Our board of directors has also delegated joint authority to our Chief Executive Officer and Chief Financial Officer to make certain stock option grants up to a maximum of 250,000 common shares to newly hired employees who are not officers within the meaning of Section 16 of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, among other limitations. Subject to the terms of our 2017 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of one common share, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2017 Plan.

The administrator has the power to modify outstanding awards under our 2017 Plan. Subject to the terms of our 2017 Plan, the administrator has the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

## Section 162(m) Limits

No participant may be granted stock awards covering more than 1,500,000 of our common shares under our 2017 Plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common shares on the date of grant. Additionally, no participant may be granted in a calendar year a performance stock award covering more than 1,500,000 of our common shares or a performance cash award having a maximum value in excess of \$10,000,000 under our 2017 Plan. These limitations enable us to grant awards that will be exempt from the \$1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code.

## Performance Awards

Our 2017 Plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the \$1,000,000 limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To enable us to grant performance-based awards that will qualify, our compensation, nominating and corporate governance committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

### Corporate Transactions

Our 2017 Plan provides that in the event of a specified corporate transaction, including without limitation a consolidation, merger, or similar transaction involving our company, the sale or other disposition of all or substantially all of the consolidated assets of our company and our subsidiaries, or a sale or disposition of more than 50% of the outstanding capital stock of our company, each stock award will terminate and be cancelled to the extent not vested or exercised prior to the effective time of the specified corporate transaction, unless the administrator elects to take one or more of the following actions with respect to such stock award:

- arrange for the assumption, continuation or substitution of a stock award by a successor corporation;
- arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- cancel the stock award to the extent not vested or not exercised prior to the effective time of the corporate transaction, in exchange for such cash consideration or no consideration as the administrator, in its sole discretion, may consider appropriate;
- arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by us; or
- cancel the stock award prior to the transaction in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the stock award.

The administrator is not obligated to treat all stock awards or portions of stock awards, even those that are of the same type, in the same manner. The administrator may take different actions with respect to the vested and unvested portions of a stock award.

### Change in Control

The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a termination of the participant's continuous service after a change in control. In the absence of such a provision, no such acceleration of the stock award will occur.

# Plan Amendment or Termination

Our board of directors has the authority to amend, suspend, or terminate our 2017 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No incentive stock options may be granted after the tenth anniversary of the date our 2017 Plan was adopted by our board of directors.

### C. Board Practices.

Our board of directors is composed of eight members. Each director is elected for a one-year term. The current members of our board of directors were appointed at our annual general meeting of shareholders held on June 9, 2020 to serve until our 2021 annual general meeting of shareholders.

We are a foreign private issuer. As a result, in accordance with the Nasdaq listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than relying on the stock exchange corporate governance requirements. However, our board of directors has undertaken a review of the independence of the directors and determined that, under current Nasdaq listing requirements, Frank Verwiel, Annette Clancy, Barbara Duncan, James I. Healy,

Ed Mathers, Rafaèle Tordjman and Jacky Vonderscher, representing seven of our eight directors, are "independent directors." In making such determination, our board of directors considered whether any director has a material relationship with us that could compromise their ability to exercise independent judgment in carrying out their responsibilities. For an overview of our corporate governance principles, see "Item 10.B—Memorandum and Articles of Association."

### **Board Committees**

Our board of directors has established an audit committee and a compensation, nominating and corporate governance committee.

#### Audit Committee

The audit committee, which consists of Barbara Duncan, Ed Mathers and Frank Verwiel, assists our board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee is directly responsible for the compensation, retention and oversight of the work of our independent registered public accounting firm and statutory auditors who are appointed by the shareholders pursuant to Swiss corporation law. Ms. Duncan serves as chairman of the committee. The audit committee consists exclusively of members of our board of directors who are financially literate, and Ms. Duncan is considered an "audit committee financial expert" as defined by the U.S. Securities and Exchange Commission, or SEC. Our board of directors has determined that Ms. Duncan, Mr. Mathers and Dr. Verwiel satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act.

The audit committee is governed by a charter that complies with Nasdaq listing rules. The audit committee is responsible for, among other things:

- recommending an auditor for submission to the shareholders;
- the compensation, retention and oversight of any auditor or accounting firm engaged for the purpose of preparing or issuing an audit report
  or performing other audit, review or attest services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services:
- reviewing and discussing with the independent auditor its responsibilities under generally accepted auditing standards, the planned scope and timing of the independent auditor's annual audit plan(s) and significant findings from the audit;
- obtaining and reviewing a report from the independent auditor describing all relationships between the independent auditor and us consistent
  with the applicable Public Company Accounting Oversight Board requirements regarding the independent auditor's communications with
  the audit committee concerning independence;
- confirming and evaluating the rotation of the audit partners on the audit engagement team as required by law;
- reviewing with management and the independent auditor, in separate meetings whenever the audit committee deems appropriate, any
  analyses or other written communications prepared by the management or the independent auditor setting forth significant financial
  reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of
  alternative IFRS methods on the financial statements, and our other critical accounting policies and practices;
- reviewing, in conjunction with our chief executive officer and chief financial officer, our disclosure controls and procedures;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters; and
- approving or ratifying any related party transaction (as defined in our related party transaction policy) in accordance with our related party transaction policy.

The audit committee meets as often as it determines is appropriate to carry out its responsibilities, but in any event will meet at least four times per year.

## Compensation, Nominating and Corporate Governance Committee

Our compensation, nominating and corporate governance committee consists of four members, Annette Clancy, Rafaèle Tordjman, Ed Mathers and James I. Healy. Our board of directors has determined that each of Ms. Clancy, Mr. Mathers and Drs. Tordjman and Healy are independent under the Nasdaq listing standards, are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act. The chair of our compensation, nominating and corporate governance committee is Ms. Clancy. The primary purpose of our compensation, nominating and corporate governance committee is to discharge our board of directors' responsibilities to oversee our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. We are subject to the Swiss Ordinance against excessive compensation in listed stock corporations, known as the "Minder" rules. As a result of the Minder rules, the members of the compensation, nominating and corporate governance committee must be elected by our shareholders and the aggregate compensation of our board of directors and executive officers must also be approved by our shareholders.

In addition, this committee is also responsible for director nominations as well as reviewing and making recommendations to the board, if required, on our corporate governance framework and guidelines.

The compensation, nominating and corporate governance committee has the responsibility to, among other things:

- review and approve, or recommend that our board of directors approve, the compensation of our executive officers based on the aggregate compensation approved by our shareholders;
- review and recommend to our board of directors the compensation of our directors based on the aggregate compensation approved by our shareholders:
- review and approve, or recommend that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- administer our share and equity incentive plans;
- select independent compensation consultants and assess whether there are any conflicts of interest with any of the committees' compensation advisers;
- review and approve, or recommend that our board of directors approve, incentive compensation and equity plans, and any other compensatory arrangements for our executive officers and other senior management, as appropriate;
- review and establish general policies relating to compensation and benefits of our employees and reviewing our overall compensation philosophy;
- identify, evaluate and select, or recommend that our board of directors approve, nominees for election to our board of directors;
- evaluate the performance of our board of directors and of individual directors;
- consider and make recommendations to our board of directors regarding the composition of the committees of the board of directors;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting;
- · review management succession plans;
- approve any loans by the company to executive officers (to the extent permitted by applicable law and our articles of association) and loans by the company to employees that are not executive officers, where the amount of any such loan exceeds \$10,000;
- develop and make recommendations to our board of directors regarding corporate governance guidelines and matters; and
- oversee periodic evaluations of the board of directors' performance.

### **Other Corporate Governance Matters**

The Sarbanes-Oxley Act of 2002, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, including our company, to comply with various corporate governance practices. In addition, Nasdaq rules provide that foreign private issuers may follow home country practice in lieu of the Nasdaq corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws.

Because we are a foreign private issuer, our members of our board of directors, executive board members and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

## D. Employees.

As of December 31, 2020, we had 45 employees. None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees. At each date shown, we had the following number of employees, broken out by department and geography.

	As of December 31,			
	2020	2019	2018	
Function				
Research and preclinical development	9	9	9	
Clinical, medical and regulatory affairs	23	25	20	
Management and administrative	13	19	16	
Total	45	53	45	
Geography				
Switzerland	41	47	39	
United States	4	6	6	

### E. Share Ownership.

For information regarding the share ownership of our directors and executive officers, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

### Item 7. Major Shareholders and Related Party Transactions

# A. Major shareholders.

The following table sets forth information with respect to the beneficial ownership of our common shares as of December 31, 2020 for:

- each beneficial owner of 5% or more of our outstanding common shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include common shares issuable upon the exercise of options that are immediately exercisable or exercisable within 60 days of December 31, 2020. Percentage ownership calculations are based on 57,552,578 common shares (excluding 3,608,281 treasury shares) outstanding as of December 31, 2020.

Except as otherwise indicated, all of the shares reflected in the table are common shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of common shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding common shares subject to options held by that person that are immediately exercisable or exercisable

within 60 days of December 31, 2020. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (\*).

Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are in care of ObsEva SA, Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland.

Name of Beneficial Owner	Number	Percentage
Principal Shareholders:		
Sofinnova Venture Partners VIII, L.P.(1)	4,749,623	8.3%
New Enterprise Associates 15, L.P.(2)	4,586,563	8.0%
Armistice Capital, LLC (3)	2,889,432	5.0%
Executive Officers and Directors:		
Brian O'Callaghan	(*)	
David Renas	(*)	
Jean-Pierre Gotteland	(*)	
Elizabeth Garner	(*)	
Wim Souverijns	(*)	
Fabien de Ladonchamps	(*)	
Ernest Loumaye(4)	4,963,355	8.5%
Annette Clancy	(*)	
Barbara Duncan	(*)	
James I. Healy(1)(5)	4,845,691	8.4%
Ed Mathers(2)(6)	4,682,631	8.1%
Rafaèle Tordjman	(*)	
Frank Verwiel	(*)	
Jacky Vonderscher	(*)	
All current directors and executive officers as a group (14 persons)(7)	15,974,923	26.7%

<sup>\*</sup> Represents beneficial ownership of less than 1%.

The information is based on the number of our common shares reported by Sofinnova Venture Partners VIII, L.P., or Sofinnova VIII, Sofinnova Management VIII, L.L.C., Dr. Michael F. Powell and Dr. James I. Healy, in notifications filed with the SIX Swiss Exchange. Consists of 4,749,623 common shares directly held by Sofinnova VIII. Sofinnova Management VIII, L.L.C. is the general partner of Sofinnova VIII, and Dr. Anand Mehra, Dr. James I. Healy (a member of our board of directors) and Dr. Michael F. Powell, the managing members of Sofinnova Management VIII, L.L.C., may be deemed to have shared voting and dispositive power with respect to such shares. The address of Sofinnova VIII is c/o Sofinnova Investments, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, California 94025.

The information is based on the number of our common shares reported by New Enterprise Associates 15, L.P., or NEA 15, NEA Partners 15, L.P., or NEA 15 GP, LLC, or NEA 15 LLC, Peter J. Barris, Forest Baskett, Anthony A. Florence, Jr., Joshua Makower, David M. Mott, Jon M. Sakoda, Scott D. Sandell, Peter W. Sonsini and Ravi Viswanathan in notifications filed with the SIX Swiss Exchange. Consists of 4,586,563 common shares directly held by NEA 15. The shares directly held by NEA 15 are indirectly held by NEA Partners 15, the sole general partner of NEA 15, NEA 15 LLC, the sole general partner of NEA Partner 15 and each of the individual Managers of NEA 15 LLC. The individual Managers of NEA 15 LLC, or collectively, the NEA 15 Managers, are Peter J. Barris, Forest Baskett, Anthony A. Florence, Jr., Joshua Makower, David M. Mott, Jon M. Sakoda, Scott D. Sandell, Peter W. Sonsini and Ravi Viswanathan. NEA 15, NEA Partners 15, NEA 15 LLC and the NEA 15 Managers share voting and dispositive power with regard to our securities directly held by NEA 15. Ed Mathers, a partner of New Enterprise Associates, Inc., is a member of our board of directors. The address of New Enterprise Associates 15, L.P. is c/o New Enterprise Associates, Inc., 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

The information is based solely on a Schedule 13G/A filed by Armistice Capital, LLC on February 16, 2021. Consists of 2,889,432 common shares directly held by Armistice Capital, LLC. Steven Boyd is the managing partner of Armistice Capital, LLC. The address of Armistice Capital, LLC is 510 Madison Avenue, 7th Floor, New York, New York 10022.

- (4) Includes 1,047,905 common shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2020.
- (5) Includes 96,068 common shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2020.
- (6) Includes 96,068 common shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2020.
- (7) Includes 2,256,737 common shares issuable upon the exercise of options that are exercisable within 60 days of December 31, 2020.

As of December 31, 2020, we estimate that approximately 30% of our outstanding common shares were held in the United States by seven holders of record. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose common shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

## **B.** Related Party Transactions.

Since January 1, 2020, we have engaged in the following transactions with our directors, executive officers and holders of more than five percent (5%) of our outstanding voting securities and their affiliates, which we refer to as our related-parties.

### **Director and Executive Officer Compensation**

See "Item 6.B—Compensation of Directors and Executive Officers" for information regarding compensation of directors and executive officers.

#### **Indemnification Agreements**

We entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements and our articles of association require us to indemnify our directors and executive officers to the fullest extent permitted by law.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## Registration Rights Agreement

We have entered into a registration rights agreement with certain of our existing shareholders pursuant to which we have granted them customary registration rights for the resale of the common shares held by certain of our existing shareholders.

### 2020 Private Placement

In September 2020, concurrent with our underwritten public offering, our former Chief Executive Officer, Ernest Loumaye, purchased 516,352 units at an effective price of \$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 \$3.43 per share, in a private placement. We received \$1.5 million in total net proceeds from the private placement.

# **Related-Party Transactions Policy**

We have adopted a related-party transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related-party transactions. For purposes of our policy only, a related-party transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related parties are, were or will be participants, which are not (1) in the ordinary course of business, (2) at arms' length and (3) in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. For purposes of this policy, a related party is any executive officer, director (or nominee for director) or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related-party transaction, including any transaction that was not a related-party transaction when originally consummated or any transaction that was not initially identified as a related-party transaction prior to consummation, our management must present information regarding the related-party transaction to our board of directors for review, consideration and approval. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related parties, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant shareholder to enable us to identify any existing or potential related-party transactions and to effectuate the terms of the policy. In addition, our board of directors has adopted a Code of Business Conduct and Ethics, under which our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related-party transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related party is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related-party transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our shareholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

# C. Interests of Experts and Counsel.

Not applicable.

### **Item 8. Financial Information**

### A. Consolidated Statements and Other Financial Information.

## **Consolidated Financial Statements**

Our consolidated financial statements are appended at the end of this Annual Report, starting at page F-1, and incorporated herein by reference.

# **Dividend Distribution Policy**

Since our incorporation, we have never paid a dividend, and we do not anticipate paying dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. As a result, investors in our common shares will benefit in the foreseeable future only if our common shares appreciate in value.

Under Swiss law, any dividend must be proposed by our board of directors and approved by a shareholders' meeting. In addition, our auditors must confirm that the dividend proposal of our board of directors conforms to Swiss statutory law and our articles of association. A Swiss corporation may pay dividends only if it has sufficient distributable profits brought forward from the previous business years or if it has distributable reserves, each as evidenced by its audited stand-alone statutory balance sheet prepared pursuant to Swiss law and after allocations to reserves required by Swiss law and its articles of association have been deducted. Distributable reserves are generally booked either as "retained earnings" (réserves issues du bénéfice) or as "capital reserves" (réserves issues du capital). Distributions out of issued share capital, which is the aggregate par value of a corporation's issued shares, may be made only by way of a share capital reduction. See "Item 10. B—Memorandum and Articles of Association" for further details on the limitations on our ability to declare and pay dividends.

## **Legal Proceedings**

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

# **B.** Significant Changes.

Not applicable.

# Item 9. The Offer and Listing.

### A. Offer and Listing Details.

The common shares have been listed on Nasdaq Global Select Market, or Nasdaq, under the symbol "OBSV" since January 26, 2017, and on SIX Swiss Exchange, or SIX, under the symbol "OBSN" since July 13, 2018. Prior to January 26, 2017, there was no public trading market for common shares.

### B. Plan of Distribution.

Not applicable.

### C. Markets.

Our common shares have been listed on Nasdaq under the symbol "OBSV" since January 26, 2017, and on SIX under the symbol "OBSN" since July 13, 2018.

### D. Selling Shareholders.

Not applicable.

# E. Dilution.

Not applicable.

### F. Expenses of the Issue.

Not applicable.

### Item 10. Additional Information.

### A. Share Capital.

Not applicable.

# B. Memorandum and Articles of Association.

Subject to the specifications mentioned below, the information set forth in our Registration Statement on Form F-3 (File No. 333-233069) as filed with the SEC on August 7, 2019 and declared effective by the SEC on August 14, 2019, under the headings "Description of Share Capital—The Company," "Description of Share Capital—Articles of Association," "Description of Share Capital—General Meeting of Shareholders," "Description of Share Capital—Voting Rights," "Description of Share Capital—Dividends and Other Distributions," "Description of Share Capital—Transfer of Shares," "Description of Share Capital—Lispection of Books and Records," "Description of Share Capital—Compulsory Acquisitions; Appraisal Rights," "Description of Share Capital—Board of Directors," "Description of Share Capital—Conflict of Interest, Management Transactions" "Description of Share Capital—Principles of the Compensation of the Board of Directors and the Executive Management," "Comparison of Swiss Law and Delaware Law" and "Enforcement of Judgments" is incorporated herein by reference.

## **Share Capital**

As of March 5, 2021, our issued and fully paid-in share capital registered with the commercial registry of the Swiss canton of Geneva, Switzerland, consisted of 81,220,471 common shares, par value CHF 1/13 per share, or approximately CHF 0.0769 per share, and no preferred shares. 4,000,000 additional common shares have been issued, but not yet registered with the commercial registry of the Swiss canton of Geneva, Switzerland, bringing our effective issued and fully paid-in share capital to 85,220,471 common shares.

Under our articles of association, as amended on February 12, 2021, our share capital may be increased by a maximum aggregate amount of CHF 692,649.00 through the issuance of not more than 9,004,437 common shares, par value CHF 1/13 per share, in connection with our equity incentive plans.

Under our articles of association, as amended on February 12, 2021, our share capital may be increased by a maximum aggregate amount of CHF 1,040,544 and 1/13th of a Swiss franc through the issuance of not more than 13,527,073 common shares, which would have to be fully paid-in, with a par value of CHF 1/13 each, by the exercise of option and conversion rights granted in connection with convertible bonds or similar instruments of the Company or one of our subsidiaries. Since February 12, 2021, 4,000,000 additional common shares have been issued out of our conditional capital for financing purposes, reducing such conditional share capital to an aggregate amount of CHF 732,851 and 10/13th of a Swiss franc allowing the issuance of up to 9,527,073 common shares. These changes have however not yet been reflected in our articles of association or registered with the commercial registry of the Swiss canton of Geneva, Switzerland.

Our share capital activity was as follows:

Common shares registered in the commercial registry at January 1, 2017	23,181,262
Common shares registered in the commercial registry in January 2017	6,450,000
Common shares registered in the commercial registry in October 2017	5,140,625
Common shares registered in the commercial registry in December 2017	2,359,375
Common shares registered in the commercial registry at December 31, 2017	37,131,262
Common shares registered in the commercial registry in March 2018	3,499,990
Common shares registered in the commercial registry in June 2018	4,750,000
Common shares registered in the commercial registry at December 31, 2018	45,381,252
Common shares registered in the commercial registry in March 2019	110,364
Common shares registered in the commercial registry in July 2019	3,064,048
Common shares registered in the commercial registry at December 31, 2019	48,555,664
Common shares registered in the commercial registry in April 2020	3,320,337
Common shares registered in the commercial registry on September 8, 2020	7,810,266
Common shares registered in the commercial registry on September 29, 2020	516,352
Common shares registered in the commercial registry at December 31, 2020	60,202,619

From January 1, 2017 through March 5, 2021, the following events have changed the number of our issued common shares:

- On January 30, 2017, we issued 6,450,000 common shares at a price per share of \$15.00 in connection with our initial public offering of our common shares on Nasdaq. On the same date, all Series A preferred shares, Series B preferred shares and non-voting shares were converted into common shares.
- On October 9, 2017, our board of directors decided to increase our share capital through the issuance of 5,140,625 common shares at a price of \$8.00 per share and approved the issuance of warrants to purchase an aggregate of 2,359,375 common shares at an exercise price of \$8.00 per share.
- On October 13, 2017, we completed a private placement of 5,140,625 common shares at a price of \$8.00 per share and warrants to purchase an aggregate of 2,359,375 common shares with an exercise price of \$8.00 per share. The warrants were exercised on October 13, 2017. We received net proceeds of \$56.3 million from the private placement.
- On October 24, 2017, the increase of our share capital, through the issuance of 5,140,625 common shares, par value CHF 1/13 per share, was recorded with the commercial registry of the Swiss canton of Geneva.
- On December 7, 2017, our articles of association were amended in order to reflect the increase of our share capital by 2,359,375 common shares, issued on October 13, 2017 upon exercise of warrants. These changes were recorded with the commercial registry of the Swiss canton of Geneva, on December 13, 2017.

- During an extraordinary general meeting of shareholders, held on January 26, 2018, our shareholders voted to amend our articles of association in order to authorize our board of directors, at any time until January 26, 2020, to increase our share capital by a maximum aggregate par value of CHF 1,428,125 through the issuance of not more than 18,565,625 common shares, which would have to be fully paid-in, with a par value of CHF 1/13 per share. In addition, our shareholders voted to amend our articles of association in order to enable the increase of our share capital from time to time by the issuance of up to 14,393,002 common shares, par value CHF 1/13 per share, upon exercise of option or conversion rights granted in connection with financial instruments issued by us or our subsidiaries. Our revised articles of association were recorded with the commercial registry of the Swiss canton of Geneva on January 31, 2018.
- On March 12, 2018, our board of directors decided to issue 3,499,990 common shares at par value, by way of self-subscription for the purpose of rebuilding our pool of treasury shares. The increase of our share capital was recorded with the commercial registry of the Swiss canton of Geneva, on March 31, 2018.
- During our 2018 annual general meeting of shareholders, held on May 9, 2018, our shareholders decided to amend the articles of association of the company in order to authorize our board of directors, at any time until May 9, 2020, to increase our share capital by a maximum aggregate par value of CHF 1,562,740 through the issuance of not more than 20,315,620 common shares, which would have to be fully paid-in, with a par value of CHF 1/13. In addition, our shareholders decided to amend the articles of association of the company in order to enable the increase of our share capital from time to time by the issuance of up to 5,922,618 common shares, par value CHF 1/13 per share, upon exercise of options or pre-emptive rights thereof, which have been issued or granted to employees, directors or consultants of our company or of one of our subsidiaries under the terms of our equity plans. Our revised articles of association were recorded with the commercial registry of the Swiss canton of Geneva on May 11, 2018.
- On June 20, 2018, our board of directors decided to increase our share capital through the issuance of 4,750,000 common shares at a price of \$15.39 per share.
- On June 22, 2018, we completed a public offering of 4,750,000 common shares at a price of \$15.39 per share. We received net proceeds of \$68.0 million from the public offering. The increase of our share capital, through the issuance of 4,750,000 common shares, par value CHF 1/13 per share, was recorded with the commercial registry of the Swiss canton of Geneva, on June 22, 2018.
- On March 26, 2019, our articles of association were amended in order to reflect the increase of our share capital by 110,364 common shares, issued upon exercise of stock options under our equity plans. These changes were recorded with the commercial registry of the Swiss canton of Geneva, on March 27, 2019.
- During our 2019 annual general meeting of shareholders, held on May 8, 2019, our shareholders decided to amend the articles of association of the company in order to authorize our board of directors, at any time until May 8, 2021, to increase our share capital by a maximum aggregate par value of CHF 1,749,677 through the issuance of not more than 22,745,801 common shares, which would have to be fully paid-in, with a par value of CHF 1/13 per share. In addition, our shareholders decided to amend the articles of association of the company in order to enable the increase of our share capital from time to time by the issuance of up to 16,933,553 common shares, par value CHF 1/13 per share, upon exercise of option or conversion rights granted in connection with financial instruments issued by us or our subsidiaries. Our revised articles of association were recorded with the commercial registry of the Swiss canton of Geneva on May 9, 2019.
- On July 17, 2019, our board decided to issue 3,064,048 common shares, at par value, which were subscribed for by our U.S. wholly-owned subsidiary, ObsEva USA Inc., for the purpose of rebuilding our pool of treasury shares. The increase of our share capital was recorded with the commercial registry of the Swiss canton of Geneva, on July 19, 2019.
- On April 10, 2020, our board decided to issue 3,308,396 common shares, at par value, which were subscribed for by our U.S. wholly-owned subsidiary, ObsEva USA Inc., for the purpose of rebuilding our pool of treasury shares. The increase of our share capital was recorded with the commercial registry of the Swiss canton of Geneva, on April 28, 2020.
- On April 14, 2020, our articles of association were amended in order to reflect the increase of our share capital by 11,941 common shares, issued upon exercise of stock options under our equity plans. These changes were recorded with the commercial registry of the Swiss canton of Geneva, on April 28, 2020.
- During the 2020 Annual General Meeting, our shareholders decided to amend the articles of association of the company in order to authorize our board of directors, at any time until June 9, 2022, to increase our share capital

by a maximum aggregate par value of CHF 1,995,230 through the issuance of not more than 25,937,990 common shares, which would have to be fully paid-in, with a par value of CHF 1/13 per share. In addition, our shareholders decided to amend the articles of association of the company in order to enable the increase of our share capital from time to time by the issuance of up to 9,004,437 common shares, par value CHF 1/13 per share, upon exercise of options or pre-emptive rights thereof, which have been issued or granted to employees, directors or consultants of our company or of one of our subsidiaries under the terms of our equity plans. Our revised articles of association were recorded with the commercial registry of the Swiss canton of Geneva on June 11, 2020.

- 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 this context, our board decided, on September 3, 2020, to issue 5,490,000 common shares for the purpose of the underwritten offering and 2,320,266 common shares, at par value, which were subscribed for by our U.S. wholly-owned subsidiary, ObsEva USA Inc., for the purpose of rebuilding our pool of treasury shares. The increase of our share capital was recorded with the commercial registry of the Swiss canton of Geneva, on September 8, 2020.
- In September 2020, we completed a private placement of 516,352 units at an effective price of \$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 \$3.43 per share. In this context, our board of directors decided, on September 18, 2020, to issue 516,352 common shares. The increase of our share capital was recorded with the commercial registry of the Swiss canton of Geneva, on September 29, 2020.
- On January 27, 2021, our board decided to issue 6,020,248 common shares, at par value, which were subscribed for by our U.S. wholly-owned subsidiary, ObsEva USA Inc., for the purpose of rebuilding our pool of treasury shares. The increase of our share capital was recorded with the commercial registry of the Swiss canton of Geneva, on February 1, 2021.
- On February 10, 2021, our board decided to issue 11,591,124 common shares, at par value, which were subscribed for by our U.S. wholly-owned subsidiary, ObsEva USA Inc., for the purpose of rebuilding our pool of treasury shares. The increase of our share capital was recorded with the commercial registry of the Swiss canton of Geneva, on February 15, 2021.
- On February 12, 2021, our articles of association were amended in order to reflect the increase of our share capital by 3,406,480 common shares, issued upon exercise of options granted in connection with financial market instruments. These changes were recorded with the commercial registry of the Swiss canton of Geneva, on February 15, 2021.
- Since February 12, 2021, 4,000,000 additional common shares have been issued out of our conditional capital for financing purposes, further to the exercise of outstanding warrants issued in the context of the underwritten offering of September 2020. The issuance of these shares has not yet been reflected in our articles of association or registered with the commercial registry of the Swiss canton of Geneva, Switzerland.

#### Articles of Association

When we refer to our articles of association in this Form 20-F, we refer to our amended and restated articles of association dated as of February 12, 2021.

Under our articles of association, as amended on February 12, 2021, our share capital may be increased by a maximum aggregate amount of CHF 1,040,544 and 1/13th of a Swiss franc through the issuance of not more than 13,527,073 common shares, which would have to be fully paid-in, with a par value of CHF 1/13 each, by the exercise of option and conversion rights granted in connection with convertible bonds or similar instruments of the Company or one of our subsidiaries. Since February 12, 2021, 4,000,000 additional common shares have been issued out of our conditional capital for financing purposes, reducing such conditional share capital to an aggregate amount of CHF 732,851 and 10/13th of a Swiss franc allowing the issuance of up to 9,527,073 common shares. These changes have however not yet been reflected in our articles of association or registered with the commercial registry of the Swiss canton of Geneva, Switzerland.

Under our articles of association, as amended on February 12, 2021, our share capital may be increased by a maximum aggregate amount of CHF 692,649.00 through the issuance of not more than 9,004,437 common shares, par value CHF 1/13 per share, in connection with our equity incentive plans.

### C. Material Contracts.

#### **Underwriting Agreement**

We entered into an underwriting and placement agency agreement with H.C. Wainwright & Co., LLC, on September 3, 2020, with respect to the common shares sold in our September 2020 underwritten public offering in the United States and concurrent private placement. We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of such liabilities.

### At the Market (ATM) Program

On March 16, 2018, we entered into an agreement with Jefferies LLC to sell treasury shares from time to time at our discretion under an "at the market" (ATM) program, with aggregate gross sales proceeds of up to \$50.0 million. On August 7, 2019, this agreement was amended to increase the aggregate gross sales proceeds that may be generated under the ATM program by \$25.0 million, for aggregate gross sales proceeds of up to \$75.0 million. Through December 31, 2020, we have generated gross proceeds of \$40.5 million under the program.

### **Credit Facility Agreement**

On August 7, 2019, we entered into the Credit Facility Agreement with 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. In April 2020, we entered into an amendment to the Credit Facility Agreement, pursuant to which 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.

### Sublicense Agreement with Yuyuan

In January 2020, we entered into a sublicense agreement, or the 2020 sublicense agreement, with Hangzhou Yuyuan BioScience Technology Co., Ltd., or 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 People's Republic of China, including Hong Kong and Macau. Yuyuan will be responsible for the continued development of nolasiban in China at its sole cost, and is required to use commercially reasonable efforts to develop the product in accordance with certain development milestones. Yuyuan will be responsible for commercialization of nolasiban in China at its sole cost. We are obligated to supply Yuyuan with its clinical and commercial requirements of the product at cost. Yuyuan has agreed to not develop, market or sell any oxytocin receptor antagonist other than nolasiban during the term of the 2020 sublicense agreement. The development and commercialization activities for nolasiban will be governed by a joint development committee and joint commercialization committee, respectively, with each party having final decision making authority for its territory. 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 \$15.0 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.

We have the first right to file, prosecute and maintain the licensed patents in China. In the event that we do not elect to file, prosecute or maintain a licensed patent in China, Yuyuan will have the right to request an assignment of such patent, in which event, Yuyuan would be responsible for further filing, prosecution and maintenance. We have the first right to enforce licensed patents in China. Subject to the consent of our licensor of the licensed patents, Yuyuan will have a back-up right to enforce licensed patents in China. The 2020 sublicense agreement expires on the date of expiration of all royalty obligations. The 2020 sublicense agreement is subject to earlier termination by either party upon an uncured material breach of the 2020 sublicense agreement by the other party or an unresolved force majeure event. Yuyuan may terminate the agreement upon specified written notice in the event that certain clinical results are negative. Additionally, we may terminate the agreement if Yuyuan fails to make certain payments in a timely manner, if Yuyuan is acquired by a party with a competing product, if

Yuyuan fails to achieve first commercial sale within a specified timeframe after approval, and in the event that Yuyuan challenges the validity, enforceability or patentability of the licensed patents.

For additional information on our material contracts, please see "Item 4. Information on the Company," Item 6. Directors, Senior Management and Employees," and "Item 7.B. Related Party Transactions" of this Annual Report on 20-F.

## D. Exchange Controls.

There are no Swiss governmental laws, decrees or regulations that restrict, in a manner material to us, the export or import of capital, including any foreign exchange controls, or that generally affect the remittance of dividends or other payments to non-residents or non-citizens of Switzerland who hold our common shares.

#### E. Taxation.

#### **Swiss Tax Considerations**

In the opinion of Lenz & Staehelin, the following are the material Swiss income tax consequences of owning and disposing of our common shares.

This summary of material Swiss tax consequences is based on Swiss law and regulations and the practice of the Swiss tax administration as in effect on the date hereof, all of which are subject to change (or subject to changes in interpretation), possibly with retroactive effect. The summary does not purport to take into account the specific circumstances of any particular shareholder or potential investor and does not relate to persons in the business of buying and selling common shares or other securities. The summary is not intended to be, and should not be interpreted as, legal or tax advice to any particular potential shareholder, and no representation with respect to the tax consequences to any particular shareholder is made.

Current and prospective shareholders are advised to consult their own tax advisors in light of their particular circumstances as to the Swiss tax laws, regulations and regulatory practices that could be relevant for them in connection with the offering, the acquiring, owning and selling or otherwise disposing of common shares and receiving dividends and similar cash or in-kind distributions on common shares (including dividends on liquidation proceeds and stock dividends) or distributions on common shares based upon a capital reduction (remboursements liés à la réduction de la valeur nominale des actions) or distributions paid out of capital contributions reserves (réserves issues d'apports de capital) and the consequences thereof under the tax laws, regulations and regulatory practices of Switzerland.

### **Taxation of Common Shares**

### Swiss Federal Withholding Tax on Dividends and Distributions

Dividend payments and similar cash or in-kind distributions on the common shares (including dividends on liquidation proceeds and stock dividends) that the Company makes to shareholders are subject to Swiss federal withholding tax (*impôt anticipé*) at a rate of 35% on the gross amount of the dividend. We are required to withhold the Swiss federal withholding tax from the dividend and remit it to the Swiss Federal Tax Administration. Distributions based upon a capital reduction (*remboursements liés à la réduction de la valeur nominale des actions*) and distributions paid out of capital contributions reserves (*réserves issues d'apports de capital*) recognized by the Swiss Federal Tax Administration are not subject to Swiss federal withholding tax.

The Swiss federal withholding tax may also apply to gains realized upon a repurchase of shares by the company, on the difference between the repurchase price and the par value of the shares; a different basis of taxation may apply under the capital contribution principle.

The Swiss federal withholding tax is refundable or creditable in full to a Swiss tax resident corporate and individual shareholder as well as to a non-Swiss tax resident corporate or individual shareholder who holds the common shares as part of a trade or business carried on in Switzerland through a permanent establishment or fixed place of business situated for tax purposes in Switzerland, if such person is the beneficial owner of the distribution and, in the case of a Swiss tax resident individual who holds the common shares as part of his private assets, duly reports the gross distribution received in his individual income tax return or, in the case of a person who holds the common shares as part of a trade or business carried on in Switzerland through a permanent establishment or fixed place of business situated for tax purposes in Switzerland, recognizes the gross dividend distribution for tax purposes as earnings in the income statements and reports the annual profit in the income tax return.

If a shareholder who is not a Swiss resident for tax purposes and does not hold the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes in Switzerland, receives a distribution from us, the shareholder may be entitled to a full or partial refund or credit of Swiss federal withholding tax incurred on a taxable distribution if the country in which such shareholder is resident for tax purposes has entered into a treaty for the avoidance of double taxation with Switzerland and the further prerequisites of the treaty for a refund have been met. Shareholders not resident in Switzerland should be aware that the procedures for claiming treaty benefits (and the time required for obtaining a refund or credit) may differ from country to country.

Besides the bilateral treaties Switzerland has entered into an agreement with the European Community providing for an automatic exchange of information based on the OECD's global standard for the automatic exchange of information. This agreement contains in its Article 9 provisions on taxation of dividends which apply with respect to EU member states and provides for an exemption of Withholding Tax for companies under certain circumstances.

## Individual and Corporate Income Tax on Dividends

Swiss resident individuals holding the common shares as part of their private assets who receive dividends and similar distributions (including stock dividends and liquidation proceeds), which are not repayments of the par value of the common shares or distributions paid out of capital contributions reserves (*réserves issues d'apports de capital*) recognized by the Swiss Federal Tax Administration are required to report such payments in their individual income tax returns and are liable to Swiss federal, cantonal and communal income taxes on any net taxable income for the relevant tax period. Furthermore, for the purpose of the Direct Federal Tax, dividends, shares in profits, liquidation proceeds and pecuniary benefits from shares (including bonus shares) are included in the tax base for only 70% of their value, if the investment amounts to at least 10% of our nominal capital. All cantons have introduced similar partial taxation measures at cantonal and communal levels.

Swiss resident individuals as well as non-Swiss resident individual taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognize dividends, distributions based upon a capital reduction (*remboursements liés à la réduction de la valeur nominale des actions*) and distributions paid out of capital contributions reserves (*réserves issues d'apports de capital*) recognized by the Swiss Federal Tax Administration in their income statements for the relevant tax period and are liable to Swiss federal, cantonal and communal individual or corporate income taxes, as the case may be, on any net taxable earnings accumulated (including the payment of dividends) for such period. Furthermore, for the purpose of the Direct Federal Tax, dividends, shares in profits, liquidation proceeds and pecuniary benefits from shares (including bonus shares) are included in the tax base for only 70%, if the investment is held in connection with the conduct of a trade or business or qualifies as an opted business asset according to Swiss tax law and amounts to at least 10% of our nominal capital. All cantons have introduced similar partial taxation measures at cantonal and communal levels.

Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognize dividends, distributions based upon a capital reduction (*remboursements liés à la réduction de la valeur nominale des actions*) and distributions paid out of capital contributions reserves (*réserves issues d'apports de capital*) recognized by the Swiss Federal Tax Administration in their income statements for the relevant tax period and are liable to Swiss federal, cantonal and communal corporate income taxes on any net taxable earnings accumulated for such period. Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland may be eligible for dividend relief (*réduction pour participation*) in respect of dividends and distributions based upon a capital reduction (*remboursements liés à la réduction de la valeur nominale des actions*) and distributions paid out of capital contributions reserves (*réserves issues d'apports de capital*) recognized by the Swiss Federal Tax Administration if the common shares held by them as part of a Swiss business have an aggregate market value of at least CHF 1 million of represent at least 10% of our share capital or give entitlement to at least 10% of our profits and reserves, respectively.

Recipients of dividends and similar distributions on the common shares (including stock dividends and liquidation proceeds) who are neither residents of Switzerland nor during the current taxation year have engaged in a trade or business in Switzerland and who are not subject to taxation in Switzerland for any other reason are not subject to Swiss federal, cantonal or communal individual or corporate income taxes in respect of dividend payments and similar distributions because of the mere holding of the common shares.

## Wealth and Annual Capital Tax on Holding of Common Shares

Swiss resident individuals and non-Swiss resident individuals holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to report their common shares as part of their wealth and will be subject to cantonal and communal wealth tax to the extent the aggregate taxable net wealth is allocable to Switzerland.

Swiss resident corporate taxpayers and non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, will be subject to cantonal and communal annual capital tax on the taxable capital to the extent the aggregate taxable capital is allocable to Switzerland.

Individuals and corporate taxpayers not resident in Switzerland for tax purposes and not holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are not subject to wealth or annual capital tax in Switzerland because of the mere holding of the common shares.

## Capital Gains on Disposal of Common Shares

Swiss resident individuals who sell or otherwise dispose of the common shares realize a tax-free capital gain, or a non-deductible capital loss, as the case may be, provided that they hold the common shares as part of their private assets.

Capital gains realized on the sale of the common shares held by Swiss resident individuals, Swiss resident corporate taxpayers as well as non-Swiss resident individuals and corporate taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, will be subject to Swiss federal, cantonal and communal individual or corporate income tax, as the case may be. This also applies to Swiss resident individuals who, for individual income tax purposes, are deemed to be professional securities dealers for reasons of, inter alia, frequent dealing and debt-financed purchases. Capital gains realized by resident individuals who hold the common shares as business assets might be entitled to reductions or partial taxations similar to those mentioned above for dividends if certain conditions are met (e.g. holding period of at least one year and participation of at least 10% of nominal capital).

Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business, through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognize such capital gain in their income statements for the relevant tax period. Corporate taxpayers may qualify for participation relief on capital gains (*réduction pour participations*), if the common shares sold during the tax period reflect an interest of at least 10% in our capital or if the common shares sold allow for at least 10% of our profit and reserve and were held for at least one year. The tax relief applies to the difference between the sale proceeds of common shares by us and the investment cost of the participation.

Individuals and corporations not resident in Switzerland for tax purposes and not holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are not subject to Swiss federal, cantonal and communal individual income or corporate income tax, as the case may be, on capital gains realized on the sale of the common shares.

## Gift and Inheritance Tax

Transfers of common shares may be subject to cantonal or communal inheritance or gift taxes if the deceased or the donor or the recipient were resident in a Canton levying such taxes and, in international circumstances where residency requirements are satisfied, if the applicable tax treaty were to allocate the right to tax to Switzerland.

# Swiss Issuance Stamp Duty

We will be subject to and pay to the Swiss Federal Tax Administration a 1% Swiss federal issuance stamp duty (*droit de timbre d'émissions*) on the consideration received by it for the issuance of the Shares less certain costs incurred in connection with the issuance.

## Swiss Securities Transfer Stamp Duty

The purchase or sale of the common shares, whether by Swiss residents or non-Swiss residents, may be subject to Swiss securities transfer stamp duty of up to 0.15%, calculated on the purchase price or the proceeds if the purchase or sale occurs through or with a Swiss bank or other Swiss securities dealer as defined in the Swiss Federal Stamp Duty Act as an intermediary or party to the transaction unless an exemption applies. The issuance of the common shares to the initial shareholders at the offering price is not subject to Swiss securities transfer stamp duty.

## Material U.S. Federal Income Tax Consequences for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to U.S. Holders (as defined below) of acquiring, owning and disposing of common shares, but it does not purport to be a comprehensive description of all the tax consequences relating thereto. This discussion applies only to a U.S. Holder that will hold common shares as "capital assets" for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential impact of the Medicare contribution tax on net investment income (except to the extent specifically set forth below) or tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the common shares;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- S corporations, partnerships, or entities or arrangements classified as partnerships for U.S. federal income tax purposes;
- tax-exempt entities;
- persons that own or are deemed to own ten percent or more of the voting power or value of our stock;
- persons who acquired our voting stock pursuant to the exercise of a stock option or otherwise as compensation; or
- persons holding our shares in connection with a trade or business conducted outside of the United States.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships considering the acquisition of common shares and partners in such partnerships should consult their tax advisors as to their particular U.S. federal income tax consequences of owning and disposing of the common shares.

This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Switzerland and the United States, or the Treaty, all as of the date hereof, any of which is subject to change, possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of common shares who is eligible for the benefits of the Treaty and is:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (a) that is subject to the primary supervision of a court within the United States and the control of one or more United States persons as described in Section 7701(a)(30) of the Code, or (b) that has a valid election in effect under applicable Treasury regulations to be treated as a United States person.

U.S. Holders should consult their tax advisors concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of common shares in their particular circumstances.

## Passive Foreign Investment Company Rules

In general, a non-U.S. corporation will be a "passive foreign investment corporation" or "PFIC" for any taxable year in which (1) 75% or more of its gross income consists of passive income (the "PFIC income test") or (2) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income (the "PFIC asset test"). For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% (by value) of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. Passive income generally includes dividends, interest, certain rents and royalties, and capital gains. Assets that produce, or are held for the production of, passive income include cash, cash equivalents and marketable securities.

Based on our analysis of our income, assets, activities and market capitalization for our taxable year ending December 31, 2020, we do not believe that we were a PFIC for our taxable year ending December 31, 2020. However, our operations generate very limited amounts of non-passive income. Until we generate sufficient revenue from active licensing and other non-passive sources, there is a risk that we will be a PFIC under the PFIC income test. Moreover, we hold a substantial amount of cash and cash equivalents. Because the calculation of the value of our assets may be based in part on the value of our common shares, the value of which may fluctuate considerably, our PFIC status may change from year to year and it is difficult to predict whether we will be a PFIC under the PFIC asset test for the current year or any future year. Therefore, we have not yet made any determination as to our expected PFIC status for the current year. Even if we determine that we are not a PFIC after the close of a taxable year, there can be no assurance that the IRS will agree with our conclusion. Because PFIC status is a fact specific determination, and generally cannot be made until the close of the taxable year in question, no assurance can be given that we will not be a PFIC for our current taxable year and that we will not be a PFIC in future taxable years. Furthermore, because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification of certain income and assets as non-passive or our valuation of our tangible and intangible assets, each of which may result in us being treated as a PFIC for our taxable year ending December 31, 2020 or us becoming a PFIC for the current taxable year or any future taxable years. Our United States counsel expresses no opinion with respect to our PFIC status for prior years, the current taxable year or any future years.

Under attribution rules, if we are a PFIC, U.S. Holders will be deemed to own their proportionate shares of the stock of foreign corporations that we own and which are PFICs, or lower-tier PFICs and will be subject to U.S. federal income tax according to the rules described in the following paragraphs on (1) certain distributions by a lower-tier PFIC and (2) a disposition of shares of a lower-tier PFIC, in each case as if the U.S. Holder held such shares directly, even though such holders have not received the proceeds of those distributions or dispositions directly.

If we are a PFIC for any taxable year during which a U.S. Holder holds our common shares, the U.S. Holder may be subject to certain adverse tax consequences. Unless a holder makes a timely "mark-to-market" election or "qualified electing fund" election, each as discussed below, gain recognized on a disposition (including, under certain circumstances, a pledge) of common shares by the U.S. Holder, or on an indirect disposition of shares of a lower-tier PFIC, will be allocated ratably over the U.S. Holder's holding period for the shares. The amounts allocated to the taxable year of disposition and to years before we became a PFIC will be taxed as ordinary income arising in the taxable year of disposition. The amounts allocated to each other taxable year will be subject to tax at the highest rate in effect for that taxable year for individuals or corporations, as appropriate, and an interest charge will be imposed on the tax attributable to the allocated amounts. Further, to the extent that any distribution received by a U.S. Holder on our common shares (or a distribution by a lower-tier PFIC that is deemed to be received by a U.S. Holder) exceeds 125% of the average of the annual distributions with respect to such shares received during the preceding three taxable years or the U.S. Holder's holding period, whichever is shorter, the distribution will be subject to taxation in the same manner as gain on disposition of common shares, described immediately above.

If we are a PFIC for any year during which a U.S. Holder holds common shares, we generally will continue to be treated as a PFIC with respect to such holder for all succeeding years during which such U.S. Holder holds common shares, even if we cease to meet the threshold requirements for PFIC status. U.S. Holders should consult their tax advisors regarding the potential availability of a "deemed sale" election that would allow them to eliminate this continuing PFIC status under certain circumstances.

If the common shares are "regularly traded" on a "qualified exchange," a U.S. Holder may make a mark-to-market election that would result in tax treatment different from the general tax treatment for PFICs described above. The common shares will be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of the common shares is traded on a qualified exchange on at least 15 days during each calendar quarter. The Nasdaq Global Market, on which we currently list our common shares, is a qualified exchange for this purpose. Once made, the election cannot be revoked without the consent of the IRS unless the common shares cease to meet these requirements. U.S. Holders should consult their tax advisors regarding the availability and advisability of making a mark-to-market election in their particular circumstances. In particular, U.S. Holders should carefully consider the impact of a mark-to-market election with respect to their common

shares given that we may have lower-tier PFICs for which a mark-to-market election would not be available. Consequently, a U.S. Holder could be subject to the PFIC rules with respect to income of the lower-tier PFICs the value of which already had been taken into account indirectly via mark-to-market adjustments.

If a U.S. Holder makes the mark-to-market election, such holder generally will recognize as ordinary income any excess of the fair market value of their common shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of their common shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, such holder's tax basis in their common shares will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other disposition of common shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). Distributions paid on common shares will be treated as discussed below under "Taxation of Distributions."

Alternatively, a U.S. Holder can make a "qualified electing fund election," or a QEF Election, if we provide the information required to treat us and each lower-tier PFIC as a qualified electing fund in the first taxable year that we are a PFIC with respect to such holder. A U.S. Holder makes a QEF Election for us (and each lower-tier PFIC) by attaching a separate properly completed IRS Form 8621 for us (and each lower-tier PFIC) to the holder's timely filed U.S. federal income tax return. If we are a PFIC for our taxable year ending December 31, 2021, or any subsequent taxable years, we currently intend to provide U.S. Holders, upon request, the information necessary for a U.S. Holder to make a QEF Election with respect to us and we currently intend to cause each lower-tier PFIC that we control to provide such information and take any additional steps that may be necessary to allow a U.S. Holder to make a QEF Election for us and each such lower-tier PFIC. Notwithstanding the foregoing, we cannot provide any assurance that we will in fact provide the information necessary to permit QEF elections to be made.

If a U.S. Holder makes a QEF Election with respect to us, the electing U.S. Holder will be currently taxable on its pro rata share of our ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that we are a PFIC with respect to such U.S. Holder. Distributions paid by us out of our earnings and profits that were included in the holder's income as a result of the holder having made a QEF Election will not be included in the gross income of the holder. A U.S. Holder will increase its adjusted tax basis in our common shares by an amount equal to its pro rata share of our ordinary earnings and net capital gain included in gross income and decrease its adjusted tax basis in our common shares by an amount distributed on those common shares to the extent the distribution is not included in the holder's gross income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of our common shares in an amount equal to the difference between the amount realized and the holder's adjusted tax basis in our common shares. U.S. Holders should note that if they make QEF Elections with respect to us and lower-tier PFICs, they may be required to pay U.S. federal income tax with respect to their common shares for any taxable year significantly in excess of any cash distributions received on the shares for such taxable year. U.S. Holders should consult their tax advisors regarding making QEF Elections in their particular circumstances.

If we are a PFIC for any taxable year during which a U.S. Holder holds common shares, such U.S. Holder may be required to file an annual information report with such U.S. Holder's U.S. federal income tax return on IRS Form 8621.

U.S. Holders should consult their tax advisors concerning our PFIC status and the tax considerations and reporting requirements relevant to an investment in a PFIC.

# Taxation of Distributions

As described in the section entitled "Dividend Policy," we do not anticipate paying dividends in the foreseeable future. However, if we do make distributions of cash or property on our common shares, subject to the PFIC rules described above, such distributions, other than certain pro rata distributions of common shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, it is expected that distributions generally will be reported to U.S. Holders as dividends. The amount of a dividend will include any amounts withheld by us in respect of Swiss taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in Swiss Francs will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is

converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Dividends paid by us will generally be taxable to a non-corporate U.S. Holder at the preferential reduced rate normally applicable to long-term capital gains, provided our common shares remain readily tradable on an established securities market in the United States, we are not a PFIC in the taxable year in which the dividends are received or in the preceding taxable year, and certain holding period requirements are met. However, as discussed above under "Passive Foreign Investment Company Rules," if we are considered a PFIC, the preferential reduced rate will not be available with respect to dividends paid by us.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder's circumstances, Swiss income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. Swiss taxes withheld in excess of the rate applicable under the Treaty will not be eligible for credit against a U.S. Holder's federal income tax liability. The rules governing foreign tax credits are complex, and U.S. Holders should consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including the Swiss tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

### Sale or Other Taxable Disposition of Common Shares

Subject to the PFIC rules described above, for U.S. federal income tax purposes, gain or loss realized on the sale or other taxable disposition of common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than one year at the time of sale or other taxable disposition. The amount of the gain or loss will equal the difference between the amount realized on the disposition of the common shares and such U.S. Holder's adjusted tax basis in the common shares, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. Subject to the PFIC rules described above, long-term capital gains recognized by certain non-corporate U.S. Holders (including individuals) will generally be subject to reduced rates of U.S. federal income tax. A U.S. Holder's ability to deduct capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the common shares are treated as traded on an "established securities market" and a U.S. Holder is either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), such U.S. Holder will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If a U.S. Holder is an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, such U.S. Holder will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

#### Medicare Tax on Net Investment Income

Certain U.S. Holders who are individuals, estates or trusts are subject to an additional 3.8% U.S. federal income tax on all or a portion of their "net investment income," which generally includes dividends on the common shares and net gains from the disposition of the common shares. U.S. Holders that are individuals, estates or trusts should consult their tax advisors regarding the applicability of the Medicare tax to them.

## Information Reporting and Backup Withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (1) the U.S. Holder is a corporation or other exempt recipient or (2) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding, or otherwise establishes an exemption.

The amount of any backup withholding from a payment to a U.S. Holder may be allowed as a credit against such holder's U.S. federal income tax liability and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

# Information With Respect to Foreign Financial Assets

Certain U.S. Holders who are individuals or that are certain entities are required to report information relating to an interest in our common shares, subject to certain exceptions (including an exception for common shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisors regarding the effect, if any, of this legislation on their ownership and disposition of the common shares.

## F. Dividends and Paying Agents.

Not applicable.

## G. Statement by Experts.

Not applicable.

## H. Documents on Display.

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at *www.obseva.com*. We intend to post our Annual Report on Form 20-F on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report on Form 20-F. We have included our website address in this Annual Report on Form 20-F solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (*www.sec.gov*) that contains reports, proxy and information statements and other information regarding registrants, such as ObsEva, that file electronically with the SEC.

With respect to references made in this Annual Report on Form 20-F to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this Annual Report on Form 20-F for copies of the actual contract or document.

# I. Subsidiary Information.

Not required.

# Item 11. Quantitative and Qualitative Disclosures About Market Risk.

We operate primarily in Switzerland, Europe and in the United States and are therefore exposed to market risk, which represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates.

As of December 31, 2020, we had \$31.2 million of cash and cash equivalents and we had a debt instrument outstanding for a carrying value of \$25.3 million.

### **Interest Rate Risk**

We are primarily exposed to changes in short-term interest rates with respect to our cost of borrowing under our 2019 Facility with Oxford. We monitor our cost of borrowing under the 2019 Facility, taking into account our funding requirements, and our expectation for short-term rates in the future. As of December 31, 2020, an increase in the interest rate on our 2019 Facility by 100 basis points would increase our annual interest expense by approximately \$14'000.

## Foreign Currency Exchange Risk

We operate primarily in Switzerland, Europe and in the United States and our functional currency is the U.S. Dollar, and as a result, we are exposed to transactional foreign exchange risk when we or a subsidiary enter into a transaction in a currency other than our or its functional currency.

## Transactional Risk

Our expenses are generally denominated in the currencies of the countries where the relevant transaction takes place, which is primarily in Switzerland, the United States, Euro-zone countries and to a lesser extent in the United Kingdom. Transactions in foreign currencies of our Swiss company are recorded in Swiss francs at the applicable exchange rate on the date of the relevant transaction. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign currency exchange rates.

### Translational Risk

Because our reporting currency is the U.S. dollar, we may be exposed to translation risk when the income statements of us and our subsidiaries located in countries outside the United States are converted into U.S. dollars using the average exchange rate for the period, and whilst revenues and costs are unchanged in local currency, changes in exchange rates may lead to effects on the converted balances of revenue, costs and the result in U.S. dollars.

To date, our risk management policy is to economically hedge 100% of anticipated transactions in each major currency for the subsequent 12 months. As our operations grow, we will continue to reassess our approach to manage our risk relating to fluctuations in foreign currency rates.

### Capital Risk

We are not regulated and not subject to specific capital requirements, however, we aim to be compliant with the specific needs of the Swiss law. To ensure that statutory capital requirements are met, we monitor capital periodically on an interim basis as well as annually. From time to time, we may take appropriate measures or propose capital increases at the shareholders' meeting to ensure the necessary capital remains intact.

## Item 12. Description of Securities Other than Equity Securities.

A. Debt Securities.

Not applicable.

B. Warrants and Rights.

Not applicable.

C. Other Securities.

Not applicable.

D. American Depositary Shares.

Not applicable.

### PART II

### Item 13. Defaults, Dividend Arrearages and Delinquencies.

Not applicable.

### Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds.

In January 2017, we completed our initial public offering of common shares. Under the registration statement, we sold an aggregate of 6,450,000 common shares. All of these common shares were sold at a price to the public of \$15.00 per share, yielding net proceeds of \$88.5 million after deducting \$6.8 million of underwriting discounts and commissions, excluding estimated offering expenses. Credit Suisse Securities (USA) LLC, Jefferies LLC and Leerink Partners LLC were joint book-running managers for the initial public offering. We paid the offering expenses in connection with the initial public offering, which were \$3.2 million, and which included SEC registration fees, FINRA filing fees, Nasdaq listing fees, legal fees and expenses, printing expenses, accounting fees and expenses as well as other miscellaneous costs, but excluded the underwriting discounts and commissions.

In October 2017, we completed a private placement of 5,140,626 common shares at a price of \$8.00 per share and prepaid warrants to purchase an aggregate of 2,359,375 common shares with an exercise price of \$8.00 per share. The warrants were exercised on October 13, 2017. We received net proceeds of \$56.3 million from the private placement.

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.

In June 2018, we completed an underwritten public offering of common shares and issued 4,750,000 shares at a price of \$15.39 per share, raising \$68.0 million in net proceeds after deducting \$5.1 million of underwriting discounts, commissions and other offering expenses. In July 2018, we raised additional funds for net proceeds of \$4.4 million from the exercise of the option available to the underwriters in connection with the June 2018 offering.

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 former Chief Executive Officer, purchased 516,352 units at an effective price of \$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 \$3.43 per share, in a concurrent private placement. The net proceeds from the offering (including exercise of pre-funded warrants) and the concurrent private placement were \$20.0 million, after deducting underwriting discounts, commissions and other offering expenses. In January 2021, we raised additional funds of \$19.4 million from the partial exercise of the warrants included in the units sold in the underwritten public offering, as well as from the sale of treasury shares as part of our ATM program.

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 ATM program, generating total net proceeds of \$3.5 million after deducting \$0.1 million of directly-related issuance costs.

During the year ended December 31, 2020, we sold a total of 5,995,897 treasury shares at an average price of \$2.82 per share, as part of our ATM program, for a total gross amount of \$16.9 million.

We anticipate that we will use the remaining net proceeds from our ATM program and our September 2020 offering to advance the development of linzagolix, ebopiprant and nolasiban and to fund other research and development activities, as well as for working capital and other general corporate purposes. None of the net proceeds were used to make payments (other than compensation paid to our executive officers, directors and an affiliate of one of our directors, each as described in this Annual Report), directly or indirectly, to (i) any of our directors, officers or their associates, (ii) any persons owning 10% or more of our common shares or (iii) any of our affiliates. The intended use of the net proceeds has not materially changed from the information mentioned in (i) the prospectus relating to the Registration Statement on Form F-1, relating to our initial public offering, (ii) the prospectus supplement relating to the Registration Statement on Form F-3, relating to our June 2018 offering and (iv) the prospectus supplement relating to the Registration Statement on Form F-3, relating to our September 2020 offering.

### Item 15. Controls and Procedures.

#### **Disclosure Controls and Procedures**

Our Chief Executive Officer (*principal executive officer*) and Chief Financial Officer (*principal financial officer*), after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of December 31, 2020, have concluded that, as of such date, our disclosure controls and procedures were effective and ensured that information required to be disclosed by us in reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer (*principal executive officer*) and Chief Financial Officer (*principal financial officer*), to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms.

# Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal controls over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. Under the supervision and with the participation of our Chief Executive Officer (*principal executive officer*) and Chief Financial Officer (*principal financial officer*), management assessed our internal control over financial reporting based upon the framework in *Internal Control — Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2020.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for emerging growth companies.

# Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

#### Item 16. Reserved.

Not applicable.

### Item 16A. Audit Committees Financial Expert.

Our board of directors has determined that Barbara Duncan is an "audit committee financial expert" as defined by SEC rules and has the requisite financial sophistication under the applicable rules and regulations of the Nasdaq Stock Market. Ms. Duncan is independent as such term is defined in Rule 10A-3 under the Exchange Act and under the listing standards of the Nasdaq Stock Market.

# Item 16B. Code of Business Conduct and Ethics.

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, executive officers and directors. A copy of the Code of Conduct is available on our website at <a href="https://www.obseva.com">www.obseva.com</a>.

## Item 16C. Principal Accountant Fees and Services.

PricewaterhouseCoopers SA, or PwC, has served as our independent registered public accounting firm for 2020 and 2019. Our accountants billed the following fees to us for professional services in each of those fiscal years:

	December 31,			
	2020		20	19
	(in thousands)			
Audit Fees	\$	413	\$	444
Audit-Related Fees		283		150
Tax Fees		_		38
Other Fees		_		15
Total	\$	696	\$	647

<sup>&</sup>quot;<u>Audit Fees</u>" consist of fees billed for the annual audit of our consolidated financial statements, and the statutory audit of our consolidated and stand-alone financial statements. Audit Fees also include services that only our independent external auditor can reasonably provide, such as the review of documents filed with the U.S. stock exchange.

### **Audit and Non-Audit Services Pre-Approval Policy**

To ensure the independence and objectivity of our external auditors, the provision of all non-audit services by the external auditors are pre- approved by our audit committee.

### Item 16D. Exemptions from the Listing Standards for Audit Committees.

Not applicable.

## Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

Not applicable.

# Item 16F. Change in Registrant's Certifying Accountant.

Not applicable.

## Item 16G. Corporate Governance.

# Summary of Significant Corporate Governance Differences From Nasdaq Listing Standards

Our common shares are listed on Nasdaq. We are therefore required to comply with certain of the Nasdaq's corporate governance listing standards, or the Nasdaq Standards. As a foreign private issuer, we may follow our home country's corporate governance practices in lieu of certain of the Nasdaq Standards. Our corporate governance practices differ in certain respects from those that U.S. companies must adopt in order to maintain a Nasdaq listing. A brief, general summary of those differences is provided as follows.

<sup>&</sup>quot;<u>Audit-Related Fees</u>" consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of its financial statements or that are traditionally performed by the external auditor, and mainly include services such as comfort letters issued in connection with securities offerings, due diligence and agreed-upon or expanded audit procedures.

<sup>&</sup>quot;Tax Fees" consist of tax consultations, such as advice in connection with employees' taxation arising from share-based compensation.

<sup>&</sup>quot;Other Fees" consist of advisory services relating to the adoption or application of IFRS.

## **Independent Directors**

Swiss law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present.

## Quorum requirements

In accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

# Solicitation of proxies

Our articles of association provide for an independent proxy holder elected by our shareholders, who may represent our shareholders at a general meeting of shareholders, and we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders. However, Swiss law does not have a regulatory regime for the solicitation of proxies and company solicitation of proxies is prohibited for public companies in Switzerland, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies.

## Item 16H. Mine Safety Disclosure.

Not applicable.

# PART III

# Item 17. Financial Statements.

See pages F-1 through F-27 of this Annual Report on Form 20-F.

# Item 18. Financial Statements.

Not applicable.

# Item 19. Exhibits.

Exhibit	Description	Schedule/ Form	Incorpora File Number	ited by Reference Exhibit	File Date
1.1*	Articles of Association of the Registrant				
2.1	<u>Description of securities</u>	Form 20-F	001-37993	2.1	03/05/2020
4.1	Registration Rights Agreement by and among the Registrant and certain holders of its capital shares, dated as of January 17, 2017	Form F-1/A	333-215383	4.1	01/23/2017
4.2	Series B Shareholders Agreement by and among the Registrant and certain holders of its capital shares, dated as of November 19, 2015	Form F-1	333-215383	4.2	12/30/2016
4.3#	License Agreement, by and between the Registrant and Ares Trading S.A., dated as of August 28, 2013	Form F-1	333-215383	10.1	12/30/2016
4.4#	License Agreement, by and between the Registrant and Ares Trading S.A., dated as of June 10, 2015, as amended	Form F-1	333-215383	10.2	12/30/2016
4.5#	Exclusive License Agreement, by and between the Registrant and Kissei Pharmaceutical Co., Ltd., dated as of November 19, 2015	Form F-1	333-215383	10.3	12/30/2016
4.6#	Cost Splitting Agreement, by and between the Registrant and Kissei Pharmaceutical Co., Ltd., dated as of February 6, 2017	Form 20-F	001-37993	4.6	04/21/2017
4.7	English language translation of Lease Agreement between the Registrant and Eldista GmbH, dated as of July 1, 2013, as amended	Form F-1	333-215383	10.4	12/30/2016
4.8	<u>Securities Purchase Agreement, by and between the Registrant and the investors named therein, dated as of October 9, 2017</u>	Form 6-K	001-37993	99.1	10/11/2017
4.9	Registration Rights Agreement, by and between the Registrant and the investors named therein, dated as of October 9, 2017	Form 6-K	001-37993	99.2	10/11/2017
4.10†	Form of Indemnification Agreement between the Registrant and each of its executive officers and directors	Form F-1/A	333-215383	10.5	01/17/2017
4.11†	Incentive Plan (including form of Issuance Agreement)	Form F-1/A	333-215383	10.6	01/06/2017
4.12†	2017 Equity Incentive Plan	Form F-1/A	333-215383	10.7	01/17/2017
4.13†	Form of Stock Option Grant Notice and Stock Option Agreement under 2017 Equity Incentive Plan	Form F-1/A	333-215383	10.8	01/17/2017
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		Schedule/	Incorporated by Reference lule/ File		File
Exhibit	Description	Form	Number	Exhibit	Date
4.14	Open Market Sales Agreement by and between the Registrant and Jefferies LLC	Form 6-K	001-37993	1.1	03/16/2018
4.15	<u>Underwriting and Placement Agency Agreement, dated as of September 3, 2020, between the Registrant and H.C. Wainwright &amp; Co., LLC.</u>	Form 6-K	001-37993	1.1	09/08/2020
4.16*+	Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of August 7, 2019, as amended by the First Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of December 6, 2019, the Second Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of February 18, 2020, the Third Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of April 7, 2020 and the Fourth Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of January 27, 2021.				
4.17	Sublicense Agreement among the Registrant and Hangzhou Yuyuan BioScience Technology Co., Ltd., dated January 13, 2020	Form 20-F	001-37993	4.17	03/05/2020
8.1	List of subsidiaries of the Registrant	Form F-1	333-215383	21.1	12/30/2016
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities  Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to  Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
13.2**	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
15.1*	Consent of PricewaterhouseCoopers SA				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
* Fil.	ed herewith				

<sup>\*</sup> Filed herewith.

<sup>\*\*</sup> Furnished herewith.

- Indicates a management contract or any compensatory plan, contract or arrangement.
- Confidential treatment has been granted from the Securities and Exchange Commission as to certain portions of this document.

  Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and would likely cause competitive harm to ObsEva SA if publicly disclosed.

# **Index to Financial Statements**

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#### REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of ObsEva SA:

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of ObsEva SA and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of comprehensive loss, of cash flows and of changes in equity for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Change in Accounting Principle

As discussed in Note 2.4 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2019.

### **Basis for Opinion**

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

### **Emphasis of Matter**

As discussed in Note 23 to the consolidated financial statements, the Company will require additional financing to fund future operations. Management's plans in regard to this matter are also described in Note 23.

/s/ PricewaterhouseCoopers SA

Geneva, Switzerland March 5, 2021

We have served as the Company's auditor since 2013.

# **Consolidated Balance Sheets**

(in USD '000)	_	As at Decembe	er 31,
	Notes	2020	2019
ASSETS			
Current assets			
Cash and cash equivalents	4	31,183	69,370
Other receivables	5	397	1,044
Prepaid expenses	6	5,388	4,359
Total current assets		36,968	74,773
Non-current assets			
Right-of-use assets	9	1,425	2,042
Furniture, fixtures and equipment	7	151	245
Intangible assets	8	26,608	26,608
Other long-term assets	10	295	275
Total non-current assets		28,479	29,170
Total assets		65,447	103,943
LIABILITIES AND EQUITY	-		
Current liabilities			
Other payables and current liabilities	5	10,760	8,432
Accrued expenses	6	10,248	10,418
Current lease liabilities	9	696	618
Total current liabilities		21,704	19,468
Non-current liabilities			
Non-current lease liabilities	9	952	1,541
Non-current borrowings	12	25,300	24,917
Post-employment obligations	11	8,218	7,946
Other long-term liabilities	10	919	1,116
Total non-current liabilities		35,389	35,520
Shareholders' equity			
Share capital	13	4,574	3,499
Share premium	13	356,822	320,955
Reserves	13	26,353	21,912
Accumulated losses	13	(379,395)	(297,411)
Total shareholders' equity		8,354	48,955
Total liabilities and shareholders' equity	=	65,447	103,943

# **Consolidated Statements of Comprehensive Loss**

(in USD '000, except per share data)

	_	Year	ended December 31,	
	Notes	2020	2019	2018
Operating income other than revenue	14	17	16	15
OPERATING EXPENSES				
Research and development expenses	15	(67,536)	(88,053)	(62,872)
General and administrative expenses	15	(12,182)	(19,058)	(14,297)
Total operating expenses		(79,718)	(107,111)	(77,169)
OPERATING LOSS		(79,701)	(107,095)	(77,154)
Finance income	17	648	854	393
Finance expense	17	(3,879)	(2,482)	_
NET LOSS BEFORE TAX	•	(82,932)	(108,723)	(76,761)
Income tax (expense) / benefit	18	(34)	(67)	45
NET LOSS FOR THE YEAR		(82,966)	(108,790)	(76,716)
Net loss per share	<del>-</del>			
Basic	19	(1.67)	(2.49)	(1.91)
Diluted	19	(1.67)	(2.49)	(1.91)
OTHER COMPREHENSIVE INCOME / (LOSS)				
Items that will not be reclassified to profit and loss				
Remeasurements on post-employment benefit plans, net of tax		982	(4,694)	(544)
Items that may be reclassified to profit or loss				
Currency translation differences	_			<u> </u>
TOTAL OTHER COMPREHENSIVE INCOME / (LOSS)		982	(4,694)	(544)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(81,984)	(113,484)	(77,260)

# **Consolidated Statements of Cash Flows**

(in USD '000)		Year	ended December 31,	
	Notes	2020	2019	2018
NET LOSS BEFORE TAX FOR THE YEAR	<u>_</u>	(82,932)	(108,723)	(76,761)
Adjustments for:				
Depreciation expense	7 & 9	721	737	109
Post-employment cost / (benefit)		492	(477)	(96)
Share-based compensation expense	20	6,506	11,884	9,152
Income tax paid		(52)	(80)	(11)
Finance expense / (income), net		3,231	1,628	(359)
Decrease / (increase) in other receivables		326	193	(96)
(Increase) / decrease in prepaid expenses, deferred costs and other long-term		(1.000)	1.256	(4.225)
assets		(1,029)	1,356	(4,225)
Increase / (decrease) in other payables and current liabilities		2,141	5,499	(16)
(Decrease) / increase in accrued expenses and other long-term liabilities		(170)	(2,628)	8,362
NET CASH FLOWS USED IN OPERATING ACTIVITIES	_	(70,766)	(90,611)	(63,941)
Cash used for rental deposits				(83)
Payments for plant and equipment	7	(5)	(46)	(188)
Acquisition of a license	8	<u> </u>	(5,000)	<u> </u>
NET CASH FLOWS USED IN INVESTING ACTIVITIES		(5)	(5,046)	(271)
Proceeds from issuance of shares	13	37,254	3,206	97,861
Payment of share issuance costs	13	(2,054)	(119)	(6,881)
Proceeds from exercise of stock-options	13	_	193	672
Proceeds from issuance of debt, net of issuance costs	12	_	24,736	_
Principal elements of lease payments	9	(630)	(571)	_
Interest paid		(2,321)	(818)	_
NET CASH FLOWS FROM FINANCING ACTIVITIES	_	32,249	26,627	91,652
Net (decrease) / increase in cash and cash equivalents	3.2	(38,522)	(69,030)	27,440
Cash and cash equivalents as at January 1,		69,370	138,640	110,841
Effects of exchange rate changes on cash and cash equivalents		335	(240)	359
Cash and cash equivalents as at December 31,	4	31,183	69,370	138,640

# **Consolidated Statements of Changes in Equity**

4. VOD 1000	<b>N</b>	Share	Share	Share- based payments	Foreign currency translation	Total	Accumulated	m . 1
(in USD '000)  December 31, 2017	Notes	capital	<u>premium</u> 219,335	7,608	(489)	7,119	losses (106,667)	Total 122,651
Loss for the year		2,004	210,000	7,000	(405)	7,115	(76,716)	(76,716)
Other comprehensive loss		_					(544)	(544)
Total comprehensive loss							(77,260)	(77,260)
Issuance of shares - EIP 2013	13	27	2,947	(2,947)		(2,947)	(//,_00)	27
Issuance of shares - June 2018 offering	13	392	77,431	( <b>-</b> ,5 .7)	_	( <u>_</u> ,;; ., /	_	77,823
Issuance of shares - ATM program	13	130	19,881	-	_	-	_	20,011
Share issuance costs		_	(6,160)	_	_	_	_	(6,160)
Exercise of stock-options - EIP 2017	20	7	1,131	(466)	_	(466)	_	672
Share-based remuneration	20	_	_	9,152	_	9,152	_	9,152
December 31, 2018		3,420	314,565	13,347	(489)	12,858	(183,927)	146,916
Loss for the year							(108,790)	(108,790)
Other comprehensive loss		_			_		(4,694)	(4,694)
Total comprehensive loss		_				_	(113,484)	(113,484)
Issuance of shares - EIP 2013	13	21	2,696	(2,696)		(2,696)		21
Issuance of shares - ATM program	13	56	3,498	_	_	_	_	3,554
Share issuance costs		-	(130)	_	_	_	_	(130)
Exercise of stock-options - EIP 2017	20	2	326	(134)	_	(134)	_	194
Share-based remuneration	20			11,884		11,884		11,884
December 31, 2019		3,499	320,955	22,401	(489)	21,912	(297,411)	48,955
Loss for the year							(82,966)	(82,966)
Other comprehensive income							982	982
Total comprehensive loss		_				_	(81,984)	(81,984)
Issuance of shares - EIP 2013	13	15	2,065	(2,065)		(2,065)		15
Issuance of shares - Underwritten offering		591	19,408	_	_	_	_	19,999
Issuance of shares - ATM program	13	469	16,437	_	_	_	_	16,906
Share issuance costs		_	(2,043)	_	_	_	_	(2,043)
Share-based remuneration	20		<u> </u>	6,506		6,506		6,506
December 31, 2020		4,574	356,822	26,842	(489)	26,353	(379,395)	8,354

#### **Notes to the 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 2.2).

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, ebopiprant and nolasiban) being developed in four indications. The Group has no currently marketed products.

These 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 consolidated financial statements were authorized for issue by the Company's Board of Directors (the "Board of Directors") on March 4, 2021.

# 2. Accounting principles applied in the preparation of the consolidated financial statements

### 2.1 Basis of preparation

These consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). The consolidated financial statements are based on a historical cost basis.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in note 2.5.

Due to rounding, numbers presented throughout these consolidated financial statements may not add up precisely to the totals provided. All ratios and variances are calculated using the underlying amount rather than the presented rounded amount.

### 2.2 Scope of consolidation

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The Company currently 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 December 31, 2020 and 2019.

# 2.3 Standards and interpretations published by the IASB

The IASB and the International Financing Reporting Standards Interpretations Committee have recently issued new standards and interpretations to be applied to the Group's consolidated financial statements. None of these new standards and amendments applied by the Group in 2020 had a material impact on its consolidated financial statements. In addition, there are no new standards and amendments published but not yet effective that are expected to have a material impact on the consolidated financial statements of the Group.

### 2.4 Significant accounting policies

#### Cash and cash equivalents

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the balance sheet.

#### Current assets

Other receivables and prepaid expenses are carried at their nominal value.

Individual receivables that are known to be uncollectible are written off by reducing the carrying amount directly. The Group considers that there is evidence of impairment if any of the following indicators are present:

- significant financial difficulties of the debtor;
- probability that the debtor will enter bankruptcy or financial reorganization; and
- default or delinquency in payments (more than 30 days overdue).

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all receivables.

### Furniture, fixtures and equipment

Furniture, fixtures and equipment are carried at cost less depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Depreciation is calculated using the straight-line method, on the basis of the following useful lives:

furniture
 hardware
 leasehold improvement
 5 years
 3 years
 duration of lease

Furniture, fixtures and equipment are reviewed for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable, on an individual basis. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

#### Leases

On January 1, 2019, the Group adopted IFRS 16 *Leases*, which replaced IAS 17 *Leases and Related Interpretations*, applied by the Group until December 31, 2018. The Group leases various office buildings and equipment, which are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable,
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as at the commencement date,
- amounts expected to be payable by the Group under residual value guarantees,
- the exercise price of a purchase option if the Group is reasonably certain to exercise that option,
- lease payments to be made under reasonably certain extension options, and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that option.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is generally the case for leases in the Group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following:

- · the amount of the initial measurement of lease liability,
- any lease payments made at or before the commencement date less any lease incentives received,
- any initial direct costs, and
- restoration costs.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life. Payments associated with short-term leases of equipment and vehicles and all leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise small items of office furniture and equipment.

### **Intangible assets**

Separately acquired patents, licenses and other intangible assets are recorded at historical cost and subsequently measured at cost less accumulated amortization and any impairment losses.

The acquisition of certain intangible assets, mainly licenses, may involve additional payments contingent on the occurrence of specific events or milestones. Unless the Group already has a present obligation to make the payment at a future date, the initial measurement of the intangible asset does not include such contingent payments. Instead, such payments are subsequently capitalized as intangible assets when the contingency or milestone occurs.

Estimated useful life is the lower of legal duration and economic useful life, which does not exceed 20 years. The estimated useful life of the intangible assets is annually reviewed, and if necessary, the future amortization charge is accelerated.

For licenses, the amortization starts when the assets become available for use, generally once proper regulatory and marketing approval are obtained.

Intangible assets are subject to impairment testing annually, and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

### Post-employment benefits

Group companies operate two pension schemes.

All employees of ObsEva SA participate in a retirement defined benefit plan. A defined benefit plan is a pension plan that defines an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and compensation. The liability recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the end of the reporting period less the fair value of plan assets. The defined benefit obligation is calculated annually by an independent actuary, using the projected unit credit method. The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating to the terms of the related pension obligation.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to equity in other comprehensive income in the period in which they arise. Past-service costs are recognized immediately in the consolidated statement of comprehensive loss.

During 2017, ObsEva USA, Inc. established a 401K, defined contribution plan, for the employees of the company. A defined contribution plan is a pension plan under which the amounts paid by the employer are fixed in advance. The plan assets are held by a third party custodian. ObsEva USA, Inc. contributions to the defined contribution plan are charged to the income statement as incurred. The Group has no further obligation once the contributions have been paid.

### **Borrowings**

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Borrowings that are due within 12 months after the end of the reporting period are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability until more than 12 months after the reporting period.

#### **Equity**

Incremental costs directly attributable to the issuance of common shares and options are recognized as a deduction from equity, net of any tax effects. Shares held by the Group are disclosed as treasury shares and deducted from equity.

### Research and development

Research expenses are charged to the consolidated statement of comprehensive loss as incurred. Development expenses are capitalized as intangible assets when it is probable that future economic benefits will flow to the Group, and the following criteria are fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;
- management intends to complete the intangible asset and use or sell it;
- there is an ability to use or sell the intangible asset;
- the asset will generate probable future economic benefits and demonstrate the existence of a market;
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

In the opinion of management, due to uncertainties inherent in the development of the Group's product candidates, the criteria for development costs to be recognized as an asset as defined by IAS 38 *Intangible Assets* are not met.

### Foreign currencies

Functional and presentation currency

Items included in the consolidated financial statements of the Group are measured using the currency of the primary economic environment in which each Group's entity operates (the "functional currencies").

The functional and presentation currencies of the Company is the US dollar (USD), which is also the functional currency of ObsEva USA, Inc.

Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions or valuation where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings are presented in the consolidated statement of comprehensive loss, within finance costs. All other foreign exchange gains and losses are presented in the consolidated statement of comprehensive loss on a net basis within other income or other expenses.

### **Share-based compensation**

The Group operates two equity incentive plans.

A share-based, equity-settled, plan was formally set-up by the Group in 2013 (the "2013 EIP"). Participants eligible for awards under the 2013 EIP are executives, directors, employees, agents and consultants. The fair value of the shares granted under the 2013 EIP is determined at each grant date by using either an option pricing method that uses a Black-Scholes model or a hybrid method, as appropriate, both based on a combination of the discounted cash flow method, under the income approach, and the backsolve method.

A share-based, equity-settled, plan was formally set-up by the Group in 2017 (the "2017 EIP"). Participants eligible for awards under this plan are executives, directors, employees, agents and consultants. The fair value of the stock-options granted under the 2017 EIP is determined at each grant date by using a Black-Scholes model.

When the equity instruments granted do not vest until the counterparty completes a specified period of services, the Group accounts for those services as they are rendered by the counterparty, during the vesting period, with a corresponding increase in equity.

#### **Deferred income taxes**

Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, if the deferred income tax arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit and loss, it is not accounted for. Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

#### **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 (Chief Operating Decision Maker) reviews the consolidated statement of operations of the Group on an aggregated basis and manages the operations of the Group as a single operating segment.

The Group currently generates no revenue from the sales of therapeutics products.

The Group's activities are not affected by any significant seasonal effect.

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

	As at Decem	ber 31,
in USD '000	2020	2019
Switzerland	27,936	28,391
USA	543	779
Total non-current assets	28,479	29,170

The geographical analysis of operating expenses is as follows:

	Yea	Year ended December 31,		
in USD '000	2020	2019	2018	
Switzerland	77,476	102,492	73,050	
USA	2,242	4,619	4,119	
Total operating expenses	79,718	107,111	77,169	

### 2.5 Critical accounting estimates and judgments

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

# Critical accounting estimates and assumptions

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will not necessarily equal to related actual outcome. The following areas involve a higher degree of judgement or complexity or are areas where assumptions and estimates can have a significant impact on the consolidated financial statements:

- Post-employment obligations: the actuarial valuation involves making assumptions about discount rates, future salary increases, mortality rates and future pension increases. Due to the long-term nature of these plans, such estimates are subject to significant uncertainty (note 11);
- Leases: the calculation of right of use assets and lease liabilities involves making assumptions about lessee's incremental borrowing rate and renewal options, which are subject to judgment (note 9);
- Share-based compensation: the determination of the fair value of the equity instruments granted involves the use of certain assumptions subject to judgement (note 20);
- Commencement of depreciation and amortization: the depreciation and amortization starts when the assets are available for use in the manner intended by management, which requires judgement (notes 7 and 8);
- Research and development costs: the Group recognizes expenditure incurred in carrying out its research and development activities until it becomes probable that future economic benefits will flow to the Group, which results in recognizing such costs as intangible assets, involving a certain degree of judgement (note 15);
- Deferred taxes: the recognition of deferred tax assets requires assessment of whether it is probable that sufficient future taxable profit will be available against which the deferred tax assets can be utilized (note 18);
- Impairment of assets: as part of impairment tests, the recoverable amounts of tested assets have been determined based on fair value calculations requiring the use of certain assumptions, subject to judgement (note 8);
- Going concern: significant judgement is involved when assessing whether financial statements are to be prepared on a going concern basis or whether there is substantial doubt about the Group's ability to continue as a going concern (note 23).

The Group bases the estimates on historical experience and on various other assumptions that the Group 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 expenses. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Group's business, results of operations and financial condition, including but not limited to expenses, progress of the Group'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, such as when effective vaccines or other treatment would be made available to public, 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 Group has made estimates of the impact of COVID-19 within these consolidated financial statements. If in the future such estimates and assumptions, which are based on management's best judgment at the date of the 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.

### 3. Financial risk management

#### 3.1 Financial risk factors

The Group's activities expose it to a variety of financial risks such as foreign exchange risk, credit risk, interest rate risk and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance. Financial risk management is carried out by the Group's finance department subject to and pursuing policies approved by the Board of Directors.

### Foreign exchange risk

The Group operates internationally and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the Swiss franc (CHF), Euro (EUR) and British Pound (GBP). Foreign exchange risk arises from future commercial transactions (e.g. costs for clinical services) and recognized assets and liabilities. Management has set up a policy to manage the foreign exchange risk against their functional currency. To manage its foreign exchange risk arising from future commercial transactions and recognized assets and liabilities, the Group's finance department maintains foreign currency cash balances to cover anticipated future requirements.

The sensitivity of profit or loss to changes in the exchange rates arises mainly from CHF- and EUR-denominated financial instruments held at the end of the reported periods.

CHF positions	Increase /decrease exchange rate vs USD	Effect on profit before tax (in USD '000)	Effect on shareholders' equity (in USD '000)
2020	+5%	(688)	(688)
	5%	688	688
2019	+5%	(185)	(185)
	-5%	185	185
EUR positions	Increase /decrease exchange rate vs USD	Effect on profit before tax (in USD '000)	Effect on shareholders' equity (in USD '000)
EUR positions 2020			
	exchange rate vs USD	(in ÛSD '000)	(in USD '000)
	exchange rate vs USD +5%	(in ÛSD '000) 26	(in USD '000) 26

### Credit risk

Cash and cash equivalents are deposited with top tier banks and institutions with a short-term rating of "A-1" or "P-1" with Standard & Poor's and Moody's, respectively.

The maximum credit risk exposure the Group faces in connection with its financial assets, being cash and cash equivalents and other receivables, is the carrying amounts of these balances as shown in the consolidated balance sheet.

# Interest rate risk

Interest rate risks arise from changes in interest rates that may have a negative impact on the Group's financial position and results. Fluctuations in interest rates lead to changes in interest expense on floating-rate liabilities and thus affect the financial result. The financial liabilities subject to interest rate risk are exclusively floating-rate debt instruments denominated in USD, carried at amortized cost. The Group does not hold hedging instruments to manage the interest rate risk.

The below table shows sensitivity to changes in market interest rates for the Group's debt instruments.

	Impact on loss be	efore taxes
in USD '000	2020	2019
Interest rates - increase by 100 basis points	(14)	(47)
Interest rates - decrease by 100 basis points		

# 3.2 Capital and liquidity management

The Group's principal source of liquidity is the cash reserves which are obtained through the issuance of new shares and debt instruments. The Group's policy is to invest these funds in low risk investments including interest bearing deposits. The ability of the Group to maintain adequate cash reserves to sustain its activities in the medium term is subject to risk as it is highly dependent on the Group's ability to raise further funds from the sale of new shares.

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to ensure the financing of successful research and development activities so that future profits can be generated and to maintain sufficient financial resources to mitigate against risks and unforeseen events.

The Group is also subject to capital maintenance requirements under Swiss law. To ensure that statutory capital requirements are met, the Group monitors capital periodically.

A reconciliation of the net debt position is shown in the table below.

(in USD '000)	Borrowings	Lease liabilities	Total liabilities from financing activities	Cash and cash equivalents	Total
Net debt as at December 31, 2018				138,640	138,640
Recognized on adoption of IFRS 16		(2,707)	(2,707)		(2,707)
		(2,707)	(2,707)	138,640	135,933
Cash flows	(24,736)	690	(24,046)	(69,030)	(93,077)
Interest expense	(368)	(119)	(487)	_	(487)
Foreign exchange adjustments	_	(23)	(23)	(240)	(263)
Net debt as at December 31, 2019	(25,104)	(2,159)	(27,263)	69,370	42,107
Cash flows	2,206	722	2,928	(38,522)	(35,595)
Interest expense	(2,589)	(92)	(2,681)	_	(2,681)
Foreign exchange adjustments	_	(119)	(119)	335	216
Net debt as at December 31, 2020	(25,487)	(1,648)	(27,135)	31,183	4,048

In addition, the maturity profile of the Group's financial liabilities is presented in the table below.

(in USD '000)	Carrying amount	Total undiscounted cash flows	up to 1 year	1 to 5 years	Maturities more than 5 years
Trade and other payables	(9,450)	(9,450)	(9,450)		
Borrowings	(25,487)	(32,646)	(2,200)	(30,446)	_
Lease liabilities	(1,648)	(1,738)	(758)	(980)	_
Total as at December 31, 2020	(36,585)	(43,834)	(12,408)	(31,426)	
		Total undiscounted			Maturities more
(in USD '000)	Carrying amount	cash flows	up to 1 year	1 to 5 years	Maturities more than 5 years
(in USD '000) Trade and other payables	Carrying amount (7,873)		up to 1 year (7,873)	1 to 5 years	
` '		cash flows		1 to 5 years — (32,646)	
Trade and other payables	(7,873)	<u>cash flows</u> (7,873)	(7,873)		

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

# 4. Cash and cash equivalents

	As at Dece	ember 31,
in USD '000	2020	2019
Bank deposits	31,183	69,370
Interest bearing deposits	_	_
Total cash and cash equivalents	31,183	69,370

Split by currency:

	2020	2019
CHF	2%	14%
USD	87%	73%
EUR	11%	12%
GBP	0%	1%

### 5. Receivables and payables

As at December 31, 2020 and 2019, other receivables consist mainly of reimbursements to be received from third parties, including VAT, insurance premiums and shared-costs of research and development studies, and other payables and other current liabilities include mainly costs of clinical services. All receivables and payables are due from and to third parties and carried at amortized cost.

All payables have a contract maturity within one year.

# 6. Prepaid and accrued expenses

As at December 31, 2020 and 2019, prepaid expenses mainly consist of advance or milestone payments made as part of our ongoing clinical trials.

As at December 31, 2020 and 2019, accrued expenses consisted of the following:

	As at Decen	As at December 31,	
in USD '000	2020	2019	
Accrued research and development expenses	7,662	7,244	
Accrued compensation-related expenses	2,334	1,882	
Accrued other expenses	252	1,292	
Total accrued expenses	10,248	10,418	

### 7. Furniture, fixtures and equipment

in USD '000	2020	2019
Net book value as at January 1	245	319
Additions	10	46
Depreciation charge	(104)	(120)
Currency translation effects	_	_
Net book value as at December 31	151	245
Total cost	652	653
Accumulated depreciation	(501)	(408)

Furniture, fixtures and equipment assets mainly consist of office furniture and leasehold improvements.

# 8. Intangible assets

in USD '000	2020	2019
Net book value as at January 1	26,608	21,608
Additions	_	5,000
Amortization charge	_	_
Currency translation effects	_	_
Net book value as at December 31	26,608	26,608
Total cost	26,608	26,608
Accumulated amortization	_	

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

### **Merck Serono licenses**

On August 28, 2013, the Group in-licensed nolasiban for USD 4.9 million from Ares Trading S.A., an affiliate of Merck Serono ("Merck Serono").

In June 2015, the Group acquired the in-license for ebopiprant from Merck Serono for an amount of USD 2.4 million.

### Kissei license

On November 19, 2015, the Group entered into an exclusive in-license and supply agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei") to acquire the product candidate linzagolix (formerly OBE2109) for which Kissei successfully completed a Phase 2 trial in Japan. This in-license agreement grants the Group an exclusive license to use, develop and commercialize the product candidate worldwide excluding certain Asian countries. This in-license was acquired for an upfront cash consideration of USD 10 million, with additional contingent payments upon occurrence of certain milestones (note 21).

On April 25, 2017, the Group announced the initiation of its Phase 3 clinical program for linzagolix in uterine fibroids and related activation of sites and start of recruitment. This event triggered the recognition and payment of a USD 5.0 million milestone to Kissei during the second quarter of 2017, that was accounted for as an intangible asset.

Similarly, 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, accounted for as an intangible asset.

The Group has concluded that the Merck Serono licenses and the Kissei license acquisitions do not qualify as business combinations per IFRS 3, as the Group did not acquire processes that are capable of producing outputs given the in-licensed compounds are very early-stage.

### **Amortization and impairment**

The Group's intangible assets are subject to a multi-phase clinical trials process and the licenses are currently not amortized as no regulatory and marketing approvals were obtained as of December 31, 2020.

In accordance with IAS 38, the licenses have been reviewed for impairment by assessing the fair value less costs of disposal ("FVLCOD"). The valuation is considered to be Level 3 in the fair value hierarchy due to unobservable inputs used in the valuation. No impairment was identified.

The key assumptions used in the valuation model (income approach) to determine the FVLCOD of the licenses are as follows:

- Expected research and development costs;
- Probabilities of achieving development milestones based on industry standards;
- Reported disease prevalence;
- Expected market share;
- Commercialization expectations;
- Drug reimbursement, costs of goods and marketing expenses; and
- Expected patent life.

The valuation model covers a 20-year period due to the length of the development cycle for assets of this nature. A discount factor of 15%, based on the assumed cost of capital for the Group, has been used over the forecast period.

Based on sensitivity analysis performed, including changes in discount rates and peak sales assumptions, no reasonably possible change in assumption would cause the carrying value of the licenses to exceed their recoverable amount.

The Group has also collectively reviewed its licenses for impairment on the basis of the market capitalization for the entire Group as at December 31, 2020 less the value of its tangible assets as well as cash and cash equivalents. This analysis resulted in a headroom exceeding USD 61 million. The valuation is considered to be Level 1 in the fair value hierarchy and further supported the Group's conclusion that no impairment was identified as of December 31, 2020 and 2019.

### 9. Leases

The consolidated financial statements show the following amounts relating to leases:

# Right-of-use assets

in USD '000	2020	2019
Net book value as at January 1	2,042	2,658
Additions	_	_
Depreciation charge	(617)	(616)
Currency translation effects	_	_
Net book value as at December 31	1,425	2,042
Total cost	2,658	2,658
Accumulated depreciation	(1,233)	(616)

Rights-of-use assets mainly relate to office buildings. The expense relating to short-term and low-value leases is not material. For the years ended December 31, 2020 and 2019, the total cash outflows for leases amounted to USD 0.7 million and USD 0.7 million, respectively.

#### Lease liabilities

	As at Decem	As at December 31,		
in USD '000	2020	2019		
Current	696	618		
Non-current	952	1,541		
Total lease liabilities	1,648	2,159		

The lease liabilities have been measured based on the Group's weighted average incremental borrowing rate of 4.9%. The maturity of the lease liabilities is provided in note 3.2.

### 10. Other long-term assets and liabilities

The Group's other long-term assets mainly consist of security rental deposits for the Group's offices.

The Group's other long-term liabilities consist of various provisions.

### 11. Post-employment benefits

In accordance with the mandatory Swiss pension fund law, all employees of the Company participate in a retirement defined benefit plan. Swiss based pension plans are governed by the Swiss Federal Law on Occupational Retirement, Survivors' and Disability Pension Plans (the "LPP"), which stipulates that pension plans are to be managed by independent, legally autonomous units. Under the terms of the pension plan, participants are insured against the financial consequences of old age, disability and death. The various insurance benefits are governed by regulations, with the LPP specifying the minimum benefits that are to be provided. The employer and employees pay contributions to the pension plan. In the event the pension plan's statutory funding falls below a certain level, various measures can be taken to increase funding above such level, such as increasing the current contribution, lowering the interest rate on the retirement account balances or reducing the additional prospective benefits. The employer can also make additional restructuring contributions. Since the risks of death and disability are fully reinsured by an insurance group, the savings plan must be qualified as a defined benefit plan. As required by IAS 19 *Employee Benefits*, the projected unit credit method has been used in the calculation of present value of the benefit obligations and the related current service cost.

The investment risk is borne by the insurer and the reinsurer respectively, and the investment decision is taken by the board of trustees of the collective insurance.

In 2019, the contributions levels for certain employees was changed, which has been considered as a plan amendment.

in USD '000	2020	2019
Change in defined benefit obligation		
Defined benefit obligation at January 1,	(24,705)	(14,502)
Current service cost	(1,864)	(1,269)
Interest cost	(46)	(140)
Net benefits paid	4,643	(4,071)
Currency translation effects	(2,208)	(536)
Remeasurements:		
Impact of plan amendment	_	527
Effect of changes in demographic assumptions	510	366
Effect of changes in financial assumptions	(418)	(3,037)
Effect in experience assumptions	840	(2,043)
Defined benefit obligation at December 31,	(23,248)	(24,705)

in USD '000	2020	2019
Change in plan assets		
Fair value of plan assets at January 1,	16,759	10,955
Interest income	31	115
Employer contributions	703	622
Employee contributions	703	622
Net benefits paid	(4,643)	4,071
Currency translation effects	1,427	354
Remeasurements: return on plan assets (excluding		
interest income)	50	20
Fair value of plan assets at December 31,	15,030	16,759
	Year ended Dec	ember 31
in USD '000	2020	2019
Components of defined benefit cost		
Current service cost	1,864	1,269
Interest expense on defined benefit obligation	46	140
Interest income on plan assets	(31)	(115)
Employee contributions	(703)	(622)
Impact of plan amendment		(527)
Total included in staff costs (note 16)	1,176	145
(		
	V	b 21
in USD '000	Year ended Dece 2020	2019
Remeasurements recognized in other comprehensive loss		
Effect of changes in demographic assumptions	510	366
Effect of changes in financial assumptions	(418)	(3,037)
Effect in experience assumptions	840	(2,043)
Return on plan assets (excluding interest income)	50	20
Total remeasurements recognized as other		
comprehensive loss	982	(4,694)
Cumulative amount of remeasurements immediately		(1,001)
recognized in other comprehensive loss	(7,837)	(8,819)
recognized in other comprehensive ross	(7,007)	(0,015)
	A + D	L 21
in USD '000	As at December 2020	2019
Amounts recognized in the statement of financial position		
Defined benefit obligation	(23,248)	(24,705)
Fair value of plan assets	15,030	16,759
Net liability	(8,218)	(7,946)
		( ) )
in USD '000	2020	2019
Change in defined benefit liability		
Net defined benefit liability at January 1,	(7,946)	(3,547)
Defined benefit cost included in statement of		
comprehensive loss	(1,176)	(145)
Total remeasurements included in other		
comprehensive loss	982	(4,694)
Employer contributions	703	622
Currency translation effects	(781)	(182)
Net defined benefit liability at December 31,	(8,218)	(7,946)

As of the date of preparation of these consolidated financial statements, the annual report for 2020 of the pension fund has not yet been issued, and therefore the detailed structures and assets held at December 31, 2020, are not currently available for presentation. The detailed structures and assets held at December 31, 2019, are as follows:

Plan assets	As at December 31, 2019
Cash	0.8%
Bonds	62.5%
Shares	12.1%
Real estate	16.6%
Mortgages	8.0%
Alternative investments	0%
Total	100.0 %

The principal actuarial assumptions used were as follows:

	2020	2019
Discount rate	0.10%	0.20%
Salary increase (including inflation)	1.00%	1.00%
Rate of pension increases	0.25%	0.25%
Post-employment mortality table	LPP 2020 G	LPP 2015 G

Sensitivity analysis illustrates the sensitivity of the Group defined benefit obligation at December 31, 2020 by varying the discount rate and the salary increase rate by plus / minus 50 basis points:

in USD '000	Discount rate	Discount rate	Salary increase	Salary increase	Rate of pension increase	Rate of pension increase
Sensitivity analysis	plus	minus	plus	minus	plus	minus
	50bps	50bps	50bps	50bps	25bps	25bps
Discount rate	0.60%	(0.40)%	0.10%	0.10%	0.10%	0.10%
Salary increase	1.00%	1.00%	1.50%	0.50%	1.00%	1.00%
Rate of pension increases	0.25%	0.25%	0.25%	0.25%	0.50%	0.00%
Defined benefit obligation	(21,223)	(25,594)	(23,305)	(23,195)	(23,809)	(22,717)

Average duration of the defined benefit		
obligation	2020	2019
Duration in years	18.7	20.2

The methods and types of assumptions used in preparing the sensitivity analysis did not change compared to the prior period.

Expected contributions by the employer to be paid to the post-employment benefit plans during the annual period beginning after the end of the reporting period amount to approximately USD 714,000.

### 12. Borrowings

In August 2019, the Company entered into a loan and security agreement, or the credit facility, with Oxford Finance LLC 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. In April 2020, the Company entered into an amendment to the loan and security agreement, pursuant to which 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 presented in the balance sheet as follows:

in USD '000	2020	2019
Borrowings as of January 1,	25,104	_
New borrowings	_	25,000
Transaction costs	_	(264)
Interest expense	2,589	1,067
Interest paid	(2,206)	(699)
Borrowings as of December 31,	25,487	25,104
Of which are:		
Current	187	187
Non-current	25,300	24,917

The credit facility is secured by substantially all of the Company's assets, including cash and cash equivalents as well as the Company's intellectual property and licenses. 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 December 31, 2020, the Company was in compliance with its covenants.

### 13. Shareholders' equity

		in USD '000	
Number of common shares	Share capital	Share premium	Total
43,443,911	3,420	314,565	317,985
261,984	21	2,696	2,717
691,133	56	3,498	3,554
_	_	(130)	(130)
26,420	2	326	328
44,423,448	3,499	320,955	324,454
	shares 43,443,911 261,984 691,133 — 26,420	shares         capital           43,443,911         3,420           261,984         21           691,133         56           —         —           26,420         2	Number of common shares         Share capital         Share premium           43,443,911         3,420         314,565           261,984         21         2,696           691,133         56         3,498           —         —         (130)           26,420         2         326

			in USD '000	
	Number of common shares	Share capital	Share premium	Total
January 1, 2020	44,423,448	3,499	320,955	324,454
Issuance of shares - EIP 2013	168,641	15	2,065	2,080
Issuance of shares - Underwritten offering	6,964,592	591	19,408	19,999
Issuance of shares - ATM program	5,995,897	469	16,437	16,906
Share issuance costs	_	_	(2,043)	(2,043)
December 31, 2020	57,552,578	4,574	356,822	361,396

### Share capital and share premium

As at December 31, 2020, the total outstanding share capital of USD 4.6 million, fully paid, consists of 57,552,578 common shares, excluding 3,608,281 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.

In July 2019, the Company issued 3,064,048 common shares at par value of 1/13 of a Swiss franc per share. The shares were fully subscribed for by the Group, and were initially held as treasury shares, hence the operation did not impact the share capital.

During the year ended December 31, 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 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 year ended December 31, 2020, the Company sold a total of 5,995,897 treasury shares at an average price of USD 2.82 per share, as part of its ATM program. These multiple daily transactions generated total gross proceeds of USD 16.9 million. Directly related share issuance costs of USD 0.5 million were recorded as a deduction in equity.

In April 2020 and September 2020, the Company 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 a wholly-owned subsidiary of the Company 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 former 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, including exercise of pre-funded warrants, were USD 20.0 million, after deducting underwriting discounts, commissions and other offering expenses paid by the Company. As of December 31, 2020, none of the 15-month purchase warrants have been exercised.

# **Equity incentive plans**

In 2020, the Company issued 168,641 common shares (2019: 261,984) under its 2013 EIP (see note 20). All shares issued under the 2013 EIP have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date.

### Authorized share capital

The authorized share capital that is not outstanding is as follows:

	As at Decer	As at December 31,		
Number of shares	2020	2019		
Authorized share capital	17,611,372	19,681,753		

### 14. Revenue and other operating income

The Group currently derives no revenue from sales of its biopharmaceutical product candidates.

Operating income other than revenue mainly relates to compensation received from the Swiss tax authorities as the Company acts as collecting agent of the withholding tax on salaries.

### 15. Operating expenses by nature

	Year ended December 31,		
in USD '000	2020	2019	2018
External research and development costs	51,803	70,531	49,480
Staff costs (note 16)	19,643	24,556	19,537
Professional fees	3,994	7,072	3,871
Rents	22	21	827
Travel expenses	156	1,398	1,044
Patent registration costs	813	882	1,002
Depreciation	721	737	109
Other	2,566	1,914	1,299
Total operating expenses by nature	79,718	107,111	77,169

Due to the difficulty in assessing when research and development projects would generate revenue, the Group expenses all research and development costs on the consolidated statement of comprehensive loss. In 2020, research and development expenses amounted to USD 67.5 million (2019: USD 88.1 million, 2018: USD 62.9 million).

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. In January 2021, the Group announced its decision to discontinue our EDELWEISS 2 clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing 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.

The depreciation expense has been allocated as follows:

	Year ended December 31,		
in USD '000	2020	2019	2018
Research and development expenses	447	429	63
General and administrative expenses	274	308	46
Total depreciation	721	737	109

#### 16. Staff costs

	Year ended December 31,		
in USD '000	2020	2019	2018
Wages and salaries	10,262	10,403	9,023
Social charges	1,699	2,124	946
Post-employment benefits expense	1,176	145	416
Share-based payments	6,506	11,884	9,152
Total staff costs	19,643	24,556	19,537

The Group employed on average 46.2 full-time equivalents ("FTE") in 2020, compared to 48.5 FTE in 2019 and 39.6 FTE in 2018, and 42.7 FTE as at December 31, 2020 compared to 50.1 FTE as at December 31, 2019 and 43.2 FTE as at December 31, 2018.

For the years ended December 31, 2019 and 2018, the post-employment benefits line included a gain of USD: 527 thousand and USD 172 thousand, respectively, relating to the plan amendments enacted during these years. No amendment occurred during the year ended December 31, 2020.

### 17. Finance income and expense

Our finance income and expense primarily consist of foreign exchange gain and loss as well as interest expense associated with our lease liabilities and debt instruments.

	 Year ended December 31,				
	 2020		2019		2018
			(in thousands)		
Foreign exchange (loss) / gain, net	\$ (527)	\$	(442)	\$	393
Interest expense	(2,704)		(1,186)		_
Finance result, net	\$ (3,231)	\$	(1,628)	\$	393

#### 18. Income taxes and deferred taxes

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

Subsequent to the enforcing of the "Federal Act on Tax Reform and AHV Financing" (TRAF) on January 1, 2020, the Company is subject in Switzerland to a municipal and cantonal income tax rate of 14% (2019: 22.6%) and to a federal tax rate of 8.5% (2019: 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 years ended December 31, 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 December 31, 2020 and December 31, 2019.

The following table details the tax losses carry forwards of the Company and their respective expiring dates.

### **Expiring tax losses**

	As at December 31,		
in USD '000	2020	2019	
2020	_	2,950	
2021	12,828	11,687	
2022	17,993	16,394	
2023	31,696	28,879	
2024	64,869	59,103	
2025	75,364	68,662	
2026	109,663	99,915	
2027	80,105	_	
Total unrecorded tax losses carry forwards	392,518	287,590	

The Company's Irish subsidiary has no activity, and, therefore, no income tax expense was recorded in such entity for the years ended December 31, 2020 and 2019.

The Company's U.S. subsidiary, ObsEva USA Inc., 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 for the year ended December 31, 2020 and 2019 were subject to a total U.S. income tax rate of 27.3% based on both the U.S. federal and Massachusetts state tax rates. The income tax for the year ended December 31, 2020 and 2019 was USD 34 thousand and USD 67 thousand, respectively. Additionally, since ObsEva USA Inc. is totally dependent on ObsEva SA for revenue, there is uncertainty as to whether ObsEva USA Inc. will be able to use a deferred tax asset for tax purposes in the future, therefore, no deferred taxes have been recognized on the balance sheet of the Group as of December 31, 2020 and December 31, 2019.

The following elements explain the difference between the income tax expense at the applicable Group tax rate and the effective income tax expense:

	Year ended December 31, 2020		
in USD '000	ObsEva SA	ObsEva USA	Total Group
Net loss before tax	(82,804)	(128)	(82,932)
Statutory tax rate (blended at Group level)	7.8%	27.3%	7.9%
Income tax credit at statutory tax rates	(6,487)	(35)	(6,522)
Tax impact of permanent differences	595	17	612
Temporary differences not recognized as deferred tax assets	(1)	52	51
Tax on losses not recognized as deferred tax assets	5,893	_	5,893
Effective income tax expense		34	34
Effective tax rate	0.0%	(26.7)%	0.0%

	Year e	Year ended December 31, 2019			
in USD '000	ObsEva SA	ObsEva USA	Total Group		
Net loss before tax	(107,120)	(1,603)	(108,723)		
Statutory tax rate (blended at Group level)	7.8%	27.3%	8.1%		
Income tax credit at statutory tax rates	(8,355)	(438)	(8,793)		
Tax impact of permanent differences	770	76	846		
Temporary differences not recognized as deferred tax assets	_	448	448		
Tax on losses not recognized as deferred tax assets	7,586	(19)	7,567		
Effective income tax expense		67	67		
Effective tax rate	0.0%	(4.2)%	(0.1)%		

## 19. Loss per share

As of December 31, 2020, 2019 and 2018, the Company has one category of shares, which are common shares, since the Company's non-voting shares and series A and series B preferred shares were converted into common shares upon the closing of the IPO on January 25, 2017.

The basic loss per share is calculated by dividing the loss of the period attributable to the ordinary shares by the weighted average number of ordinary shares outstanding during the period as follows:

	Year ended December 31,			
	2020	2019	2018	
Net loss attributable to shareholders (in USD '000)	(82,966)	(108,790)	(76,716)	
Weighted average number of shares outstanding	49,820,451	43,674,746	40,172,498	
Basic and diluted loss per share (in USD)	(1.67)	(2.49)	(1.91)	

For the year ended December 31, 2020, 7,035,388 and 6,964,592 shares issuable upon the exercise of stock-options and warrants, respectively, which would have an anti-dilutive impact on the calculation of the diluted earnings per share, were excluded from the calculation. For the year ended December 31, 2019, 168,641 non-vested shares and 4,626,385 shares issuable upon the exercise of stock-options were excluded. For the year ended December 31, 2018, 430,625 non-vested shares and 3,028,275 shares issuable upon the exercise of stock-options were excluded.

# 20. Share-based compensation

The total expenses arising from share-based payment transactions recognized during the period as part of staff costs were as follows:

	Yea	Year ended December 31,		
in USD '000	2020	2019	2018	
Employee 2013 EIP	220	1,006	2,242	
Employee 2017 EIP	6,286	10,878	6,910	
Total share-based compensation	6,506	11,884	9,152	

### Employee equity incentive plan 2013

The Company established the 2013 EIP for employees, executives, directors and consultants (the "Beneficiaries") of the Group.

Upon enrollment in the 2013 EIP, Beneficiaries were granted a certain number of shares which they were entitled to acquire at a pre-determined price of 1/13 of a Swiss franc. The pre-determined price was generally paid by the Beneficiaries at the grant date and recognized as a pre-payment until the vesting period elapses resulting in the shares issuance being accounted for.

The shares generally fully vest over a four-year vesting period, with 25% of the shares underlying the grant vesting after one year, and 1/48th of the shares underlying the grant vesting each month over a further period of three years.

The Group has no present obligation to repurchase or settle the shares in cash.

	2020	2019	2018
Number of shares issued under the 2013 EIP	168,641	261,984	347,509
Expense arising from the 2013 EIP (in USD '000)	220	1,006	2,242

The fair value of the shares was calculated using a combination of the discounted cash flow method, under the income approach, and the backsolve method. The income approach estimates value based on the expectation of future cash flows that the Company will generate, such as cash earnings, costs savings, tax deduction and the proceeds from disposition. These future cash flows were discounted to their present values using a discount rate derived based on an analysis of the cost of capital of comparable publicly traded companies in similar lines of business, as of each valuation date, and was adjusted to reflect the risks inherent in the Company's cash flows. The backsolve method, a form of the market approach to valuation, derives the implied enterprise equity value and the fair value of the non-voting share from a recent and contemporaneous transaction involving the Company's own securities, using the following assumptions: rights and preferences of the different categories of shares, probability of various liquidity event scenarios, expected timing of a liquidity event, volatility and expected value in a liquidity event.

The Group has stopped granting equity instruments under the 2013 EIP in 2016, resulting in the 2013 EIP being fully vested as of December 31, 2020.

# Employee equity incentive plan 2017

The Company established in 2017 the 2017 EIP for Beneficiaries of the Group, under which 4,543,952 and 1,683,303 stock-options were granted during the year ended December 31, 2020 and 2019, respectively. The stock-options typically vest under a 3-year or 4-year vesting schedule, have a 10-year expiration term and have an exercise price equivalent to the share price at grant date. Certain grants also include non-market performance vesting conditions, common to all employees, regularly assessed to determine the numbers of awards expected to vest.

Movements in the number of stock-options outstanding under the 2017 EIP were as follows:

	2020		2019	
	Average exercise price (USD)	Number of options	Average exercise price (USD)	Number of options
At January 1,	10.51	4,626,385	11.39	3,028,275
Granted	2.93	4,543,952	8.89	1,683,303
Forfeited/Expired	7.62	(2,134,949)	10.94	(58,773)
Exercised		<u> </u>	7.32	(26,420)
At December 31,	6.49	7,035,388	10.51	4,626,385

The weighted average share price at the date of exercise of options exercised during the year ended December 31, 2019 was USD 11.64. No exercise of options occurred during the year ended December 31, 2020.

The outstanding stock-options have the following range of exercise prices and remaining contractual life:

Range of exercise prices         2020         2019           USD 15.00 to USD 17.99         361,500         361,500           USD 12.00 to USD 14.99         1,050,143         1,276,240           USD 9.00 to USD 11.99         1,331,981         1,458,595           USD 6.00 to USD 8.99         161,979         1,530,050           USD 1.50 to USD 5.99         4,129,785         —           Total outstanding options         7,035,388         4,626,385           out of which are exercisable         2,083,159         1,312,557           Weighted-average remaining contractual life (in years)         8.6         8.8		As at December	As at December 31,	
USD 12.00 to USD 14.99       1,050,143       1,276,240         USD 9.00 to USD 11.99       1,331,981       1,458,595         USD 6.00 to USD 8.99       161,979       1,530,050         USD 1.50 to USD 5.99       4,129,785       —         Total outstanding options       7,035,388       4,626,385         out of which are exercisable       2,083,159       1,312,557	Range of exercise prices	2020	2019	
USD 9.00 to USD 11.99       1,331,981       1,458,595         USD 6.00 to USD 8.99       161,979       1,530,050         USD 1.50 to USD 5.99       4,129,785       —         Total outstanding options       7,035,388       4,626,385         out of which are exercisable       2,083,159       1,312,557	USD 15.00 to USD 17.99	361,500	361,500	
USD 6.00 to USD 8.99       1,530,050         USD 1.50 to USD 5.99       4,129,785       —         Total outstanding options       7,035,388       4,626,385         out of which are exercisable       2,083,159       1,312,557	USD 12.00 to USD 14.99	1,050,143	1,276,240	
USD 1.50 to USD 5.99       4,129,785       —         Total outstanding options       7,035,388       4,626,385         out of which are exercisable       2,083,159       1,312,557	USD 9.00 to USD 11.99	1,331,981	1,458,595	
Total outstanding options         7,035,388         4,626,385           out of which are exercisable         2,083,159         1,312,557	USD 6.00 to USD 8.99	161,979	1,530,050	
out of which are exercisable 2,083,159 1,312,557	USD 1.50 to USD 5.99	4,129,785	<u> </u>	
_,=====================================	Total outstanding options	7,035,388	4,626,385	
Weighted-average remaining contractual life (in years) 8.6 8.8	out of which are exercisable	2,083,159	1,312,557	
	Weighted-average remaining contractual life (in years)	8.6	8.8	

The weighted average fair value of the stock-options granted during the years ended December 31, 2020 and 2019, determined using a Black-Scholes model was USD 2.31 and USD 6.45, respectively. The significant inputs to the model were:

	2020	2019
Weighted average share price at grant date	USD 2.93	USD 8.89
Weighted average exercise price	USD 2.93	USD 8.89
Weighted average 10-year volatility	77%	65%
Dividend yield	0%	0%
Weighted average 10-year risk free rate	1.28%	1.88%

Since the Company has a short track record as a public company, expected volatility has been determined based on the historical trend of an appropriate sample of public companies operating in the biotech and pharmaceutical industry.

# 21. Commitments and contingencies

### **Operating lease commitments**

The Group leases arrangements mostly relate to buildings offices for its headquarters in Geneva, Switzerland and its subsidiary's lease in Boston, Massachusetts, USA, accounted for in accordance with IFRS 16 *Leases*. Future lease liabilities payments and associated maturities are provided in note 3.2.

### **Contingencies**

As a result of the licenses granted to the Group, the following contingencies are to be noted:

#### Kissei license

Under the terms of the license and supply agreement, the Group would be obligated to make milestone payments upon the achievement of specified regulatory milestones with respect to linzagolix. The total of all potential undiscounted future payments that the Group could be required to make under this arrangement ranges between USD 0 and USD 188 million, of which USD 10 million have already been paid.

Pursuant to the Kissei license and supply agreement, the Group has agreed to exclusively purchase the active pharmaceutical ingredient for linzagolix from Kissei. During the development stage, the Group is obligated to pay Kissei a specified supply price. Following the first commercial sale of licensed product, the Group is obligated to pay Kissei a royalty payment in the low twenty percent range as a percentage of net sales, which includes payment for Kissei's supply of the active pharmaceutical ingredient until the latest of the date that the valid claim of a patent for the product has expired, the expiration of our regulatory exclusivity period or 15 years from the first commercial sale of such product on a country-by-country and product-by-product basis.

### Merck Serono licenses

Under the terms of the two license agreements with Merck Serono for ebopiprant and nolasiban, the Group would be obligated to pay Merck Serono a high-single digit and a mid-single digit royalty, respectively, of net sales generated by the Group, its affiliates or sub-licensees of any product containing the in-licensed compounds.

# 22. Related parties transactions

As of December 31, 2020, the Group's related parties include key management (Board of Directors and Executive Committee) and members of their immediate families. The following transactions were carried out with related parties:

Key management remuneration

The Board of Directors is composed of eight members, whereas the Executive Committee is composed of five members. The following table sets forth the total remuneration recorded for members of the Board of Directors and Executive Committee:

	Year ended December 31,	
in USD '000	2020	2019
Short-term employee benefits (including base and variable		
cash remuneration)	3,388	4,181
Post-employment benefits	272	186
Share-based payments	4,038	8,485
Total	7,698	12,852

Other transactions with related parties

In September 2020, concurrent with the Company's underwritten public offering indicated in note 13, the Company's former Chief Executive Officer, Ernest Loumaye, 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 private placement. The Company received USD 1.5 million in net proceeds from the private placement.

There were no other significant transactions with related parties during the years presented.

### 23. Going concern

The Company has incurred recurring losses since inception, including net losses of USD 83.0 million for the year ended December 31, 2020. As of December 31, 2020, the Company had accumulated losses of USD 410.0 million, 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 December 31, 2020, the Company had cash and cash equivalents of USD 31.2 million. Subsequent to December 31, 2020, the Company raised additional proceeds of USD 55.6 million (see note 24) and expects that its current cash and cash equivalents will be sufficient to fund its operations (without consideration of any commercialization expenses) and meet all of its obligations as they fall due for at least twelve months from the date of the issuance of these consolidated financial statements for the year ended December 31, 2020. These audited 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, 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, obtaining sufficient funding on terms acceptable to the Company, or if at all, which could have a material adverse effect on the Group's business, results of operations and financial conditions.

### 24. Events after the reporting period

### Capital increases

In January and February 2021, the Company announced the issuance of 6,020,248 and 11,591,124 common shares, respectively, at par value of 1/13 of a Swiss franc per share. The shares were fully subscribed for by a fully-owned subsidiary of the Company, and listed on the SIX Swiss Exchange accordingly. The shares are held as treasury shares, hence the operation did not impact the outstanding share capital.

# ATM proceeds

From January 1, 2021 until February 28, 2021, the Group sold an additional 9,337,047 treasury shares at an average price of USD 3.70 per share, as part of its ATM program. Total gross proceeds amounted to USD 34.5 million.

# Warrant Proceeds

From January 1, 2021 until February 28, 2021, the Company raised additional funds of USD 22.1 million from the exercise of the 6,448,240 warrants included in the units sold in the Company's underwritten public offering in September 2020.

There were no other material events after the balance sheet date.

# **SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

# **OBSEVA SA**

/s/ Brian O'Callaghan

By: Brian O'Callaghan
Title: Chief Executive Officer
(Principal Executive Officer)

Date: March 5, 2021

### **STATUTS**

### ARTICLES OF ASSOCIATION

DE

OF

ObsEva SA (ObsEva Ltd) (ObsEva AG) ObsEva SA (ObsEva Ltd) (ObsEva AG)

### TITRE I: RAISON SOCIALE - SIEGE - BUT - DUREE

# TITLE I: CORPORATE NAME - REGISTERED OFFICE - PURPOSE - DURATION

### Article 1: Raison sociale

Article 1: Corporate Name

Il existe sous la raison sociale

There exists under the name

ObsEva SA (ObsEva Ltd) (ObsEva AG) ObsEva SA (ObsEva Ltd) (ObsEva AG)

une société anonyme qui est régie par les présents statuts et, pour tous les cas qui n'y sont pas prévus, par le titre XXVI du Code suisse des obligations ("CO").

a company limited by shares which is governed by these articles of association and for any situation not provided herein by the Title XXVI of the Swiss Code of Obligations ("**CO**").

# Article 2: Siège

### Article 2: Registered Office

La société a son siège à Plan-les-Ouates (GE).

The registered office of the company is in Plan-les-Ouates (GE).

# Article 3: But

# Article 3: Purpose

La société a pour but toutes activités et services dans les domaines de la recherche, du développement, de la fabrication, de l'enregistrement, de la promotion et de la commercialisation de produits biotechniques et pharmaceutiques.

The purpose of the company is all activities and services in the domains of research, development, fabrication, registration, promotion and commercialization of biotechnological and pharmaceutical products.

La société peut effectuer toute transaction commerciale et financière, directement ou indirectement liée à son but. Elle peut faire inscrire des succursales et des filiales en Suisse et à l'étranger, ainsi qu'acquérir, détenir, gérer et vendre des immeubles.

The company may carry out all commercial and financial transactions which are directly or indirectly related to its purpose. The company may establish branch offices and subsidiaries in Switzerland and abroad as well as acquire, manage, hold and sell real estate.

La société peut accorder des prêts ou tout autre forme de financement à des sociétés du même groupe, ainsi que donner des sûretés de tout genre, au bénéfice direct ou indirect de sociétés du même groupe ou de tiers, en particulier sous la forme de garanties, gages ou sûretés sur les actifs de la société.

# Article 4: Durée

La durée de la société est indéterminée.

# TITRE II: CAPITAL-ACTIONS ET ACTIONS

# Article 5: Montant nominal et division

Le capital-actions est fixé à la somme de CHF 6'247'728 et 7/13 de franc, entièrement libéré.

Il est divisé en 81'220'471 actions d'une valeur nominale de 1/13 de franc chacune.

### Article 5b: Capital conditionnel en vue de financement

Le capital-actions de la société peut être augmenté d'un montant maximum total de CHF 1'040'544 et 1/13 de franc par l'émission d'un maximum de 13'527'073 actions nominatives ordinaires, d'une valeur nominale de 1/13 de franc chacune, à libérer entièrement, suite à l'exercice de droits de conversion et/ou d'option accordés en relation avec des obligations, d'autres formes comparables de titres de dette, des emprunts ou d'autres instruments similaires du marché des capitaux ou des obligations contractuelles de la société ou de l'une de ses filiales, et/ou par l'exercice de droits d'option émis par la société ou l'une de ses filiales (les "instruments financiers"). Le droit préférentiel de souscription des actionnaires est exclu. Le droit de souscrire les nouvelles actions appartient aux détenteurs des instruments financiers. Le conseil d'administration fixe les conditions des instruments financiers.

Lors de l'émission d'instruments financiers, le conseil d'administration peut limiter ou exclure les droits des actionnaires de souscrire les instruments financiers par préférence dans les cas suivants: The company may grant loans and other forms of financing to other group companies and provide security of any sort for the direct or indirect benefit of group companies or third parties, in particular in the form of guarantees, pledges or fiduciary assignments of assets of the company.

### **Article 4: Duration**

The duration of the company is indefinite.

### TITLE II: SHARE CAPITAL AND SHARES

### Article 5: Par value and number of shares

The share capital of the company is set at the amount of CHF 6,247,728 and 7/13 of a franc, fully paid up.

It is divided into 81,220,471 shares with a par value of 1/13 of a franc each.

# Article 5b: Conditional share capital for financing purposes

The company's share capital shall be increased by a maximum aggregate amount of CHF 1,040,544 and 1/13 of a franc through the issuance of not more than 13,527,073 registered shares, which will have to be fully paid- in, with a par value of 1/13 of a franc each, by the exercise of option and conversion rights which are granted in connection with bonds, similar debt instruments, loans or other financial market instruments or contractual obligations of the company or one of its subsidiaries, and/or by the exercise of option rights issued by the company or one of its subsidiaries ("financial instruments"). The pre-emptive rights of shareholders are excluded. The right to subscribe for the new shares shall be held by the holders of the financial instruments. The board of directors shall determine the terms of the financial instruments.

When issuing financial instruments, the board of directors shall have the right to limit or exclude the right of shareholders to subscribe for the financial instruments by preference:

- a) pour financer ou refinancer l'acquisition d'entreprises ou de parts d'entreprise, ou de nouvelles participations, produits, droits de propriété intellectuelle, licences, ou pour favoriser des coopérations ou nouveaux plans d'investissements de la société;
- b) si l'émission se fait sur des marchés internationaux des capitaux, y compris par placement privé; ou
- c) en vue de la souscription des instruments financiers par une institution bancaire ou un consortium de banques avec offre publique subséquente.
- Si le droit des actionnaires de souscrire aux instruments financiers par préférence est exclu, (i) les instruments financiers doivent être attribués aux conditions du marché; (ii) la période d'exercice, la période d'échange ou la période de conversion des instruments financiers ne doit pas dépasser 10 ans à partir de la date à laquelle ces instruments sont émis; et (iii) le prix de conversion, le prix d'échange ou tout autre prix d'exercice des instruments financiers doit être fixé par référence aux conditions du marché.

# Article 5c: Capital conditionnel pour les plans d'intéressement

Le capital-actions de la société peut être augmenté d'un montant maximum total de

CHF 692'649 par l'émission d'un maximum de 9'004'437 actions nominatives ordinaires, entièrement libérées, d'une valeur nominale d'1/13 de franc chacune, lors de l'exercice de droits d'option ou de souscription accordés ou attribués à des employés, membres du conseil d'administration ou consultants de la société ou de l'une de ses filiales selon les termes d'un ou de plusieurs plans d'intéressement ou règlements adoptés par le conseil d'administration. Le droit préférentiel de souscription des actionnaires est exclu à l'égard de ces actions. Le conseil d'administration fixe les conditions des plans d'intéressement et des règlements, ainsi que de l'émission des actions.

- a) for the purpose of financing or refinancing the acquisition of enterprises, divisions thereof, or of participations, products, intellectual property rights, licenses, cooperations or of newly planned investments of the company;
- b) if the issuance is made on domestic or international capital markets, including by means of private placements; or
- c) for purposes of an underwriting of the financial instruments by a banking institution or a consortium of banks with subsequent offering to the public.

To the extent that the right of shareholders to subscribe for the financial instruments by preference is excluded, (i) the financial instruments shall be placed at market conditions; (ii) the exercise period, the conversion period or the exchange period of the financial instruments shall not exceed 10 years as of the date of the issue; and (iii) the conversion price, the exchange price or other exercise price of the financial instruments shall be determined by reference to market prices.

### Article 5c: Conditional share capital for equity plans

The company's share capital shall be increased by a maximum aggregate amount of CHF 692,649 through the issuance of not more than 9,004,437 registered ordinary shares, which shall be fully paid-in, with a par value of 1/13 of a franc each, by issuance of shares upon the exercise of options or pre-emptive rights thereof, which have been issued or granted to employees, members of the board of directors or consultants of the company or of one of its subsidiaries under the terms of one or more equity incentive plans or regulations adopted by the board of directors. The pre-emptive rights of shareholders are excluded. The board of directors shall determine the terms of the equity incentive plans or regulations and of the issuance of the shares.

Les actions sont nominatives.

Par une modification des statuts, l'assemblée générale peut en tout temps convertir des actions nominatives en actions au porteur et des actions au porteur en actions nominatives.

Par une modification des statuts, l'assemblée générale peut aussi en tout temps convertir des actions d'une catégorie en actions d'une autre catégorie, ou encore des bons de participation en actions. L'art. 654 CO et les dispositions de ces statuts sont réservés.

Sous réserve du paragraphe ci-dessous, les actions nominatives de la société sont émises sous forme de droits-valeur (tels que définis par le CO) et de titres intermédiés (tels que définis par la Loi fédérale suisse sur les titres intermédiés).

Suite à son inscription au registre des actions, un actionnaire peut demander en tout temps à la société d'établir un relevé des actions nominatives qu'il détient. Il n'a cependant pas de droit à exiger l'impression et la livraison de certificats d'actions. En revanche, la société peut à tout moment imprimer et livrer des certificats incorporant des actions nominatives. La société peut aussi, à son choix, retirer les actions nominatives revêtant la forme de titres intermédiés des divers organismes de dépôt auprès desquelles elles ont été enregistrées, et avec le consentement de l'actionnaire, annuler sans les remplacer les certificats d'action qui lui auront été remis.

Si la société décide d'imprimer et de livrer des certificats d'actions, ces derniers doivent porter la signature de deux signataires autorisés de la société, dont l'un au moins doit être membre du conseil d'administration. Les signatures peuvent être apposées par facsimilé.

### Article 7: Droits et obligations des actionnaires

Chaque action est indivisible à l'égard de la société, qui ne reconnaît qu'un propriétaire pour une action.

Chaque action donne droit à une part proportionnelle du bénéfice résultant du bilan et du produit de la liquidation en proportion des versements opérés au capital-actions. The shares shall be registered.

The general meeting of shareholders may, at any time, by modifying these articles of association, convert the registered shares into bearer shares and convert bearer shares into registered shares.

The general meeting of shareholders may also, at any time, by modifying these articles of association, convert shares of one class into shares of another class, or non-voting shares into voting shares. Article 654 CO and the provisions of these articles of association are reserved.

Subject to the paragraph below, the registered shares of the company will be uncertificated securities (in terms of the CO) and intermediated securities (in terms of the Swiss Federal Intermediated Securities Act).

A shareholder registered in the company's shareholders' register may request from the company a statement of the shareholder's registered shares at any time. Shareholders do not have a right to the printing and delivery of share certificates. The company may, however, print and deliver certificates for shares at any time at its option. The company may also, at its option, withdraw uncertificated shares from the custodian system where they have been registered and, with the consent of the shareholder, cancel issued certificates that are returned to the company.

If the company decides to print and deliver share certificates, the share certificates shall bear the signatures of two duly authorized signatories of the company, at least one of which shall be a member of the board of directors. These signatures may be facsimile signatures.

### Article 7: Shareholders' rights and duties

Each share shall be indivisible towards the company, which only recognizes one legal owner for each share.

Each share confers the right to a portion of the profit resulting from the balance sheet and the proceeds of liquidation, in proportion to the payments made to pay-in the share capital.

Les actionnaires ne sont tenus que des prestations statutaires. Ils ne répondent pas personnellement des dettes sociales.

Article 8: Transfert des actions

Le transfert de la propriété des actions émises sous forme de papiervaleur requiert la remise du titre endossé à l'acquéreur.

Le transfert de la propriété d'actions détenues sous forme de titres intermédiés s'opère conformément aux dispositions de la Loi fédérale suisse sur les titres intermédiés.

Les actions nominatives non incorporées dans un papier-valeur et qui ne sont pas détenues sous la forme de titres intermédiés, respectivement les droits y afférents, eux-mêmes non incorporés dans un papier-valeur, ne peuvent être transférés que par cession. La cession n'est valable que si elle est notifiée à la société.

Article 9: Registre des actions

La société tient un registre des actions qui mentionne le nom et l'adresse des propriétaires et des usufruitiers des actions nominatives.

Est considéré comme actionnaire ou usufruitier à l'égard de la société celui qui est inscrit au registre des actions. Un actionnaire peut demander à la société une confirmation qu'il est dûment inscrit au registre des actions.

Si un actionnaire change d'adresse, il doit en informer la société. Tant qu'il ne l'aura pas fait, toute communication sera valablement faite à sa dernière adresse inscrite au registre des actions. The obligations of the shareholders are limited to those specified in these articles of association. The shareholders are not personally liable for the debts of the company.

**Article 8: Transfer of shares** 

The transfer of ownership of certificated shares shall require delivery of the properly endorsed share certificate to the purchaser.

The transfer of ownership of shares held as book entry securities shall be carried out according to the provisions of the Swiss Federal Intermediated Securities Act.

Registered shares not incorporated into a certificate and that are not held as book entry securities as well as the respective rights associated therewith which are not incorporated into any certificate may be transferred only by assignment. Such assignment shall be valid only if the company has been notified thereof.

Article 9: Share register

The company shall keep a share register, which shall contain the names and addresses of the owners of the shares or the persons benefiting from an usufruct interest in the shares.

Only the persons registered in the share register shall be considered shareholders or holders of a usufruct interest in the shares towards the company. A shareholder may request from the company a confirmation that he is duly registered in the share register.

Should a shareholder change his address, he must so inform the company. As long as a shareholder has not provided notice of a change of address to the company, any communication shall be validly made to his last address entered in the share register.

TITRE III: ORGANISATION DE LA SOCIETE

TITLE III: ORGANIZATION OF THE COMPANY

#### A. ASSEMBLEE GENERALE

#### Article 10: Droits intransmissibles

L'assemblée générale des actionnaires est le pouvoir suprême de la société.

Elle a les droits intransmissibles:

- 1.d'adopter et de modifier les statuts;
- 2.de nommer les membres du conseil d'administration, de l'organe de révision, le président du conseil d'administration, les membres du comité de rémunération et le représentant indépendant des actionnaires;
- 3. d'approuver le rapport annuel et les comptes consolidés de la société;
- 4.d'approuver les comptes annuels et de déterminer l'emploi du bénéfice résultant du bilan, en particulier de fixer le dividende;
- 5.sur proposition du conseil d'administration, d'approuver la rémunération des membres du conseil d'administration et du comité exécutif;
- 6.de donner décharge aux membres du conseil d'administration;
- 7.de prendre toutes les décisions qui lui sont réservées par la loi et ces statuts.

#### Article 11: Assemblées générales ordinaires et extraordinaires

L'assemblée générale ordinaire a lieu chaque année dans les six mois qui suivent la clôture de l'exercice; des assemblées générales extraordinaires sont convoquées aussi souvent qu'il est nécessaire, notamment dans les cas prévus par la loi.

L'assemblée générale se réunit au lieu désigné par le conseil d'administration.

Article 12: Convocation de l'assemblée générale

#### A. GENERAL MEETING

#### Article 10: Non-transferable rights

The general meeting of shareholders is the highest authority of the company.

It has the non-transferable rights:

- 1.to adopt and amend the articles of association
- 2.to elect the members of the board of directors, the auditors, the chairman of the board of directors, the members of the compensation committee and the independent representative of shareholders;
- 3.to approve the business report and the consolidated financial statements of the company;
- 4.to approve the annual statutory financial statements of the company and to decide upon the allocation of profits as shown on the balance sheet, in particular with regard to dividends;
- 5.on proposal of the board of directors, to approve the compensation of members of the board of directors and of executive committee;
- 6.to discharge the members of the board of directors from liability; and
- 7.to decide on all matters reserved to it by law and by these articles of association.

#### Article 11: Annual and extraordinary general meetings

The annual general meeting of shareholders shall be held every year within six months following the end of the business year; extraordinary general meetings of shareholders may be convened as often as necessary, in particular in the cases provided by law.

The general meeting of shareholders shall meet at the place determined by the board of directors.

Article 12: Invitation to the general meeting

L'assemblée générale est convoquée par le conseil d'administration et, dans les cas prévus par la loi ou ces statuts, par l'organe de révision, les liquidateurs ou, le cas échéant, les représentants des obligataires.

Un ou plusieurs actionnaires représentant ensemble 10 pour cent au moins du capital-actions peuvent aussi requérir la convocation de l'assemblée générale. Des actionnaires qui représentent des actions totalisant une valeur nominale de un million de Francs suisses peuvent requérir l'inscription d'un objet à l'ordre du jour. La convocation et l'inscription d'un objet à l'ordre du jour doivent être requises par écrit 60 jours au moins avant la date de l'assemblée et inclure une courte description des points à porter à l'ordre du jour et les propositions.

#### Article 13: Mode de convocation

Les assemblées générales ordinaires ou extraordinaires sont convoquées par publication dans la Feuille officielle suisse du commerce au moins vingt jours avant la date prévue pour la réunion.

Une assemblée générale des actionnaires peut également être convoquée par communication écrite à chacun des actionnaires à l'adresse figurant au registre des actions. Dans un tel cas, le délai de convocation de vingt jours mentionné ci-dessus débute le jour suivant la date à laquelle la communication écrite a été expédiée.

La convocation à une assemblée mentionne les objets portés à l'ordre du jour, ainsi que les propositions du conseil d'administration et des actionnaires qui ont demandé la convocation de l'assemblée générale ou requis l'inscription d'un objet à l'ordre du jour.

Aucune décision ne peut être prise sur des objets qui n'ont pas été dûment portés à l'ordre du jour, à l'exception des propositions déposées par un actionnaire dans le but de convoquer une assemblée générale extraordinaire, d'instituer un contrôle spécial ou d'élire des auditeurs.

Il n'est pas nécessaire d'annoncer à l'avance les propositions entrant dans le cadre des objets portés à l'ordre du jour ni les délibérations qui ne doivent pas être suivies d'un vote. The general meetings of shareholders shall be called by the board of directors or, if required by law or these articles of association, by the auditors, the liquidators of the company or the representatives of the bond holders, if any.

One or several shareholders, holding together at least ten per cent of the share capital, may also request that a general meeting be convened. Shareholders representing shares of a total par value of one million Swiss Francs may require that items be included on the agenda of the meeting. Such requests must be made in writing not less than 60 days ahead of the meeting and shall include a brief description of the items to be discussed and the proposals.

#### Article 13: Notice of Meeting

Annual or extraordinary general meetings of shareholders shall be called by notice in the "Swiss Official Gazette of Commerce" not less than twenty days before the date fixed for the meeting.

A general meeting of shareholders may also be called by means of a notice sent to the shareholders at their address registered in the share register. In such a case, the twenty-day notice period referred to above shall begin on the day following the date on which the notices shall have been mailed.

The notice of a meeting shall state the items on the agenda and the proposals of the board of directors and of the shareholders who requested that a general meeting be convened or that items be included in the agenda.

No resolution shall be passed at a general meeting of shareholders on matters which do not appear on the agenda except for a resolution convening an extraordinary general meeting, the setting up of a special audit or the election of auditors.

No prior notice is required to bring motions related to items already on the agenda or for the discussion of matters on which no resolution is to be taken.

#### Article 14: Légitimation des actionnaires

Tout actionnaire qui ne participe pas à l'assemblée générale des actionnaires en personne peut faire représenter ses actions à l'assemblée par le représentant indépendant ou par une autre personne ou entité qui ne doit pas nécessairement être un actionnaire. Le conseil d'administration règle les exigences régissant la participation et la représentation à l'assemblée générale.

Sauf dispositions contraires de ces statuts, une assemblée générale des actionnaires est dûment convoquée et apte à statuer quel que soit le nombre d'actions représentées.

#### Article 15: Présidence; procès-verbal

L'assemblée générale des actionnaires est présidée par le président du conseil d'administration, le vice-président ou par toute autre personne désignée à cet effet par le conseil d'administration. A leur défaut, la personne désignée par l'assemblée générale des actionnaires préside.

Le président désigne le secrétaire de l'assemblée et les scrutateurs, qui ne doivent pas nécessairement être actionnaires.

Le président a les pouvoirs et compétences nécessaires et suffisantes pour assurer le bon déroulement de l'assemblée générale des actionnaires.

Les procès-verbaux de l'assemblée générale des actionnaires sont signés par le président et le secrétaire de l'assemblée.

#### Article 16: Droit de vote

Chaque action donne droit à une voix.

#### Article 17: Décisions et élections

Sauf disposition contraire de la loi ou de ces statuts, l'assemblée générale prend ses décisions et procède aux élections à la majorité absolue des voix exprimées.

#### Article 14: Representation of shareholders

Each shareholder who does not attend the general meeting of shareholders in person may have his shares represented at the meeting by the independent representative or by another person or entity, who does not have to be a shareholder. The board of directors shall determine the requirements regarding participation and representation in the general meeting of shareholders.

Subject to provisions to the contrary in these articles of association, a general meeting of shareholders is duly convened and capable of passing resolutions regardless of the number of shares represented.

#### Article 15: Acting chair; minutes

The general meeting of shareholders is chaired by the chairman of the board of directors, the vice-chairman or by any other person designated to that effect by the board of directors. In the absence of such persons, the person appointed by the general meeting of shareholders shall take the chair.

The chairperson shall appoint the secretary of the meeting and the vote counters, none of whom need to be a shareholder.

The chairperson shall have all powers and authority necessary and appropriate to ensure the orderly conduct of the general meeting of shareholders.

The minutes of the general meeting of shareholders shall be signed by the chairman and the secretary of the meeting.

#### Article 16: Voting right

Each share shall convey the right to one vote.

#### Article 17: Resolutions and elections

Unless required otherwise by law or these articles of association, the general meeting of shareholders shall make resolutions and proceed to elections by an absolute majority of the votes cast.

Une décision de l'assemblée générale recueillant au moins les deux tiers des voix attribuées aux actions représentées et la majorité absolue des valeurs nominales représentées est nécessaire pour:

En cas de partage égal des voix, celle du président est prépondérante.

1.la modification du but social;

2.l'introduction d'actions à droit de vote privilégié;

3.la restriction de la transmissibilité des actions nominatives;

4.l'augmentation autorisée ou conditionnelle du capital-actions;

5.l'augmentation du capital-actions au moyen des fonds propres, contre apport en nature ou en vue d'une reprise de biens et l'octroi d'avantages particuliers;

6.la limitation ou la suppression du droit préférentiel de souscription

7.le transfert du siège de la société;

8.la dissolution de la société.

9.abroger ou modifier l'article 20 al. 1, de ces statuts; ou

10. révoquer un membre en fonction du conseil d'administration.

Toute décision relative à la fusion, la scission ou la transformation de la société sera prise en conformité avec les dispositions de la loi fédérale suisse sur la fusion, la scission, la transformation et le transfert de patrimoine.

#### **B. REPRESENTANT INDEPENDANT DES ACTIONNAIRES**

Article 18. Election, durée du mandat et révocation

L'assemblée générale des actionnaires élit le représentant indépendant des actionnaires.

In the event the votes are evenly split, the chairman shall have a casting vote.

A resolution of the general meeting of shareholders approved by at least two-thirds of the votes allotted to the shares represented at the meeting, and the absolute majority of the aggregate par value of the shares represented is necessary to:

1.amend the purpose of the company;

2.create shares with privileged voting rights;

3.restrict the transferability of the registered shares;

4.authorize or conditionally authorize an increase in share capital;

5.increase the share capital through the conversion of capital surplus, through contribution in kind or for purposes of an acquisition of assets, or the granting of special privileges;

6.withdraw or limit pre-emptive rights;

7.relocate the registered office of the company;

8.dissolve the company;

9. abrogate or amend Article 20 para. 1 of these articles of association; or

10. remove a serving member of the board of directors.

Any decision related to a merger, demerger or conversion of the company shall be taken in accordance with the Swiss Federal Act on Mergers, De-mergers, Transformations and Transfers of Businesses.

### B. THE INDEPENDENT REPRESENTATIVE OF SHAREHOLDERS

Article 18. Election, office and removal

The general meeting of shareholders elects the independent representative of shareholders.

Sont éligibles les personnes physiques ou morales ou les sociétés de personnes.

L'art. 728 al. 2 à 6 CO s'applique par analogie au représentant indépendant.

Les fonctions du représentant indépendant s'achèvent à la fin de l'assemblée générale ordinaire suivante.

L'assemblée générale des actionnaires peut révoquer le représentant indépendant pour la fin de l'assemblée.

Lorsque la société n'a pas de représentant indépendant, le conseil d'administration le désigne en vue de la prochaine assemblée générale des actionnaires.

#### **B. CONSEIL D'ADMINISTRATION**

#### Article 19: Composition et durée des fonctions

Le conseil d'administration de la société est composé de huit membres au plus qui sont élus individuellement par l'assemblée générale des actionnaires pour une durée de fonctions s'achevant à la fin de l'assemblée générale ordinaire suivante. Ils sont rééligibles indéfiniment.

Le président du conseil d'administration est élu par l'assemblée générale pour une durée de fonctions s'achevant à la fin de l'assemblée générale ordinaire suivante. Il est rééligible indéfiniment.

#### Article 20: Mandats externes

Aucun membre du conseil d'administration ne peut exercer plus de 6 mandats additionnels dans des organes supérieurs de direction ou d'administration de sociétés dont les titres de participation sont cotés en bourse et 10 mandats additionnels dans des organes supérieurs de direction ou d'administration d'autres sociétés.

Les mandats suivants ne sont pas sujets aux limitations précitées:

a)les mandats dans des sociétés qui sont contrôlées par la société ou qui contrôlent la société;

Natural or legal persons or partnerships may be elected.

Article 728 para. 2 to 6 CO applies by analogy to the independent representative.

The independent representative shall hold office until the end of the next annual general meeting.

The general meeting of shareholders may remove the independent representative with effect at the end of the meeting.

If the company has no independent representative, the board of directors appoints one for the next general meeting of shareholders.

#### **B. BOARD OF DIRECTORS**

#### Article 19: Composition and term of office

The board of directors of the company shall be composed of not more than eight members, who shall be elected individually by the general meeting of shareholders for a term of office expiring after completion of the subsequent annual general meeting and who shall be indefinitely re-eligible.

The chairman of the board of directors shall also be appointed by the general meeting for a term of office expiring after completion of the subsequent annual general meeting and who shall be indefinitely reeligible.

#### Article 20: Outside mandates

No member of the board of directors may hold more than 6 additional mandates in the highest supervisory or management bodies of third party companies whose equity securities are listed on a stock exchange and 10 additional mandates in the highest management bodies of other companies.

The following mandates are not subject to these limitations:

a)mandates in companies which are controlled by the company or which control the company;

 b)les mandats dans des organes supérieurs de direction ou d'administration d'organisations caritatives, de fondations, de trusts et d'institutions de prévoyance en faveur du personnel. Aucun membre du conseil d'administration n'exercera plus de 10 mandats à ce titre.

#### **Article 21: Organisation**

Sauf disposition contraire de la loi ou de ces statuts, le conseil d'administration se constitue lui-même. Il peut désigner, parmi ses membres, un ou plusieurs vice-présidents qui assument la responsabilité de président du conseil d'administration en cas d'incapacité de ce dernier.

#### Article 22: Convocation

Le conseil d'administration est convoqué par le président aussi souvent que les affaires l'exigent.

Les délibérations et les décisions du conseil d'administration sont consignées dans un procès-verbal signé par le président et le secrétaire.

#### Article 23: Décisions

Les décisions du conseil d'administration sont prises à la majorité des membres présents. Le règlement d'organisation adopté par le conseil d'administration peut prévoir un quorum de présence pour certaines décisions. Aucun quorum de présence n'est requis pour les décisions concernant l'exécution d'une augmentation de capital décidée antérieurement et pour la modification des statuts résultant d'une telle augmentation de capital.

Les décisions peuvent aussi être prises en la forme d'une approbation donnée par écrit à une proposition, à moins qu'une discussion ne soit requise par l'un des membres du conseil d'administration. Les approbations données par écrit sont consignées dans le procès-verbal de la séance suivante.

#### Article 24: Compétences

Le conseil d'administration peut prendre des décisions sur toutes les affaires qui ne sont pas attribuées à l'assemblée générale ou à un autre organe par la loi ou ces statuts.

b)mandates in the highest supervisory or management bodies of associations, charitable organizations, foundations, trusts and employee welfare foundations. No member of the board of directors shall hold more than 10 such mandates.

#### Article 21: Organization

Unless provided otherwise in the law or these articles of association, the board of directors shall organize itself. It may elect, among its members, one or more vice-chairpersons, who shall assume the responsibilities of the chairman of the board of directors if the latter is incapacitated.

#### Article 22: Notice of meeting

Meetings of the board of directors shall be convened by the chairman as often as business requires.

Minutes of the business discussed and resolutions carried by the board of directors shall be kept and signed by the chairman and secretary.

#### Article 23: Resolutions

Resolutions of the board of directors shall be made with a majority of the members present. The organizational regulations adopted by the board of directors may impose presence quorums for certain resolutions. No quorum requirement applies for resolutions regarding the completion of a previously decided capital increase and the amendment of the articles of association evidencing such capital increase.

Resolutions may also be made by written consent to a proposed motion, provided no member requests that it be debated orally. Such resolutions by written consent shall be entered in the minutes of the next meeting.

#### Article 24: Powers

The board of directors may pass resolutions on all matters not reserved to the general meeting or another corporate body by law or these articles of association.

Sous réserve de l'art. 716*a* CO, le conseil d'administration peut déléguer tout ou partie de la gestion de la société à un ou plusieurs de ses membres ou à des tiers, conformément aux dispositions du règlement d'organisation qu'il aura adopté à cette fin.

### **COMITE DE REMUNERATION**

#### Article 25: Composition et organisation

Le comité de rémunération se compose de deux membres au moins du conseil d'administration, qui sont élus individuellement par l'assemblée générale.

Lorsque le comité de rémunération n'est pas complet, le conseil d'administration désigne les membres manquants pour la période allant jusqu'à la fin de la durée de fonctions.

Le conseil d'administration désigne le président parmi les membres du comité de rémunération.

Pour le surplus, le comité de rémunération se constitue lui-même.

#### Article 26: Durée du mandat

Les membres du comité de rémunération sont élus pour la période s'écoulant jusqu'à la fin de l'assemblée générale ordinaire suivante.

Ils sont indéfiniment rééligibles.

#### Article 27: Compétences du comité de rémunération

Le comité de rémunération assiste le conseil d'administration dans l'établissement et l'examen périodique de la stratégie de rémunération, des directives qui s'y rapportent et des objectifs de performance, ainsi que pour la préparation des propositions à soumettre à l'assemblée générale des actionnaires pour la rémunération du conseil d'administration et du comité exécutif. Il peut soumettre des propositions au conseil d'administration sur d'autres questions relatives à la rémunération.

Subject to Article 716a CO, the board of directors may delegate the management of all or part of the company's business to one or more of its members or to third parties, under the terms of organizational regulations that it shall have adopted for that purpose.

#### **D. COMPENSATION COMMITTEE**

#### Article 25: Composition and organisation

The compensation committee shall be composed of two or more members of the board of directors who shall be individually elected by the general meeting of shareholders.

If the compensation committee is not complete, the board of directors nominates the missing members for the remaining period of office.

The board of directors elects the chair from the members of the compensation committee.

Otherwise, the compensation committee shall constitute itself.

#### Article 26: Term of office

The members of the compensation committee shall hold office until the end of the next annual general meeting.

They shall be eligible for re-election indefinitely.

#### Article 27: Compensation committee's powers

The compensation committee shall support the board of directors in establishing and reviewing the company's compensation strategy, guidelines and the performance targets, as well as in preparing the proposals to the general meeting of shareholders regarding the compensation of the board of directors and of the executive committee. It may submit proposals to the board of directors in other compensation-related issues.

Le conseil d'administration détermine dans le règlement d'organisation (i) pour quelles fonctions du conseil d'administration et du comité exécutif le comité de rémunération fait des propositions au conseil d'administration pour ce qui concerne la rémunération et (ii) pour quelles autres fonctions le comité de rémunération fixe lui-même la rémunération conformément à ces statuts et aux directives concernant la rémunération.

Le conseil d'administration peut déléguer au comité de rémunération d'autres tâches définies dans le règlement.

shall determine such compensation in accordance with these articles of association and the compensation guidelines.

The board of directors shall set out in the organizational regulations (i)

committee the compensation committee shall submit proposals for the

compensation, and (ii) for which positions the compensation committee

for which positions of the board of directors and of the executive

The board of directors may delegate further tasks to the compensation committee that shall be determined in regulations.

#### **E. COMITE EXECUTIF**

#### Article 28: Composition et organisation

Le conseil d'administration élit les membres du comité exécutif.

Sauf dans les cas prévus par la loi, seules des personnes physiques peuvent être élues au comité exécutif.

Le conseil d'administration désigne le président du comité exécutif (CEO). Il fixe l'organisation du comité exécutif dans le règlement d'organisation. Pour le reste, le comité exécutif se constitue lui-même.

#### Article 29: Rapports contractuels

Les contrats de durée déterminée entre des membres du comité exécutif, d'une part, et la société ou des sociétés contrôlées par la société, d'autre part, au sujet de leur rémunération, ne peuvent pas excéder un an. De tels contrats peuvent être renouvelés.

Si les contrats mentionnés à l'alinéa 1 sont conclus pour une durée indéterminée, le délai de congé ne peut excéder un an.

#### Article 30: Mandats externes

#### **E. EXECUTIVE COMMITTEE**

#### Article 28: Composition and organisation

The board of directors shall elect the members of the executive committee.

Unless specifically permitted by law, only natural persons may be elected in the executive committee.

The board of directors shall appoint the head of the executive committee (CEO). It shall determine the organization of the executive committee in the organization regulations. For the rest, the executive committee shall constitute itself.

#### Article 29: Contractual relationships

Fixed-term agreements entered into by the company or companies controlled by the company, on the one hand, and members of the executive committee, on the other hand, with regard to their compensation cannot exceed one year. Such fixed-term agreements can be renewed.

If agreements within the scope of the prior paragraph are entered into for an indefinite period of time, their notice period cannot exceed one year.

#### Article 30: Outside mandates

Aucun membre du comité exécutif ne peut exercer plus de 6 mandats dans des organes supérieurs de direction ou d'administration de sociétés tierces dont les titres de participation sont cotés en bourse et 10 mandats additionnels dans des organes supérieurs de direction ou d'administration d'autres sociétés. L'acception de tels mandats par un membre du comité exécutif requiert l'accord préalable du conseil d'administration.

Les mandats suivants ne sont pas sujets aux limitations précitées:

a)les mandats dans des sociétés qui sont contrôlées par la société ou qui contrôlent la société;

 b)les mandats dans des organes supérieurs de direction ou d'administration d'organisations caritatives, de fondations, de trusts et d'institutions de prévoyance en faveur du personnel.
 Aucun membre du comité exécutif n'exercera plus de 10 mandats à ce titre.

#### F. ORGANE DE REVISION

#### Article 31: Organe de révision

L'assemblée générale élit un ou plusieurs réviseurs comme organe de révision. Elle peut désigner des suppléants.

Au moins l'un des réviseurs doit avoir en Suisse son domicile, son siège ou une succursale inscrite au registre du commerce.

Les réviseurs doivent satisfaire les exigences de qualification et d'indépendance prévues par la loi.

L'organe de révision exerce les attributions prévues par la loi, notamment les art. 728a à 728c CO.

La durée de fonction des réviseurs est d'une année. Elle se termine à la fin de l'assemblée générale qui approuve les comptes annuels sur lesquels porte leur rapport. Ils sont immédiatement rééligibles.

Les réviseurs sont tenus de participer à l'assemblée générale ordinaire.

No member of the executive committee may hold more than 6 additional mandates in the highest supervisory or management bodies of third party companies whose equity securities are listed on a stock exchange and 10 additional mandates in the highest supervisory or management bodies of other companies. Members of the executive committee shall only accept such mandates with the prior consent of the board of directors.

The following mandates are not subject to these limitations:

a)mandates in companies which are controlled by the company or which control the company;

b)mandates in the highest governing bodies of associations, charitable organizations, foundations, trusts and employee welfare foundations. No member of the executive committee shall hold more than 10 such mandates.

#### F. AUDITORS

#### Article 31: Auditors

The general meeting of shareholders shall elect one or several auditors. It may also elect deputy auditors.

At least one auditor must have in Switzerland its domicile, registered office or branch registered in the commercial registry.

The auditors shall satisfy the qualification and independence requirements contemplated by law.

The auditors shall carry out their duties and report in accordance with the law, in particular Articles 728a to 728c CO.

The term of office of the auditors is one year. It expires at the end of the general meeting of shareholders, which approves the annual statutory financial statements to which their audit relates. They shall be immediately eligible for re-election.

The auditors shall be bound to attend the annual general meeting of shareholders.

#### TITRE IV. RÉMUNÉRATION DES MEMBRES DU CONSEIL D'ADMINISTRATION ET DU COMITÉ EXÉCUTIF

# TITLE IV. COMPENSATION OF THE MEMBERS OF THE BOARD OF DIRECTORS AND OF THE EXECUTIVE COMMITTEE

#### Article 32: Principes de rémunération

La rémunération des membres du conseil d'administration se compose d'une rémunération fixe et d'indemnités de présence. Les membres exécutifs du conseil d'administration peuvent, en outre, se voir attribuer des éléments de rémunération des membres du comité exécutif.

La rémunération des membres du comité exécutif comprend des éléments de rémunération fixes et variables. La rémunération fixe comprend le salaire de base et d'autres éléments de rémunération. La rémunération variable peut comprendre des éléments de rémunération à court et à long terme. La rémunération totale prend en compte la position et le niveau de responsabilité du bénéficiaire.

Les éléments de rémunération variable à court terme sont régis par des mesures de performance qui prennent en compte la performance de la société et de tout ou partie de ses filiales, la performance du marché, d'autres sociétés ou éléments de référence comparables et/ou d'objectifs de performance personnels quantitatifs et qualitatifs.

Les éléments de rémunération variables à long terme sont régis par des mesures de performance qui prennent en compte des objectifs stratégiques et/ou financiers, ainsi que des éléments de rétention.

Le conseil d'administration, le comité de rémunération ou tout autre organe auquel cette compétence a été déléguée détermine les mesures de performance, les objectifs de performance, ainsi que leur accomplissement.

La rémunération peut être versée en espèces ou sous d'autres formes. Elle peut être versée sous forme d'actions, d'options ou d'autres instruments financiers. Le conseil d'administration ou le comité de rémunération, si cette compétence lui a été déléguée, détermine les conditions d'octroi, d'acquisition (*vesting*), d'exercice et de déchéance. Il peut en particulier prévoir la continuation, l'accélération ou la suppression des conditions d'acquisition (*vesting*) et d'exercice, le paiement ou l'attribution d'une rémunération lors de l'atteinte des objectifs ou encore la déchéance des droits, dans chaque cas lors d'événements prédéterminés tels qu'un changement de contrôle ou la fin d'un contrat de travail ou de mandat. La société peut se procurer les actions requises par le biais d'achats sur le marché, directement ou par l'intermédiaire de sociétés qu'elle contrôle, ou par l'émission d'actions nouvelles.

#### Article 32: Compensation principles

The compensation of the members of the board of directors shall consist of a fixed compensation and attendance allowances. Executive members of the board of directors can, in addition, receive compensation elements applicable with respect to members of the executive committee.

The compensation of the members of the executive committee consists of fixed and variable compensation elements. Fixed compensation comprises the base salary and other compensation elements. Variable compensation may comprise short-term and long-term compensation elements. The total compensation shall take into account position and level of responsibility of the recipient.

Short-term variable compensation elements shall be governed by performance metrics that take into account the performance of the company and some or all of its subsidiaries, market performance, other companies or comparable benchmarks and/or individual quantitative and qualitative performance targets.

Long-term variable compensation elements shall be governed by performance metrics that take into account strategic and/or financial objectives, as well as retention elements.

The board of directors or, to the extent delegated to it, the compensation committee or another body shall determine the performance metrics, the target levels as well as their achievement.

Compensation may be paid in the form of cash or in the form of other types of benefits. It can be paid by the grant of shares, stock options or other financial instruments. The board of directors or, to the extent delegated to it, the compensation committee shall determine grant, vesting, exercise and forfeiture conditions. In particular, they may provide for continuation, acceleration or removal of vesting and exercise conditions, for payment or grant of compensation based upon assumed target achievement, or for forfeiture, in each case in the event of pre-determined events such as a change-of-control or termination of an employment or mandate agreement. The company may procure the required shares through purchases in the market, either directly or through companies controlled by it, or by issuing new shares.

Les membres du conseil d'administration et/ou du comité exécutif peuvent participer à des plans de souscription d'actions établis par la société ou par des sociétés contrôlées par celle-ci, lesquels peuvent permettre aux employés éligibles d'affecter une partie de leur rémunération à l'acquisition d'actions de la société à un prix inférieur à celui du marché.

La rémunération peut être versée par la société ou par une société qu'elle contrôle.

La société ou les sociétés qu'elle contrôle remboursent les frais encourus par les membres du conseil d'administration ou du comité exécutif. Les frais remboursés ne font pas partie de la rémunération.

#### Article 33: Prêts, crédits et prestations de prévoyance

Sous réserve de l'article 34 para. 5, la société n'accorde pas de prêts ou de crédits aux membres du conseil d'administration ou aux membres du comité exécutif.

Les cotisations de retraite et les prestations de prévoyance sont effectuées selon les règles applicables aux plans de pension auxquels participe, en Suisse ou à l'étranger, la société ou les sociétés contrôlées par celle-ci.

#### Article 34: Vote de l'assemblée générale sur les rémunérations

Sur proposition du conseil d'administration, l'assemblée générale des actionnaires approuve annuellement et séparément:

1.la rémunération totale du conseil d'administration pour la période allant jusqu'à l'assemblée générale ordinaire suivante; et

Members of the board of directors and/or executive committee may participate in share purchase plans established by the company or companies controlled by it, under the terms of which eligible employees may allocate a portion of their compensation to the purchase of shares of the company at a discount to market price.

Compensation may be paid by the company or companies controlled by it.

The company or companies controlled by it shall reimburse the expenses incurred by the members of the board of directors or executive committee. Expenses reimbursements are not part of the compensation.

#### Article 33: Loans, credits and retirement benefits

Subject to Article 34 para. 5, the company shall not grant loans or credit facilities to members of the board of directors or members of the executive committee.

Pension contributions and post-retirement benefits shall be made or provided in accordance with the regulations applicable to the pension schemes in which the company or the companies controlled by it participate in Switzerland or abroad.

## <u>Article 34: Vote of the general meeting of shareholders on the compensation</u>

Following a proposal by the board of directors, the general meeting of shareholders annually and separately approves:

1.the aggregate compensation of the board of directors until the next annual general meeting; and

2.la rémunération totale du comité exécutif pour l'exercice annuel suivant.

Le conseil d'administration peut soumettre à l'assemblée générale des propositions de rémunération portant sur des périodes différentes et se rapportant à l'ensemble des membres du conseil d'administration ou du comité exécutif ou à certains d'entre eux seulement.

Le vote de l'assemblée générale des actionnaires sur les propositions de rémunération a un caractère contraignant.

Si l'assemblée générale des actionnaires n'approuve pas une proposition de rémunération faite par le conseil d'administration, ce dernier convoque une assemblée générale extraordinaire.

Des rémunérations peuvent être payées avant approbation de l'assemblée générale des actionnaires, celles-ci devant toutefois être sujettes à approbation ultérieure et à restitution en l'absence d'une telle approbation ultérieure.

Si le montant global maximal de la rémunération déjà approuvé par l'assemblée générale des actionnaires n'est pas suffisant pour couvrir la rémunération fixe d'une personne devenant membre du comité exécutif après que l'assemblée générale a approuvé la rémunération du comité exécutif pour la période visée (nouveau membre), la société ou toute autre société qu'elle contrôle peut verser à ce ou à ces nouveaux membres un montant complémentaire pour la période de rémunération déjà approuvée. Le montant complémentaire ne doit pas dépasser (i) pour le président du comité exécutif (CEO), 140% de la rémunération annuelle totale de l'ancien CEO et (ii) pour tout autre nouveau membre, 140% de la rémunération annuelle totale la plus élevée d'un membre du comité exécutif en fonction autre que le CEO.

2.the aggregate compensation of the executive committee for the following business year.

The board of directors can submit compensation proposals to the general meeting of shareholders for other periods and for all members of the board of directors or executive committee or some of them only.

The vote of the general meeting of shareholders on the compensation proposals shall be binding.

If the general meeting of shareholders does not approve a compensation proposal made by the board of directors, the board of directors shall convene an extraordinary general meeting.

Compensation may be paid out prior to approval by the general meeting of shareholders, subject to subsequent approval and, absent such subsequent approval, to restitution to the company.

If the maximum aggregate amount of compensation already approved by the general meeting of shareholders is not sufficient to also cover the compensation of one or more persons who become members of the executive committee during a compensation period for which the general meeting of shareholders has already approved the compensation of the executive committee (new hire), the company or companies controlled by it shall be authorized to pay an additional amount with respect to the compensation period already approved. Such additional amount shall not exceed (i) for the head of the executive committee (CEO), 140% of the total annual compensation of the former CEO and (ii) for any new hire other than the CEO, 140% of the highest total annual compensation of any member of the executive committee in office other than the CEO.

**Article 35: Indemnisation** 

**Article 35: Indemnification** 

Dans toute la mesure permise par la loi, la société indemnisera et relèvera les membres actuels et anciens du conseil d'administration, du comité exécutif, ainsi que leurs héritiers, exécuteurs et administrateurs, de tous dommages, pertes, responsabilités et frais résultant d'actions, procédures ou enquêtes annoncées, pendantes ou conclues, que ces dernières soient civiles, pénales, administratives ou de toute autre nature (y compris en particulier de toute responsabilité contractuelle, délictuelle, légale ou résultant de législations ou réglementations étrangères applicables, ainsi que de tous frais ou dépenses légaux ou autres raisonnablement encourus) que l'un ou l'ensemble d'entre eux ou leurs héritiers, exécuteurs ou administrateurs auront encouru ou supporté du fait de: a) tout acte commis ou prétendument commis, perpétré ou prétendument perpétré ainsi que toute omission ou prétendue omission intervenus dans l'exercice de leurs obligations ou de leurs prétendues obligations; ou b) l'exercice de leur fonction de membre du conseil d'administration ou du comité exécutif de la société; ou c) l'exercice, sur requête de la société, de la fonction d'administrateur, d'organe, d'employé ou de représentant d'une autre personne morale, société de personnes, trust ou de toute autre entreprise.

The company shall indemnify and hold harmless, to the fullest extent permitted by law, the current and former members of the board of directors, the executive committee, and their heirs, executors and administrators out of the assets of the company from against all damages, losses, liabilities and expenses in connection with threatened, pending or completed actions, proceedings or investigations, whether civil, criminal, administrative or other (including, but not limited to, liabilities under contract, tort and statute or any applicable foreign law or regulation and all reasonable legal and other costs and expenses properly payable) which they or any of them, their heirs, executors or administrators, shall or may incur or sustain by or reason of a) any act done or alleged to be done, concurred or alleged to be concurred in or omitted or alleged to be omitted in or about the execution of their duty, or alleged duty; or b) serving as a member of the board of directors or member of the executive committee of the company; or c) serving at the request of the company as director, officer, or employee or agent of another corporation, partnership, trust or other enterprise.

Cette indemnisation ne s'étendra pas aux circonstances dans lesquelles l'une des personnes susmentionnées aura été reconnue avoir violé ses obligations de membre du conseil d'administration ou du comité exécutif intentionnellement ou par une négligence grave par un jugement ou une décision finale émanant d'une autorité judiciaire, d'un tribunal arbitral, d'une autorité gouvernementale ou administrative et non susceptible de recours.

This indemnity shall not extend to any matter in which any of the said persons is found, in a final judgment or decree of a court, arbitral tribunal or governmental or administrative authority of competent jurisdiction not subject to appeal, to have committed an intentional or grossly negligent breach of said person's duties as member of the board of directors or member of the executive committee.

Nonobstant ce qui précède, la société avancera le montant des frais judiciaires et des honoraires d'avocat se rapportant aux procédures civiles, pénales, administratives ou aux enquêtes mentionnées à l'alinéa précédent. La société pourra refuser et/ou obtenir le remboursement de telles avances si un tribunal ou une autorité gouvernementale ou administrative compétente constate dans une décision non susceptible de recours que le membre du conseil d'administration ou du comité exécutif concerné a violé ses obligations de membre du conseil d'administration ou du comité exécutif intentionnellement ou par une négligence grave. La société pourra souscrire une assurance responsabilité en faveur des membres du conseil d'administration et des membres du comité exécutif. Les primes de cette assurance seront mises à la charge et payées par la société ou par l'une de ses filiales.

Without limiting the foregoing, the company shall advance to existing and former members of the board of directors and executive committee court costs and attorney fees in connection with civil, criminal, administrative or investigative proceedings as described in the preceding paragraph. The company may reject and/or recover such advanced costs if a court or governmental or administrative authority of competent jurisdiction not subject to appeal holds that the member of the board of directors or member of the executive management in question has committed an intentional or grossly negligent breach of his statutory duties as a member of the board of directors or member of the executive committee. The company may procure directors' and officers' liability insurance for members of the board of directors and members of the executive committee of the company. The insurance premiums shall be charged to and paid by the company or its subsidiaries.

#### TITRE V. ANNEE SOCIALE -REPARTITION DU BENEFICE

#### TITLE V. BUSINESS YEAR - ALLOCATION OF PROFITS

#### Article 36: Année sociale

Le conseil d'administration détermine l'année sociale.

#### Article 37: Distribution du bénéfice

Chaque année, 5% du bénéfice de l'exercice sont affectés à la réserve générale jusqu'à ce que celle-ci atteigne 20 % du capital-actions libéré. Si, par la suite, la réserve générale n'atteint plus la limite légale de 20 %, des affectations supplémentaires devront être effectuées jusqu'à ce que cette limite soit à nouveau atteinte.

Le solde du bénéfice résultant du bilan est, sur proposition du conseil d'administration, réparti conformément aux décisions de l'assemblée générale des actionnaires dans les limites des dispositions impératives de la loi concernant la réserve légale.

#### Article 38: Dividende

Le paiement du dividende a lieu à l'époque fixée par le conseil d'administration. Tout dividende qui n'a pas été réclamé dans les cinq ans dès son exigibilité revient de plein droit à la société.

#### TITRE VI. LIQUIDATION DE LA SOCIETE

#### Article 39: Liquidation

Lorsque la dissolution de la société est décidée, la liquidation est menée par le conseil d'administration, à moins que l'assemblée générale des actionnaires ne désigne d'autres liquidateurs.

#### Article 36: Business year

The board of directors shall determine the business year.

#### Article 37: Allocation of profit

Each year 5% of the annual net profit must be transferred to a general reserve until this fund amounts to 20% of the paid-in capital. Whenever the general reserve falls below 20%, additional transfers shall be made until the 20% limit is once again reached.

The remainder of the net profit shall be allocated in the manner decided by the general meeting of shareholders, following a proposal by the board of directors and subject, however, to the mandatory provisions of the law concerning the general reserve.

#### Article 38: Dividends

Dividends shall be paid at such time as the board of directors shall determine. Any dividend not claimed within five years of it becoming due shall be forfeited to the company.

#### TITLE VI. LIQUIDATION OF THE COMPANY

#### **Article 39: Liquidation**

In the event that it is decided to dissolve the company, the liquidation thereof shall be carried out by the board of directors, unless the general meeting of shareholders appoints other liquidators.

L'un au moins des liquidateurs doit être domicilié en Suisse et avoir qualité pour représenter la société. Les liquidateurs décident du mode de signature.

#### Article 40: Compétences pendant la liquidition

Pendant la liquidation, les pouvoirs des organes sociaux sont restreints aux actes qui sont nécessaires à cette opération et qui, de par leur nature, ne sont pas du ressort des liquidateurs.

L'assemblée générale des actionnaires conserve le droit d'approuver les comptes de la liquidation et de donner décharge aux liquidateurs.

Après paiement des dettes, l'actif disponible de la société dissoute est réparti entre les actionnaires de la société au prorata des apports effectués.

#### At least one of the liquidators shall be domiciled in Switzerland and shall have the right to represent the company. The liquidators shall determine the signature rights.

#### Article 40: Powers during the liquidation

During the liquidation, the powers of the corporate bodies of the company shall be restricted to operations that are necessary for the liquidation, but which, by their nature, lie outside the scope of the function of the liquidators.

The general meeting of the shareholders shall retain the right to approve the accounts of the liquidation and to discharge the liquidators from liability.

The available assets, after discharge of liabilities, shall be distributed to the shareholders of the company in proportion to the paid-in contributions.

#### TITRE VII. PUBLICATIONS - DROIT APPLICABLE - FOR

#### **Article 41: Publications**

Sauf disposition contraire de ces statuts, les communications de la société aux actionnaires sont faites par avis écrit aux actionnaires inscrits au registre des actions ou, si le conseil d'administration le décide, par publication dans la Feuille officielle suisse du commerce.

L'organe de publication est la Feuille officielle suisse du commerce.

#### Article 42: Droit applicable et for

Une action en justice contre la société, les personnes chargées de l'administration, de la gestion, de la révision et de la liquidation peut être ouverte devant le juge ordinaire du siège de la société; le droit suisse est applicable.

### TITRE VII. ANNOUNCEMENTS – GOVERNING LAW – JURISDICTION

#### **Article 41: Announcements**

Unless these Articles provide otherwise, company notices to shareholders shall be sent out in writing to shareholders entered in the Share Register or, if the board of directors so decides, shall be published in the Swiss Official Gazette of Commerce.

The journal for publishing notices shall be the Swiss Official Gazette of Commerce.

#### Article 42: Governing law and jurisdiction

All disputes and proceedings against the company, its directors, executive officers, auditors, or liquidators shall be subject to the jurisdiction of the ordinary courts of the place of the registered office of the company; Swiss law shall apply.

La version anglaise de ces statuts est une traduction de l'original en langue française. En cas de contradiction entre la version française et la version anglaise de ces statuts, la version française fait foi.

The English version of these articles of association is a translation of the original version in French. In the event of any discrepancies between the French and English versions, the French version shall prevail.

Genève, le 12 février 2021

David Lacin, notaire:

Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of August 7, 2019, as amended by the First Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of December 6, 2019 and the Second Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of February 18, 2020, the Third Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of April 7, 2020, and the Fourth Amendment to Loan and Security Agreement among the Registrant, Oxford Finance LLC and ObsEva USA Inc., dated as of January 27, 2021.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [\*\*\*], HAS BEEN OMITTED BECAUSE OBSEVA SA HAS DETERMINED THE INFORMATION (I) IS NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO OBSEVA SA AND ITS SUBSIDIARIES IF PUBLICLY DISCLOSED.

#### LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (as the same may from time to time be amended, modified, supplemented or restated, this "Agreement") dated as of August 7, 2019 (the "Effective Date") among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("Oxford"), as collateral agent (in such capacity, "Collateral Agent"), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "Lender" and collectively, the "Lenders"), and OBSEVA SA, a stock corporation organized under the laws of Switzerland with offices located at chemin des Aulx, 12, 1228 Plan-les-Ouates, Switzerland and registered with the commercial register of the Canton of Geneva with the registration number CHE-253.914.856 ("Parent") and OBSEVA USA INC., a Delaware corporation with offices located at 1 Financial Center, 24th Floor, Boston, Ma 02111 ("ObsEva USA", Parent and ObsEva USA, individually and collectively, jointly and severally, "Borrower"), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

#### 1. ACCOUNTING AND OTHER TERMS

1.1 Accounting terms not defined in this Agreement shall be construed in accordance with IFRS. Calculations and determinations must be made in accordance with IFRS. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to "**Dollars**" or "\$" are United States Dollars, unless otherwise noted.

#### 2. LOANS AND TERMS OF PAYMENT

**2.1 Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

#### 2.2 Term Loans.

- (a) <u>Availability</u>.
- (i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make one (1) term loan to Borrower on the Effective Date in an aggregate amount of Twenty-Five Million Dollars (\$25,000,000.00) according to each Lender's Term A Loan Commitment as set forth on Schedule 1.1 hereto (such term loan is hereinafter referred to as the "**Term A Loan**"). After repayment, the Term A Loan may not be re-borrowed.
- (ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make term loans to Borrower (but in a single disbursement) in an aggregate amount of up to Twenty-Five Million Dollars (\$25,000,000.00) according to each Lender's Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "**Term B Loan**", and collectively as the "**Term B Loans**"). After repayment, no Term B Loan may be re-borrowed.
- (iii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Third Draw Period, to make term loans to Borrower (but in a single disbursement)

in an aggregate amount of up to Twenty-Five Million Dollars (\$25,000,000.00) according to each Lender's Term C Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a "Term C Loan", and collectively as the "Term C Loans"; each Term A Loan, Term B Loan or Term C Loan is hereinafter referred to singly as a "Term Loan" and the Term A Loan, the Term B Loans and the Term C Loans are hereinafter referred to collectively as the "Term Loans"). After repayment, no Term C Loan may be re-borrowed.

- (b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1st) Payment Date following the Funding Date of each Term Loan, and continuing on the Payment Date of each successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of each Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of such Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to twenty-four (24) months. All unpaid principal and accrued and unpaid interest with respect to each Term Loan is due and payable in full on the Maturity Date. Each Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).
- (c) <u>Mandatory Prepayments</u>. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Facility Fee, (iii) the Final Payment, (iv) the Prepayment Fee, plus (v) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loan(s).
- (d) Permitted Prepayment of Term Loans. Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) any unpaid portion of the Facility Fee, (C) the Final Payment, (D) the Prepayment Fee, plus (E) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

#### 2.3 Payment of Interest on the Credit Extensions.

- (a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent on the Funding Date of the applicable Term Loan and then monthly thereafter, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.
- (b) <u>Default Rate</u>. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.
- (c) <u>360-Day Year</u>. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

- (d) <u>Debit of Accounts.</u> Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.
- (e) <u>Payments</u>. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender's office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 12:00 noon Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.
- **Exhibit D** hereto (each a "**Secured Promissory Note**"), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender's Secured Promissory Note, an appropriate notation on such Lender's Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender's Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender's Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal of or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

#### **2.5 Fees.** Borrower shall pay to Collateral Agent:

- (a) <u>Facility Fee</u>. A fully earned, non-refundable facility fee of [\*\*\*] (the "Facility Fee") to be shared between the Lenders in accordance with their respective Commitment Percentages payable as follows: (i) [\*\*\*] of the Facility Fee shall be due and payable on the Effective Date, (ii) [\*\*\*] of the Facility Fee shall be due and payable on the earliest of (x) the Funding Date of the Term B Loans, (y) the date of the expiration of the Second Draw Period (whether or not the Second Draw Period commenced), and (z) the acceleration of any Term Loan or the prepayment of any Term C Loans, (y) the date of the expiration of the Third Draw Period (whether or not the Third Draw Period commenced), and (z) the acceleration of any Term Loan or the prepayment of any Term Loan pursuant to Section 2.2(c) or (d);
- (b) <u>Final Payment</u>. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;
- (c) <u>Prepayment Fee</u>. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;
- (d) <u>Good Faith Deposit</u>. Borrower has remitted to Collateral Agent [\*\*\*] as a good faith deposit, which amount shall be applied (i) first, towards the Lenders' Expenses due on the Effective Date and (ii) second, towards Facility Fee due under Section 2.5(a) hereof on the Effective Date. For the sake of clarity, Borrower shall be responsible for the entire amount of the Facility Fee payable pursuant to Section 2.5(a) hereof and the Lenders' Expenses payable under Section 2.5(e) hereof; and
- (e) <u>Lenders' Expenses</u>. All Lenders' Expenses (including reasonable and documented attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due.

**2.6 Withholding.** Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

#### 3. <u>CONDITIONS OF LOANS</u>

- **3.1 Conditions Precedent to Initial Credit Extension.** Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:
  - (a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable;
- (b) duly executed original Control Agreements or other appropriate instrument with respect to any Collateral Accounts maintained by Borrower;
- (c) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan Commitment Percentage;
  - (d) the certificate(s) for the Shares, together with Assignment(s) Separate from Certificate, duly executed in blank;
  - (e) duly executed original Swiss Security Agreements;
- (f) evidence satisfactory to Collateral Agent and the Lenders that all notifications to the banks as required under the Swiss Bank Account Security Agreement have been served by the Parent and that all such notified banks have acknowledged in writing the Liens created under the Swiss Bank Account Security Agreement;
- (g) evidence satisfactory to Collateral Agent and the Lenders that all notifications from Parent to another Borrower with respect to any intercompany loans from Parent to another Borrower as required under the Swiss Receivables Security Agreement have been served by the Parent and that all such notified Borrowers have acknowledged the Liens created under the Swiss Receivables Security Agreement;
- (h) evidence satisfactory to Collateral Agent and the Lenders of the transfer of all original insurance policies pertaining to the insurance over which Liens are created under the Swiss Receivables Security Agreement to the Collateral Agent;
- (i) the Operating Documents and good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business, each as of a date no earlier than thirty (30) days prior to the Effective Date;

(k) the Annual Projections, for the current calendar year;

(l) duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;

(m) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement

a completed Perfection Certificate for Borrower and each of its Subsidiaries;

(j)

- (m) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;
- (n) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee in the United States where Borrower or any Subsidiary maintains Collateral having a book value in excess of Five Hundred Thousand Dollars (\$500,000.00);
  - (o) duly executed legal opinions of US counsel and Swiss counsel to Borrower, each dated as of the Effective Date;
- (p) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect; and
  - (q) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.
- **3.2 Conditions Precedent to all Credit Extensions.** The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:
  - (a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;
- (b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;
- (c) in such Lender's sole discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the Annual Projections of Borrower presented to and accepted by Collateral Agent and each Lender;
- (d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and
  - (e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.
- **3.3 Covenant to Deliver.** Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any

such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

**3.4 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon Eastern time five (5) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

#### 4. <u>CREATION OF SECURITY INTEREST</u>

**4.1 Grant of Security Interest.** Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code), greater than Fifty Thousand Dollars (\$50,000.00), Borrower shall promptly notify Collateral Agent in a writing signed by Borrower, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

- **4.2 Authorization to File Financing Statements.** Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.
- 4.3 Pledge of Collateral. Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within ten (10) days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the

Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

#### 5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

Due Organization, Authorization: Power and Authority. Borrower and each of its Subsidiaries is duly existing and in good standing (to the extent such concept exists in its jurisdiction of organization) as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each a "Perfection Certificate" and collectively, the "Perfection Certificates"). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries' exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower's and its Subsidiaries' organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower's and each of its Subsidiaries' place of business, or, if more than one, its chief executive office as well as Borrower's and each of its Subsidiaries' mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person's organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower's or such Subsidiaries' organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

#### 5.2 Collateral.

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in

connection herewith with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein to the extent required hereunder. The Accounts are bona fide, existing obligations of the Account Debtors.

- (b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of Five Hundred Thousand Dollars (\$500,000.00). None of the components of the Collateral valued in excess of Five Hundred Thousand Dollars (\$500,000.00) in the aggregate shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.
  - (c) All Inventory is in all material respects of good and marketable quality, free from material defects.
- (d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. (i) Each of Borrower's and its Subsidiaries' Patents is valid and enforceable and no part of Borrower's or its Subsidiaries' Intellectual Property has been judged invalid or unenforceable, in whole or in part, and (ii) to the best of Borrower's knowledge, no claim has been made that any part of the Intellectual Property or any practice by Borrower or its Subsidiaries violates the rights of any third party except to the extent such claim could not reasonably be expected to have a Material Adverse Change. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiaries' interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within ten (10) days of Borrower or any of its Subsidiaries entering into or becoming bound by any license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).
- **5.3 Litigation.** Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries which could reasonably be expected to result in damage or costs to Borrower or such Subsidiaries of Five Hundred Thousand Dollars (\$500,000.00) or more.
- **5.4 No Material Deterioration in Financial Condition; Financial Statements.** All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with IFRS, in all material respects, as of the dates and for the time periods presented therein, the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries since the date of the most recent financial statements submitted to any Lender.
  - **5.5 Solvency.** Borrower is Solvent, and Borrower and each of its Subsidiaries, on a consolidated basis, is Solvent.
- **5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable

laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

- **5.7 Investments.** Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.
- Tax Returns and Payments; Pension Contributions. Borrower and each of its Subsidiaries has timely filed (or timely filed extensions to file) all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all federal, and all material foreign, state, and local taxes, assessments, deposits and contributions owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless (a) such taxes are being contested in accordance with the following sentence, (b) in the case of foreign, state or local taxes, if such foreign, state or local taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Fifty Thousand Dollars (\$50,000.00) or (c) disclosed on the Perfection Certificate delivered on the Effective Date in an amount not to exceed Six Hundred Fifty Thousand Dollars (\$650,000.00). Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien." Except as disclosed on the Perfection Certificate delivered on the Effective Date, neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiaries', prior tax years which could result in additional taxes in excess of Fifty Thousand Dollars (\$50,000.00) becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid (or properly accrued on their respective balance sheets) the minimum required funding amounts to each present pension, profit sharing and funded deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries (other than liability for payment of benefits to plan participants in the ordinary course), including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority other than with respect to premiums required to be paid to such Governmental Authority under applicable law.
- **5.9 Use of Proceeds.** Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.
- **5.10 Shares.** Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

- **5.11 Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading in light of the circumstances under which such statements were made, after giving effect to all supplements and updates thereto from time to time permitted hereunder (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).
- **5.12 Definition of "Knowledge."** For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.
- **5.13 Non-Bank Rules**. Borrower represents and warrants that Parent is in compliance with the Non-Bank Rules, provided that the Parent shall not be in breach of this representation if its number of creditors in respect of either the 10 Non-Bank Rule or the 20 Non-Bank Rule is exceeded solely because a Lender having (a) made an incorrect declaration of its status as to whether or not it is a Qualifying Bank, or (b) ceased to be a Qualifying Bank other than as a result of any Change in Law after the date it became a Lender under this Agreement (for the avoidance of doubt, Borrower acknowledges and agrees that Oxford is not a Qualifying Bank). For the purpose of Borrower making the representation in this Section 5.13 regarding Parent's compliance with the 20 Non-Bank Rule, the number of Lenders under this Agreement which are not Qualifying Banks shall be deemed to be ten (irrespective of whether or not there are, at any time, any such Lenders) and Borrower assumes that the Lenders have complied with the assignment provisions in Section 12.1.

#### 6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

#### 6.1 Government Compliance.

- (a) Maintain its and all its Subsidiaries' legal existence and good standing (to the extent such concept exists in the relevant jurisdiction of organization) in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.
- (b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

#### 6.2 Financial Statements, Reports, Certificates.

- (a) Deliver to each Lender:
- (i) as soon as available, but no later than forty (40) days after the last day of each month, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Borrower and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;
- (ii) as soon as available, but no later than ninety (90) days after the last day of Borrower's fiscal year or within five (5) days of filing with the SEC, audited consolidated financial statements

Borrower's Board of Directors, which such ar originally delivered to Collateral Agent and to	as soon as available after approval thereof by Borrower's Board of Directors, but no later than sixty (60) is fiscal years, Borrower's annual financial projections for the entire current fiscal year as approved by smual financial projections shall be set forth in a month-by-month format (such annual financial projections as the Lenders are referred to herein as the "Annual Projections"; provided that, any revisions of the Annual of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) days after such
(iv) generally available to Borrower's security hole	within five (5) days of delivery, copies of all non-ministerial statements, reports and notices made ders or holders of Subordinated Debt;
(v) Act of 1934, as amended, within five (5) days	in the event that Borrower becomes subject to the reporting requirements under the Securities Exchange of filing, all reports on Form 20-F and 6-K filed with the Securities and Exchange Commission,
(vi)	prompt notice of any amendments to the Operating Documents of Borrower or any of its Subsidiaries.

prepared under IFRS, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting

firm acceptable to Collateral Agent in its reasonable discretion;

together with any copies reflecting such amendments or changes with respect thereto;

(vii)

registration of any copyright, including any subsequent ownership right of Borrower or any of its Subsidiaries in or to any copyright, patent or trademark, including a copy of any such registration, and (C) any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s), and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

prompt notice of (A) any material change in the composition of the Intellectual Property, (B) the

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

- (b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than forty (40) days after the last day of each month, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.
- (c) Keep proper books of record and account in accordance with IFRS in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once every year unless (and more frequently if) an Event of Default has occurred and is continuing.
- **6.3 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date. Borrower must

promptly notify Collateral Agent and the Lenders of all returns, recoveries, disputes and claims that involve more than Two Hundred Fifty Thousand Dollars (\$250,000.00) individually or in the aggregate in any calendar year.

- **6.4 Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof and in the case of state or local taxes, if such state or local taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed Fifty Thousand Dollars (\$50,000.00), and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments (or contested payments), and pay (or properly accrue on their respective balance sheets) the minimum required funding amounts to each present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.
- 6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days prior written notice before any such policy or policies shall be materially altered or canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to One Million Dollars (\$1,000,000.00) with respect to any loss, but not exceeding One Million Dollars (\$1,000,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

#### 6.6 Operating Accounts.

- (a) Maintain all of Borrower's Collateral Accounts, as disclosed in the Perfection Certificate delivered on the Effective Date; provided that, subject to the Post-Closing Letter, such Collateral Accounts (other than Excluded Accounts) are subject to a Control Agreement or other appropriate instrument in favor of Collateral Agent with respect to such Collateral Accounts to perfect Collateral Agent's Lien in such Collateral Accounts in accordance with the terms hereunder and provide Collateral Agent with the ability to assert control with respect thereto.
- (b) Borrower shall provide Collateral Agent five (5) days' prior written notice before Borrower or any of its Subsidiaries establishes any Collateral Account at or with any Person. If Borrower desires to establish a Collateral Account with any bank or financial institution that is not disclosed in the Perfection Certificate delivered on the Effective Date, such Person shall be acceptable to Collateral Agent in its reasonable discretion. In addition, for each Collateral Account that Borrower or any of its Subsidiaries, at any time maintains, Borrower or such Subsidiary shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument in favor of Collateral Agent with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder and provide Collateral Agent with the ability to assert control with respect thereto prior to the establishment

of such Collateral Account, which Control Agreement or other appropriate instrument may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to Excluded Accounts.

- (c) Borrower shall not maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).
- **Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly upon becoming aware, advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent. If Borrower or any of its Subsidiaries (i) obtains any patent, registered trademark or servicemark, registered copyright, registered mask work, or any pending application for any of the foregoing, whether as owner, licensee or otherwise, or (ii) applies for any patent or the registration of any trademark or servicemark, then Borrower or such Subsidiary shall provide notice thereof to Collateral Agent in the next succeeding Compliance Certificate required to be delivered by Section 6.2(b) and each Lender and shall execute such intellectual property security agreements and other documents and take such other actions as Collateral Agent shall reasonably request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Collateral Agent, for the ratable benefit of the Lenders, in such property. If Borrower or any of its Subsidiaries decides to register any copyrights or mask works in the United States Copyright Office, Borrower or such Subsidiary shall: (x) provide Collateral Agent and each Lender with at least fifteen (15) days prior written notice of Borrower's or such Subsidiary's intent to register such copyrights or mask works together with a copy of the application it intends to file with the United States Copyright Office (excluding exhibits thereto); (y) execute an intellectual property security agreement and such other documents and take such other actions as Collateral Agent may reasonably request in its good faith business judgment to perfect and maintain a first priority perfected security interest in favor of Collateral Agent, for the ratable benefit of the Lenders, in the copyrights or mask works intended to be registered with the United States Copyright Office; and (z) record such intellectual property security agreement with the United States Copyright Office contemporaneously with filing the copyright or mask work application(s) with the United States Copyright Office. Borrower or such Subsidiary shall promptly provide to Collateral Agent and each Lender with evidence of the recording of the intellectual property security agreement necessary for Collateral Agent to perfect and maintain a first priority perfected security interest in such property.
- **6.8 Litigation Cooperation.** Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.
- **6.9 Notices of Litigation and Default.** Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Five Hundred Thousand Dollars (\$500,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within three (3) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.
- **6.10 Financial Covenant.** From and after the Funding Date on which the aggregate original principal amount of Term Loans funded by Lenders (without regard to the outstanding principal amount of such Term Loans), exceeds [\*\*\*] and until the Financial Covenant Termination Milestone, Borrower shall maintain not less than [\*\*\*] in cash in Collateral Accounts subject to a Control Agreement in favor of Collateral Agent.

- **6.11 Landlord Waivers; Bailee Waivers.** In the event that Borrower, after the Effective Date, intends to add any new offices or business locations (other than in Switzerland), including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower will, in the event that the new location is the chief executive office of the Borrower or such Subsidiary or the Collateral at any such new location is valued in excess of Five Hundred Thousand (\$500,000.00) in the aggregate first receive the written consent of the Collateral Agent, and deliver a bailee waiver or landlord waiver executed by such bailee or landlord, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.
- **6.12 Creation/Acquisition of Subsidiaries.** In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares of each such newly created or acquired Subsidiary.

#### 6.13 Further Assurances.

- (a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.
- (b) Deliver to Collateral Agent and Lenders, within five (5) days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.
- **6.14 Non-Bank Rules.** Comply with the Non-Bank Rules, provided that Borrower shall not be in breach of this undertaking if the number of creditors of the Parent in respect of either the 10 Non-Bank Rule or the 20 Non-Bank Rule is exceeded solely because a Lender having (a) made an incorrect declaration of its status as to whether or not it is a Qualifying Bank or (b) ceased to be a Qualifying Bank other than as a result of any Change in Law after the date it became a Lender under this Agreement (for the avoidance of doubt, Borrower acknowledges and agrees that Oxford is not a Qualifying Bank). For the purpose of determining compliance by Borrower with the 20 Non-Bank Rule under this Section 6.14, the number of Lenders under this Agreement which are not Qualifying Banks shall be deemed to be ten (irrespective of whether or not there are, at any time, any such Lenders) and Borrower assumes that the Lenders have complied with the assignment provisions in Section 12.1.

#### 7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

**7.1 Dispositions.** Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) Transfers between Borrowers or from any Subsidiary of Borrower to Borrower; (e) payments of taxes and other dispositions and uses of cash and Cash Equivalents (i) in connection with transactions that (A) are approved by Borrower's Board (to the extent Board approval is required by Borrower's policies or other organizational documents), (B) are in the ordinary course of business, and (C) not otherwise prohibited hereunder; and (f) other Transfers of property (but excluding Intellectual Property (other than any disposition of Intellectual Property not prohibited by Section 6.7) having a book value not exceeding Two Hundred Fifty Thousand Dollars (\$250,000.00) during any fiscal year.

- Changes in Business, Management, Ownership, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within five (5) days of such change, or (ii) any Person or two or more Persons acting in concert shall have acquired beneficial ownership, directly or indirectly, of, or shall have acquired by contract or otherwise, control over the voting stock of the Parent representing forty-nine percent (49%) or more of the combined voting power of all voting stock of the Parent, or (iii) Parent ceases to own all of the voting stock of ObsEva USA or ObsEva Ireland. Borrower shall not, without at least thirty (30) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (ii) contain less than Five Hundred Thousand Dollars (\$500,000.00) in assets or property of Borrower and (ii) are not Borrower's chief executive office); (B) change its chief executive office; (C) change its jurisdiction of organization, (D) change its organizational structure or type, (E) change its legal name, or (F) change any organizational number (if any) assigned by its jurisdiction of organization.
- **7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person, other than Permitted Acquisitions. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom. Without limiting the foregoing, Borrower shall not, without Collateral Agent's prior written consent, enter into any binding contractual arrangement with any Person to attempt to facilitate a merger or acquisition of Borrower, unless (i) no Event of Default exists when such agreement is entered into by Borrower, (ii) Borrower notifies Collateral Agent in advance of entering into such an agreement, and (iii) such agreement provides that the Obligations will be repaid in full concurrently with the closing of the transactions contemplated by such agreement.
- **7.4 Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.
- 7.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" herein.
  - **7.6 Maintenance of Collateral Accounts.** Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.
- **7.7 Distributions; Investments.** (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock (other than (i) repurchases pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans, provided such repurchases do not exceed One Hundred Thousand Dollars (\$100,000.00) in the aggregate per fiscal year, (ii) dividends or distributions amongst the Borrowers or by any Subsidiary of Borrower to Borrower) and (iii) in accordance with Borrower's historical business practice, purchases by Borrower consisting of subscriptions for capital stock of Parent or options to acquire capital stock of Parent at par value for the purpose of acquiring treasury stock in connection with a substantially concurrent issuance, or in anticipation of an issuance, of capital stock or convertible securities, provided that such purchases by Borrower do not exceed Fifty Thousand Dollars (\$50,000) in the aggregate for any one transaction or series of related transactions in any fiscal year, or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

- **7.8 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries and (c) transactions between the Borrowers expressly permitted by the terms of this Agreement.
- **7.9 Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof, except in accordance with the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or adversely affect the subordination thereof to Obligations owed to the Lenders.
- **7.10 Compliance.** Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any material liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.
- 7.11 Compliance with Anti-Terrorism Laws. Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.
- **7.12 Assets in ObsEva Ireland**. Transfer to, license to or permit ObsEva Ireland to hold or maintain, at any time prior to ObsEva Ireland becoming a Borrower hereunder, (a) any Intellectual Property or (b) any other assets having an aggregate value in excess of Fifty Thousand Dollars (\$50,000.00).

#### 8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "Event of Default") under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or

the date of acceleration pursuant to Section 9.1 (a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

#### 8.2 Covenant Default.

- (a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (notice of Litigation and Default), 6.10 (Financial Covenant), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or
- (b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within ten (10) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the ten (10) day period or cannot after diligent attempts by Borrower be cured within such ten (10) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;
  - **8.3 Material Adverse Change.** A Material Adverse Change occurs;

#### 8.4 Attachment; Levy; Restraint on Business.

- (a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender's Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and
- (b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business:
- **8.5 Insolvency.** (a) Borrower or any of its Subsidiaries is or becomes Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);
- **8.6 Other Agreements.** There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Five Hundred Thousand Dollars (\$500,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Collateral Agent has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified

or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower or any Guarantor;

- **8.7 Judgments.** One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars (\$500,000.00) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);
- **8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;
- **8.9 Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;
- **8.10 Guaranty.** (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the liquidation, winding up, or termination of existence of any Guarantor;
- **8.11 Governmental Approvals.** Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or
- **8.12 Lien Priority.** Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement.
- **8.13 Delisting.** The shares of common stock of Borrower are delisted from the NASDAQ Global Select Market because of failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed on any other nationally recognized stock exchange in the United States having listing standards at least as restrictive as the NASDAQ Global Select Market.

#### 9. RIGHTS AND REMEDIES

#### **9.1** Rights and Remedies.

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right at the written direction of the Required Lenders, without notice or demand, to do any or all of the following:		
	(i)	foreclose upon and/or sell or otherwise liquidate, the Collateral;
holds or controls, or (b) any amou	(ii) ınt held or o	apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or
Proceeding.	(iii)	commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency
(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:		
that Collateral Agent considers a	(i) dvisable, n	settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order orify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the

amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred.

Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

- (v) demand and receive possession of Borrower's Books;
- (vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written

consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "Exigent Circumstance" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

- **9.2 Power of Attorney.** Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.
- **9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.
- Application of Payments and Proceeds. Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable

distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

- **9.5 Liability for Collateral.** So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.
- 9.6 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.
- **9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.
- **9.8 Representation of Lenders by Collateral Agent.** In relation to any Swiss Security Agreements under which security of an accessory nature (*akzessorische Sicherheit*) is granted (the "Swiss Accessory Security Agreements"), each present and future Lender hereby appoints and authorizes the Collateral Agent for the benefit of the Lenders to, with respect to such security of an accessory nature (*akzessorische Sicherheit*), take all action and exercise all powers and discretion in the name and for the account of such Lender as its direct representative (*direkter Stellvertreter*), including, without limitation, (i) to sign the relevant Swiss Accessory Security Agreements in its name, (ii) to accept, hold, administer and, if necessary, enforce the security granted under any of the Swiss Accessory Security Agreements, (iii) to agree to amendments, restatements and other alterations of the Swiss Accessory Security Agreements, (iv) to effect any release of the security under, and the termination of, any Swiss Accessory Security Agreements, and (v) to exercise such other rights, powers, authorities and discretions granted to the Collateral Agent hereunder or under the relevant Swiss Accessory Security Agreements. In relation to any Swiss Security Agreements under which security of an non-accessory nature (*nicht-akzessorische Sicherheit*) is granted, each present and future Lender hereby appoints and authorizes the Collateral Agent for the benefit of the Lenders to, with respect to such security of an non-accessory nature (*nicht-akzessorische Sicherheit*), take all action and exercise all powers and discretion in the name of the Collateral Agent but for the account of such Lender as its indirect representative (*indirekter Stellvertreter*).

- **9.9 Creation of Parallel Obligations.** For the purposes of creating the Swiss Security Agreements, and ensuring the initial and continued validity of such Swiss Security Agreements, the Lenders, agree that, notwithstanding anything to the contrary contained in this Agreement or the Loan Documents:
- (a) Borrower shall pay to the Collateral Agent, as creditor in its own right and not as representative of any Lender, sums equal to, and in the currency of, its Obligations as and when the same fall due for payment under the Loan Documents (the "Parallel Obligations"); provided that the total amount of the Parallel Obligations shall never exceed the total amount of the Obligations;
- (b) the rights of the Lenders (other than the Collateral Agent) to receive payment of the Obligations are several and are separate from, and without prejudice to, the rights of the Collateral Agent to receive payment in respect of the Parallel Obligations;
- (c) the Collateral Agent shall have its own independent right, in its own name and stead, to demand payment of the Parallel Obligations upon the occurrence and during the continuance of an Event of Default;
- (d) the payment by Borrower of its Parallel Obligations to the Collateral Agent in accordance with this Section 9.9 (whether through direct payment by Borrower or any Lien held by the Collateral Agent securing the Parallel Obligations) shall be a good discharge in the corresponding amount of the corresponding Obligations and, similarly, the payment by Borrower of the Obligations shall be a good discharge in the corresponding amount of the corresponding Parallel Obligations owed to the Collateral Agent under this Section 9.9;
- (e) the increase of the Obligations of any Lender shall result in the increase of a corresponding amount of the corresponding Parallel Obligations to the Collateral Agent under this Section 9.9;
- (f) a Parallel Obligation is independent from, and without prejudice to, its Obligations, and shall be deemed to constitute a single obligation of Borrower to the Collateral Agent and an independent and separate claim of the Collateral Agent to receive payment of such Parallel Obligation (in its capacity as the independent and separate creditor under such Parallel Obligation and not as co-creditor in respect of the Obligations); and
- (g) nothing in this Section 9.9 shall in any way limit the Collateral Agent's right to act in the protection or preservation of, the rights under, or to enforce any, Loan Document as contemplated by this Agreement or the relevant Loan Document.

Despite the foregoing, any payment on the Parallel Obligations by Borrower shall be made to or to the order of the Collateral Agent, unless the Collateral Agent directs Borrower in writing to make such payment to any Lender thereof. Nothing in this Section 9.9 shall in any way negate or affect the obligations which Borrower has to the Lenders under this Agreement or the Loan Documents. For the purpose of this Section 9.9, the Collateral Agent acts in its own name and on behalf of itself and not as agent or representative of any Lender or as agent and the security interests granted within the Swiss Security Agreements to the Collateral Agent to secure the Parallel Obligations is granted to the Collateral Agent in its capacity as creditor in respect of the Parallel Obligations (or to do any act reasonably incidental to any of the foregoing).

### 10. <u>NOTICES</u>

All notices, consents, requests, approvals, demands, or other communication (collectively, "Communication") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower: OBSEVA USA, INC.

1 Financial Center

24th Floor

Boston, MA 02111

Attn: Tim Adams, Chief Financial Officer

Email: tim.adams@obseva.com

with a copy to:

OBSEVA SA

chemin des Aulx, 12, 1228 Plan-les-Ouates

Switzerland

Attn: Fabien de Ladonchamps, Vice President Corporate Affairs and

Finance

Email: fabien. deladon champs @obseva.ch

with a copy (which shall not constitute notice) to:

COOLEY LLP 299 Pennsylvania Avenue, NW, Suite 700

Washington, DC 20004-2400

Attn: Jonathan Bagg Fax: (202) 842-7899 Email: jbagg@cooley.com

If to Collateral Agent: OXFORD FINANCE LLC

133 North Fairfax Street Alexandria, Virginia 22314 Attention: Legal Department

Fax: (703) 519-5225

Email: Legal Department@oxford finance.com

with a copy (which shall not constitute notice) to:

DLA PIPER LLP (US) 500 8th Street, NW Washington, DC 20004 Attn: Eric Eisenberg Fax: (202) 799-5211

Email: eric.eisenberg@dlapiper.com

### 11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

The Loan Documents, with the exception of the Swiss Security Agreements, are governed by New York law without regard to principles of conflicts of law. Borrower, Lenders and Collateral Agent each submit to the exclusive jurisdiction of the State and Federal courts in the City of New York, Borough of Manhattan. NOTWITHSTANDING THE FOREGOING, COLLATERAL AGENT AND THE LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH COLLATERAL AGENT AND THE LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 9.1) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE COLLATERAL AGENT'S AND THE LENDERS' RIGHTS AGAINST BORROWER OR ITS PROPERTY. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3)

days after deposit in the U.S. mails, first class, registered or certified mail return receipt requested, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT, AND THE LENDERS EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

#### 12. GENERAL PROVISIONS

- Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower (except as otherwise provided in this Section 12.1), to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "Lender Transfer") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; provided, however, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee that would not cause a violation of the 10 Non-Bank Rule) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of (i) the Required Lenders and (ii) unless an Event of Default has occurred, the Parent to the extent such Lender Transfer would result in a breach of the 10 Non-Bank Rule (such approved assignee, an "Approved Lender"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require (an "Effective Assignment"), and the Lenders shall give the Parent prior written notice of such proposed Effective Assignment so that Borrower can assess whether such Lender Transfer may result in a breach of the 10 Non-Bank Rule by Borrower. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.
- 12.2 Indemnification. Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "Indemnified Person") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "Claims") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders' Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person's gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred

by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person's gross negligence or willful misconduct.

- **12.3 Time of Essence.** Time is of the essence for the performance of all Obligations in this Agreement.
- **12.4 Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.
- **12.5 Correction of Loan Documents.** Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.
- **12.6 Amendments in Writing; Integration.** No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:
- (i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender's written consent;
- (ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature;
- no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;
- (iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

- (b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.
- (c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.
- **12.7 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.
- **12.8 Survival.** All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.
- 12.9 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.
- **12.10 Right of Set Off.** Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

- **12.11 Cooperation of Borrower.** If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing) during reasonable business hours and upon reasonable prior written notice, and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower prior to entering into this Agreement.
- 12.12 Borrower Liability. Either Borrower may, acting singly, request Credit Extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting Credit Extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all Credit Extensions made hereunder, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

#### 13. **DEFINITIONS**

- **13.1 Definitions.** As used in this Agreement, the following terms have the following meanings:
- "10 Non-Bank Rule" means the rule that the aggregate number of creditors of the Parent under this Agreement which are not Qualifying Banks must not at any time exceed ten (10), all in accordance with the meaning of the Guidelines or legislation or explanatory notes addressing the same issues that are in force at such time.
- "20 Non-Bank Rule" means the rule that the aggregate number of creditors (including the Lenders), other than Qualifying Banks, of the Parent under all its outstanding debts relevant for classification as debenture (*Kassenobligation*) must not at any time exceed twenty (20), all in accordance with the meaning of the Guidelines or legislation or explanatory notes addressing the same issues that are in force at such time.
- "Account" is any "account" as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.
  - "Account Debtor" is any "account debtor" as defined in the Code with such additions to such term as may hereafter be made.

- "Affiliate" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person's managers and members.
  - "Agreement" is defined in the preamble hereof.
  - "Amortization Date" is September 1, 2022.
  - "Annual Projections" is defined in Section 6.2(a).
- "Anti-Terrorism Laws" are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.
- "Approved Fund" is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.
  - "Approved Lender" is defined in Section 12.1.
- "Basic Rate" is the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the sum of (a) the greater of (i) thirty (30) day U.S. LIBOR rate (the "Index Rate") reported in The Wall Street Journal on the last Business Day of the month that immediately precedes the month in which the interest will accrue and (ii) [\*\*\*], plus (b) [\*\*\*]. Notwithstanding the foregoing, (i) the Basic Rate for the Term Loans for the period from the Effective Date through and including August 31, 2019 shall be [\*\*\*], (ii) subject to clause (iii), the Index Rate for an individual Term Loan shall not reset more than one and one-half percent (1.50%) above the percentage that was the Index Rate on the Funding Date of such Term Loan, and (iii) in no event shall the Basic Rate for any Term Loan be less than [\*\*\*]. If The Wall Street Journal (or another nationally recognized rate reporting source acceptable to Collateral Agent) no longer reports the Index Rate or if such interest rate no longer exists or if The Wall Street Journal no longer publishes the Index Rate or ceases to exist, Collateral Agent may in good faith, and with reference to the margin above such interest rate in this definition, select a replacement interest rate and replacement margin above such interest rate floor and total rate in effect immediately prior to the effectiveness of such replacement interest rate and replacement publication, as the case may be, and shall notify Borrower of such replacement interest rate and replacement margin or replacement publication.
- "Blocked Person" is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports "terrorism" as defined in Executive Order No. 13224, or (e) a Person that is named a "specially designated national" or "blocked person" on the most current list published by OFAC or other similar list.

"Borrower" is defined in the preamble hereof.

"Borrower's Books" are Borrower's or any of its Subsidiaries' books and records including ledgers, federal, and state tax returns, records regarding Borrower's or its Subsidiaries' assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"Business Day" is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

"Cash Equivalents" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement or similar agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an "Auction Rate Security").

"Change in Law" means the occurrence, after the Effective Date (or with respect to any Lender, if later, the date on which such Lender becomes a Lender), of any of the following: (a) the adoption or taking effect of any law, rule, regulation or treaty, (b) any change in any law, rule, regulation or treaty or in the administration, interpretation, implementation or application thereof by any Governmental Authority or (c) the making or issuance of any request, rule, guideline or directive (whether or not having the force of law) by any Governmental Authority

"Claims" are defined in Section 12.2.

"Code" is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent's Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term "Code" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

"Collateral" is any and all properties, rights and assets of Borrower described on Exhibit A.

"Collateral Account" is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower at any time.

"Collateral Agent" is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

"Commitment Percentage" is set forth in  $\underline{Schedule~1.1}$ , as amended from time to time.

"Commodity Account" is any "commodity account" as defined in the Code with such additions to such term as may hereafter be made.

"Communication" is defined in Section 10.

"Compliance Certificate" is that certain certificate in the form attached hereto as Exhibit C.

"Contingent Obligation" is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"Control Agreement" is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

"Copyrights" are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"Credit Extension" is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower's benefit.

"Default Rate" is defined in Section 2.3(b).

"Deposit Account" is any "deposit account" as defined in the Code with such additions to such term as may hereafter be made.

"Designated Deposit Account" is Borrower's deposit account, account number ending in 0239, maintained with Silicon Valley Bank.

"Disbursement Letter" is that certain form attached hereto as Exhibit B.

"Dollars," "dollars" and "\$" each mean lawful money of the United States.

"Effective Date" is defined in the preamble of this Agreement.

securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

**"Equipment"** is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"ERISA" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"Excluded Accounts" are (a) deposit accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates delivered on the Effective Date, and (b) the deposit accounts (i) with the account numbers ending in [\*\*\*] at Credit Suisse providing cash collateral to certain lessors, and (ii) ending in [\*\*\*] at Silicon Valley Bank providing cash collateral to Silicon Valley Bank for a letter of credit provided by Silicon Valley Bank to the landlord for ObsEva USA's leased office space at 1 Financial Center, 24th Floor, Boston, Massachusetts, provided that the aggregate amount in all such accounts in respect of this clause (b) does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time.

"Event of Default" is defined in Section 8.

"Facility Fee" is defined in Section 2.5(a).

"**Final Payment**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares.

"Final Payment Percentage" is [\*\*\*].

"Financial Covenant Termination Milestone" means [\*\*\*].

"Foreign Subsidiary" is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

"Funding Date" is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

"General Intangibles" are all "general intangibles" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

- "Governmental Approval" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.
- "Governmental Authority" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.
  - "Guarantor" is any Person providing a Guaranty in favor of Collateral Agent.
- "Guaranty" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.
- "Guidelines" means, together, guideline S-02.123 in relation to interbank loans of 22 September 1986 (Merkblatt "Verrechnungssteuer auf Zinsen von Bankguthaben, deren Gläubiger Banken sind (Interbankguthaben)" vom 22. September 1986), circular letter No. 47 of 25 July 2019 (1-047-V-2019) in relation to bonds (Kreisschreiben Nr. 47 "Obligationen" vom 25. Juli 2019), guideline S-02.130.1 in relation to money market instruments and book claims of April 1999 (Merkblatt vom April 1999 betreffend Geldmarktpapiere und Buchforderungen inländischer Schuldner), circular letter No. 46 of 24 July 2019 (1-046-VS-2019) in relation to syndicated credit facilities (Kreisschreiben Nr. 46 "Steuerliche Behandlung von Konsortialdarlehen, Schuldscheindarlehen, Wechseln und Unterbeteiligungen" vom 24. Juli 2019), circular letter No. 34 of 26 July 2011 (1-034-V-2011) in relation to deposits (Kreisschreiben Nr. 34 "Kundenguthaben" vom 26. Juli 2011) and the circular letter No. 15 of 3 October 2017 (1-015-DVS-2017) in relation to bonds and derivative financial instruments as subject matter of taxation of Swiss federal income tax, Swiss Anticipatory Tax and Swiss stamp taxes (Kreisschreiben Nr. 15 "Obligationen und derivative Finanzinstrumente als Gegenstand der direkten Bundessteuer, der Verrechnungssteuer und der Stempelabgaben" vom 3. Oktober 2017), in each case as issued, amended or replaced from time to time, by the Swiss Federal Tax Administration or as substituted or superseded and overruled by any law, statute, ordinance, court decision, regulation or the like as in force from time to time.
  - "IFRS" is the International Financial Reporting Standards as issued by the International Accounting Standards Board.
- "**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.
  - "Indemnified Person" is defined in Section 12.2.
- "Insolvency Proceeding" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.
  - "Insolvent" means not Solvent.
  - "Intellectual Property" means all of Borrower's or any Subsidiary's right, title and interest in and to the following:
    - (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;
  - (c) any and all source code;

- (d) any and all design rights which may be available to Borrower;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
  - (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

"Inventory" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"Investment" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

"IP Agreement" is that certain Intellectual Property Security Agreement entered into by and between Borrower and Collateral Agent dated as of the Effective Date, as such may be amended from time to time.

"Key Person" is each of Parent's (i) Chief Executive Officer, who is Ernest Loumaye as of the Effective Date, (ii) Chief Financial Officer, who is Tim Adams as of the Effective Date, (iii) Chief Commercial Officer, who is Wim Souverijns as of the Effective Date, and (iv) Chief Scientific Officer, who is Jean-Pierre Gotteland as of the Effective Date.

"Lender" is any one of the Lenders.

"Lenders" are the Persons identified on <u>Schedule 1.1</u> hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

"Lenders' Expenses" are all audit fees and expenses, costs, and expenses (including reasonable and documented attorneys' fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

"Lien" is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"Loan Documents" are, collectively, this Agreement, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the Post Closing Letter, the Swiss Security Agreements, each IP Agreement, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

"Material Adverse Change" is (a) a material impairment in the perfection or priority of Collateral Agent's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"Maturity Date" is, for each Term Loan, August 1, 2024.

"Non-Bank Rules" means, together, the 10 Non-Bank Rule and the 20 Non-Bank Rule.

"Obligations" are all of Borrower's obligations to pay when due any debts, principal, interest, Lenders' Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents.

"ObsEva Ireland" is ObsEva Ireland Ltd., a wholly owned Subsidiary of Parent organized under the laws of Ireland.

"OFAC" is the U.S. Department of Treasury Office of Foreign Assets Control.

"OFAC Lists" are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

"Operating Documents" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"Parallel Obligations" is defined in Section 9.9.

"Patents" means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Payment Date" is the first (1st) calendar day of each calendar month, commencing on September 1, 2019.

"Perfection Certificate" and "Perfection Certificates" is defined in Section 5.1.

"**Permitted Acquisition**" means an acquisition pursuant to which Borrower acquires a Person or an ownership interest in a Person through either (i) the payment of cash consideration or no more than Five Hundred Thousand Dollars (\$500,000.00) with respect to any one acquisition and in the aggregate in each fiscal year, or (ii) the issuance of Borrower's capital stock, so long as the number of shares or the voting power of Borrower's capital stock issued with respect to any one Person is less than twenty percent (20%) of the total shares or voting power of Borrower's capital stock outstanding before the issuance, to the extent that each of the following conditions shall have been satisfied:

- (a) immediately prior to, and after giving effect thereto, no Event of Default shall have occurred and be continuing or would result therefrom;
  - (b) all transactions in connection therewith shall be consummated, in all material respects, in accordance with applicable law;
- (c) such acquired Person or assets shall be in the same line of business as is conducted by Borrower as of the Effective Date (or a line of business reasonably related thereto);
- (d) such acquisition shall not cause the focus or locations of Borrower's and its Subsidiaries' operations (when taken as a whole) to be located outside of either Switzerland or the United States;

- (e) in the case of the purchase or other acquisition of Shares, all of the Shares acquired or otherwise issued by such Person or any newly formed Subsidiary in connection with such acquisition shall be wholly owned by Borrower or a Subsidiary;
- (f) in connection with such acquisition, neither Borrower nor any of its Subsidiaries (including for this purpose, the target of the acquisition) shall acquire or be subject to any Indebtedness or Liens that are not otherwise permitted hereunder;
- (g) Borrower shall have delivered to the Collateral Agent and Lenders at least five (5) Business Days (or such shorter period as may be acceptable to Collateral Agent and Lenders) prior to such proposed acquisition (i) a copy of the purchase agreement related to the proposed acquisition (and any related documents reasonably requested by the Collateral Agent and Lenders), (ii) a general description of the acquired assets or acquired business line or unit or division and the competitive position of such business line or unit or division within the industry, (iii) the sources and uses of funds to finance the proposed acquisition, and (iv) to the extent available, quarterly and annual audited financial statements of the Person whose Shares or assets are being acquired for the twelve (12) month period immediately prior to such proposed acquisition;
  - (h) such Permitted Acquisition shall only involve assets located in Switzerland and/or in the United States;
- (i) Collateral Agent and the Lenders have received a certificate from a Responsible Officer together with Board approved projections certifying and setting forth in reasonable detail that Borrower has enough cash on hand to pay its projected expenses and all debt service when due for a period of fifteen (15) months after the consummation of such transaction (after giving effect to such transaction); and
  - (j) such Permitted Acquisition shall be consensual and shall have been approved by the target's board of directors.

Notwithstanding anything to the contrary contained herein, in order for any acquisition of Shares or assets of another Person to constitute a Permitted Acquisition, Borrower must comply with all of the following: (a) within five (5) Business Days of the closing of such Permitted Acquisition, the applicable Borrower (or Subsidiary) making such Permitted Acquisition and the target shall have executed such documents and taken such actions as may be required under Section 6.12; (b) the applicable Borrower shall have delivered to Collateral Agent and Lenders, in form and substance satisfactory to the Collateral Agent and Lenders and sufficiently in advance (and in any case no later than five (5) Business Days prior to such Permitted Acquisition), such other financial information, financial analysis, documentation or other information relating to such Permitted Acquisition and the pro forma certifications required by clause (c) below, in each case, as Collateral Agent and Lenders shall reasonably request; (c) on or prior to the date of such Permitted Acquisition, the Collateral Agent and Lenders shall have received, in form and substance reasonably satisfactory to the Collateral Agent and Lenders, a certificate of the chief financial officer of Borrower certifying compliance with the requirements contained in this definition of "Permitted Acquisition" and with the other terms of the Loan Documents (before and after giving effect to such Permitted Acquisition); and (d) Borrower shall provide to the Collateral Agent and Lenders as soon as available but in any event not later than five (5) Business Days after the execution thereof, a copy of the executed purchase agreement or similar agreement with respect to any such acquisition.

#### "Permitted Indebtedness" is:

- (a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;
- (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s);
- (c) Subordinated Debt;
- (d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness consisting of capitalized lease obligations are capitalized lease obligations.	-
Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital ass	
(i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollar	s (\$500,000.00) at any time and
(ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the propert	y so acquired or built or of such
repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvements	ent or construction is made);
(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the	e ordinary course of Borrower's
business;	

- (g) Indebtedness pursuant to intercompany loans owing from a Borrower to another Borrower; and
- (h) Indebtedness incurred in the ordinary course of business with corporate credit cards or merchant services issued for the account of Borrower or any Subsidiary in an aggregate amount not to exceed Five Hundred Thousand Dollars (\$500,000.00) at any time;
- (i) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect Borrower or a Subsidiary against fluctuation in interest rates, currency exchange rates or commodity prices in an amount not to exceed One Hundred Thousand Dollars (\$100,000.00) at any time;
- (j) Indebtedness relating to the financing of insurance premiums in an amount not to exceed One Hundred Thousand Dollars (\$100,000.00) at any time;
- (k) Indebtedness in respect of letters of credit, bank guarantees and similar instruments issued for the account of Borrower or any Subsidiary in the ordinary course of business in an aggregate amount not to exceed Five Hundred Thousand Dollars (\$500,000.00) at any time;
- (l) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (k) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be; and
  - (o) other unsecured Indebtedness not to exceed Five Hundred Thousand Dollars (\$500,000.00) at any time.

#### "Permitted Investments" are:

- (m) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;
- (n) (i) Investments consisting of cash and Cash Equivalents, and (ii) any other Investments permitted by Borrower's investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;
- (o) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;
- (p) Investments consisting of deposit accounts in which Collateral Agent has a perfected security interest to the extent required by this Agreement;
  - (q) Investments in connection with Transfers permitted by Section 7.1;

- (r) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors; not to exceed Two Hundred Thousand Dollars (\$200,000.00) in the aggregate for (i) and (ii) in any fiscal year;
- (s) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;
- (t) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (h) shall not apply to Investments of Borrower in any Subsidiary;
- (u) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology, the development of technology or the providing of technical support;
- (v) Investments (i) by Borrower in a Subsidiary that is a co-Borrower and (ii) by Subsidiaries in Borrower or in a Subsidiary that is a co-Borrower;
- (k) the formation of new Subsidiaries after the Effective Date, subject to compliance with all applicable provisions of this Agreement, including, without limitation, Section 6.12; and
  - (l) Other Investments not to exceed Five Hundred Thousand Dollars (\$500,000.00) in any fiscal year.

"Permitted Licenses" are (A) licenses of over-the-counter software that is commercially available to the public, (B) non-exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; and (iii) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement or similar agreement, and (C) an exclusive license for nolasiban, provided, that (i) Borrower delivers five (5) Business Days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, (ii) such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and shall be exclusive as to territory only as to China; (iii) such licensing agreement provides at least Seven Million Five Hundred Thousand Dollars (\$7,500,000.00) in upfront net proceeds to Borrower, and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement or similar ag

### "Permitted Liens" are:

- (w) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;
- (x) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

- (y) liens securing Indebtedness permitted under clause (e) of the definition of "**Permitted Indebtedness**," provided that (i) such liens exist prior to the acquisition of, or attach substantially simultaneous with, or within twenty (20) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;
- (z) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed One Hundred Thousand Dollars (\$100,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;
- (aa) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);
- (bb) Liens incurred in the extension, renewal or refinancing of the indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase;
- (cc) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;
- (dd) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;
- (ee) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7; and
  - (ff) Liens consisting of Permitted Licenses.

"Person" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"Post Closing Letter" is that certain Post Closing Letter dated as of the Effective Date by and between Collateral Agent and Borrower.

"**Prepayment Fee**" is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

[\*\*\*]

"Pro Rata Share" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

#### "Qualifying Bank" means:

- (i) any bank as defined in the Swiss Federal Act for Banks and Savings Banks dated 8 November 1934 (Bundesgesetz über die Banken und Sparkassen); or
- (ii) a person or entity which effectively conducts banking activities with its own infrastructure and staff as its principal purpose and which has a banking license in full force and effect issued in accordance with the banking laws in force in its jurisdiction of incorporation, or if acting through a branch, issued in accordance with the banking laws in the jurisdiction of such branch, all and in each case within the meaning of the Guidelines.
  - "Registered Organization" is any "registered organization" as defined in the Code with such additions to such term as may hereafter be made.
- "Required Lenders" means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an "Original Lender") have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender's interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.
- "Requirement of Law" is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.
  - "Responsible Officer" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.
- "Second Draw Period" is the period (i) commencing on the later of (y) December 1, 2019 if the Borrower has achieved both the Term B Milestone I and Term B Milestone II on or prior to December 1, 2019, and (z) such later date if the Borrower has achieved both the Term B Milestone I and Term B Milestone II by such date (but in no event later than January 31, 2020), and (ii) ending on the earlier of (y) January 31, 2020 and (z) the occurrence of an Event of Default that is existing at the time of the request for the Term B Loan; provided, however, that the Second Draw Period shall not commence if on the date of the occurrence of the Term B Milestone II or the Term B Milestone II an Event of Default has occurred and is continuing.
  - "Secured Promissory Note" is defined in Section 2.4.
- "Secured Promissory Note Record" is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.
  - "Securities Account" is any "securities account" as defined in the Code with such additions to such term as may hereafter be made.
- "Shares" is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower's Subsidiary, in any Subsidiary.
- "Solvent" is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with

unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

"Subordinated Debt" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

"Subsidiary" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries.

"Swiss Accessory Security Agreements" is defined in Section 9.8 hereof.

"Swiss Anticipatory Tax" means the Tax imposed based on the Swiss Federal Act on withholding tax of 13 October 1965.

"Swiss Bank Account Security Agreement" is that certain Swiss Bank Account Security Agreement entered into by and between Parent and Collateral Agent dated as of the Effective Date relating to the granting of a pledge over certain Collateral Accounts of the Parent, as such may be amended from time to time.

"Swiss IP Security Agreement" is that certain Swiss IP Security Agreement entered into by and between Parent and Collateral Agent dated as of the Effective Date relating to the granting of a pledge over certain intellectual property rights of the Parent, as such may be amended from time to time.

"Swiss Receivables Security Agreement" is that certain Swiss Receivables Security Agreement entered into by and between Parent and Collateral Agent dated as of the Effective Date relating to the granting of an assignment for security purposes of certain insurance claims, intragroup receivables and trade receivables of the Parent, as such may be amended from time to time.

"Swiss Security Agreements" are, collectively, the Swiss Bank Account Security Agreement, the Swiss IP Security Agreement and the Swiss Receivables Security Agreement.

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"Term Loan" is defined in Section 2.2(a)(iii) hereof.

"Term A Loan" is defined in Section 2.2(a)(i) hereof.

"Term B Loan" is defined in Section 2.2(a)(ii) hereof.

"Term B Milestone I" means [***].

"Term B Milestone II" means [***].

"Term C Loan" is defined in Section 2.2(a)(iii) hereof.

"Term C Milestone I" means [***].

"Term C Milestone II" means [***].
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"**Term Loan Commitment**" is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on <u>Schedule 1.1</u>. "**Term Loan Commitments**" means the aggregate amount of such commitments of all Lenders.

"Third Draw Period" is the period (i) commencing on the later of (y) July 1, 2020 if the Borrower has achieved each of the Term C Milestone I, Term C Milestone II and the Term C Milestone III on or prior to July 1, 2020, and (z) such later date if the Borrower has achieved each of the Term C Milestone I, Term C Milestone II and the Term C Milestone III by such date (but in no event later than August 31, 2020), and (ii) ending on the earlier of (y) August 31, 2020 and (z) the occurrence of an Event of Default that is existing at the time of the request for the Term C Loan; provided, however, that the Third Draw Period shall not commence if on the date of the occurrence of the Term C Milestone I, the Term C Milestone II, or the Term C Milestone III an Event of Default has occurred and is continuing.

"**Trademarks**" means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"**Transfer**" is defined in Section 7.1.

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**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:	
OBSEVA SA	
By	
Name: Title:	
inte.	
OBSEVA USA INC.	
By	
Name:	
Title:	•
COLLATERAL AGENT AND LENDER:	
OXFORD FINANCE LLC	
OXFORD FINANCE LLC	
Ву	
Name:	
Title:	•

[Signature Page to Loan and Security Agreement]

# **SCHEDULE 1.1**

# **Lenders and Commitments**

	Term A Loan	
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$25,000,000.00	100.00%
TOTAL	\$25,000,000.00	100.00%

	Term B Loans	
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$25,000,000.00	100.00%
TOTAL	\$25,000,000.00	100.00%

	Term C Loans	
Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$25,000,000.00	100.00%
TOTAL	\$25,000,000.00	100.00%

	Aggregate (all Term Loans)		
Lender	Term Loan Commitment	Commitment Percentage	
OXFORD FINANCE LLC	\$75,000,000.00	100.00%	
TOTAL	\$75,000,000.00	100.00%	

#### **EXHIBIT A**

#### **Description of Collateral**

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (including all Intellectual Property), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral"; (ii) Excluded Accounts; and (iii) any "intent to use" application for registration of a Trademark filed pursuant to Section 1(b) of the Lanham Act, 15 U.S.C. § 1051, prior to the filing of a "Statement of Use" pursuant to Section 1(d) of the Lanham Act or an "Amendment to Allege Use" pursuant to Section 1(c) of the Lanham Act with respect thereto, to the extent that, and during the period in which, the grant of a security interest therein would impair the validity or enforceability of any registration that issues from such intent-to-use application under applicable federal law.

# EXHIBIT B

# Form of Disbursement Letter

[see attached]

### DISBURSEMENT LETTER

		20	
		, ∠∪	

The undersigned, being the duly elected and acting	of OBSEVA SA, a stock corporation organized under the laws of Switzerland
with offices located at chemin des Aulx, 12, 1228 Plan-les-Ouates, Switze	erland, for itself and on behalf of all Borrowers under the Loan Agreement
(defined below) ("Borrower"), does hereby certify to OXFORD FINANCE	LLC ("Oxford" and "Lender"), as collateral agent (the "Collateral Agent")
in connection with that certain Loan and Security Agreement dated as of Au	gust 7, 2019, by and among Borrower, Collateral Agent and the Lenders from
time to time party thereto (the "Loan Agreement"; with other capitalized ter	rms used below having the meanings ascribed thereto in the Loan Agreement)
that:	

- 1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof.
- 2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
  - 3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
- 4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.
  - 5. No Material Adverse Change has occurred.
  - 6. The undersigned is a Responsible Officer.

[Balance of Page Intentionally Left Blank]

Disbursement from Oxford:	
Loan Amount	\$
Plus:	
Deposit Received	\$
Less:	
Facility Fee	(\$
[Interim Interest	(\$)
Lender's Legal Fees	(\$)
Net Proceeds due from Oxford:	\$
TOTAL Term [A][B][C] LOAN NET PROCEEDS FROM LENDERS	\$

The proceeds of the Term [A][B][C] Loan shall be disbursed as follows:

7.

<sup>\*</sup> Legal fees and costs are through the Effective Date. Postclosing legal fees and costs, payable after the Effective Date, to be invoiced and paid postclosing.

^	T1	4	T I 1 11	1	D 1 D	A C - 11
9.	The aggregate ne	t proceeds of the	Term Loans shall	be transferred to the	Designated Deposit	Account as follows:

[\*\*\*]

# [Balance of Page Intentionally Left Blank]

Dated as of the date first set forth above.	
BORROWER:	
OBSEVA SA, for itself and on behalf of all Borrowers under the Loan Agreement	
By Name: Title:	· ·
COLLATERAL AGENT AND LENDER:	
OXFORD FINANCE LLC	
By Name: Title:	

# AMORTIZATION TABLE

(Term [A][B][C] Loan)

[see attached]

#### **EXHIBIT C**

### **Compliance Certificate**

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender

FROM: OBSEVA SA, for itself and on behalf of all Borrowers under the Loan Agreement

The undersigned authorized officer ("Officer") of OBSEVA SA, for itself and on behalf of all Borrowers under the Loan Agreement ("Borrower"), hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the "Loan Agreement;" capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

- (a) Borrower is in complete compliance for the period ending \_\_\_\_\_ with all required covenants except as noted below;
- (b) There are no Events of Default, except as noted below;
- (c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date.
- (d) Borrower, and each of Borrower's Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower's Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;
- (e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with IFRS and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under "Complies" column.

	Reporting Covenant	Requirement	Actual	C	complies	
1)	Financial statements	Monthly within 40 days		Yes	No	N/A
2)	Annual (CPA Audited) statements	Within 90 days after FYE		Yes	No	N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within 60 days of FYE), and when revised		Yes	No	N/A

4)	A/R & A/P agings	If applicable	Yes	No	N/A
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 days of filing	Yes	No	N/A
6)	Compliance Certificate	Monthly within 40 days	Yes	No	N/A
7)	IP Report	When required	Yes	No	N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period		\$ Yes	No	N/A
9)	Total amount of Borrower's Subsidiarie cash and cash equivalents at the last day of the measurement period		\$ Yes	No	N/A

### **Deposit and Securities Accounts**

(Please list all accounts; attach separate sheet if additional space needed)

Hundred Thousand Dollars (\$500,000.00)?

	Institution Name	Account Number	New Accou	nt?	Account Control Agreement i	n place?
1)			Yes	No	Yes N	No
2)			Yes	No	Yes N	No
3)			Yes	No	Yes N	No
4)			Yes	No	Yes N	No

### **Financial Covenants**

3)

4)

	Covenant	Requirement	Actual	Complian	ce
1)	Subject to Section 6.10, once \$[***] has funded, minimum cash in Collateral Accounts subject to a Control Agreement	\$[***]	\$	Yes	No
Other	<u>Matters</u>				
1)	Have there been any changes in management	ent since the last Compliance Certificate?		Yes	No
2)	Have there been any transfers/sales/disposa	als/retirement of Collateral or IP prohibite	ed by the Loan Agreement?	Yes	No

Yes

Yes

No

No

Have there been any new or pending claims or causes of action against Borrower that involve more than Five

Have there been any amendments of or other changes to the Operating Documents of Borrower or any of its

Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate.

Please explain any exceptions with respect to the certificat space needed.)	ion above: (If no exceptions exist, state "No exceptions." Att	ach separate sheet if additional
OBSEVA SA, for itself and on behalf of all Borrowers under	r the Loan Agreement	
Ву	_	
Name:	_	
Title:	<u> </u>	
Date:		
	<del>_</del>	
	LENDER USE ONLY	
	Received by:	Date:
	Verified by:	Date:
	Compliance Status: Yes No	

Exceptions

# EXHIBIT D

# Form of Secured Promissory Note

[see attached]

# SECURED PROMISSORY NOTE (Term [A][B][C] Loan)

\$ Dated:, 20
FOR VALUE RECEIVED, the undersigned, OBSEVA SA, a stock corporation organized under the laws of Switzerland with offices located at chemin des Aulx, 12, 1228 Plan-les-Ouates, Switzerland ("Parent") and OBSEVA USA INC., a Delaware corporation with offices located at 1 Financial Center, 24th Floor, Boston, Ma 02111 ("ObsEva USA", Parent and ObsEva USA, individually and collectively, jointly and severally, "Borrower" HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC ("Lender") the principal amount of [] MILLION DOLLAR. (\$) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B][C] Loan made to Borrower by Lender, plu interest on the aggregate unpaid principal amount of such Term [A][B][C] Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated August 7, 2019 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "Loan Agreement"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. An capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.
Principal, interest and all other amounts due with respect to the Term [A][B][C] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "Note"). The principal amount of this Note and the interest rat applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attache hereto which is part of this Note.
The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B][C] Loan by Lender to Borrower, and (b) contain provisions for acceleration of the maturity hereof upon the happening of certain stated events.
This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.
This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B][C] Loan, interest on the Term [A][B][C] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.
Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.
Borrower shall pay all reasonable and documented fees and expenses, including, without limitation, reasonable and documented attorneys' fees and costs incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.
This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.
The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else it this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record cownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Not (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to rinterest in this Note on the part of any other person or entity.
[Balance of Page Intentionally Left Blank]

hereof.	IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the dat
	BORROWER:
	OBSEVA SA
	By Name: Title:
	OBSEVA USA INC.
	By Name: Title:

### LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL

	Principal		Scheduled	
Date	Amount	Interest Rate	Payment_Amount	Notation By

#### **CORPORATE BORROWING CERTIFICATE<sup>2</sup>**

Borrower: OBSEVA SA Date: August 7, 2019

LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

- 1. I am an authorized signatory of the Borrower. My title is as set forth below.
- 2. Borrower's exact legal name is set forth above. Borrower is ObsEva SA existing under the laws of Switzerland (CHE-253.914.856).
- 3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Articles of Association, as filed with the commercial register of the Canton of Geneva, and (ii) the extract of the commercial register of the Canton of Geneva relating to Borrower. Neither such Articles of Association nor such extract of the commercial register have been amended, annulled, rescinded, revoked or supplemented, and such Articles of Association remain in full force and effect as of the date hereof.
- 4. The copy of the written resolutions of the Board of Directors of the Borrower appended hereto as <a href="Exhibit C">Exhibit C</a> (the "Board Resolutions") is correct and complete as at the date hereof, and such resolutions are in full force and effect on the date hereof and have not been amended, revoked or superseded as at the date hereof and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.
- 5. Each individual whose name is set forth on Exhibit D hereto is duly qualified and acting as an elected or appointed officer, or an authorized representative, of the Company, and is authorized in accordance with the Board Resolutions to:

**Borrow Money**. Borrow money from the Lenders.

**Execute Loan Documents.** Execute any loan documents any Lender requires.

Grant Security. Grant Collateral Agent and, where appropriate, the secured parties a security interest in any of Borrower's assets.

**Negotiate Items**. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

**Further Acts**. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

The signature written next to such individual's name on  $\underline{\text{Exhibit }D}$  hereto is his or her genuine signature. Any one of the individuals set forth on  $\underline{\text{Exhibit }D}$  may act on behalf of Borrower and may, from time to time, add individuals as their substitutes to such list of persons authorized to act on behalf of Borrower in accordance with the Board Resolutions.

Ву:	By:	
Name:	Name:	
Title:	Title:	

### **EXHIBIT A**

### **Articles of Association**

### EXHIBIT B

### Extract of the commercial register of the Canton of Geneva

### EXHIBIT C

### **Board Resolutions**

### EXHIBIT D

### **Signature Specimens**

Ernest Loumaye	
Fabien Lefebvre de Ladonchamps	
Jean-Pierre Gotteland	

#### CORPORATE BORROWING CERTIFICATE

BORROWER: OBSEVA USA INC. Date: August 7, 2019

LENDER: OXFORD FINANCE LLC, as Collateral Agent and Lender

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.

- 2. Borrower's exact legal name is set forth above. Borrower is a OBSEVA USA INC. existing under the laws of the State of Delaware.
- 3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
- 4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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Resource Fourness, that any one of the persons designated above with a checked box beside his or her name may, from time to time, add or remove an individuals to and from the above list of persons authorized to act on behalf of Borrower.  Resource Fourness, that such individuals may, on behalf of Borrower.  Resource Fourness, that such individuals may, on behalf of Borrower.  Borrow Money. Borrow money from the Lenders.  Fixerted Loan Documents. Execute any loan documents any Lender requires.  Grant Scurity. Grant Collateral Agent a security interest in any of Borrower's assets.  Negotiate Irens. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.  Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.  Resourae Fournase, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.  [Balance of Page Intentionally Left Blank]	RESOLVED, that any one of the following of	ficers or employees of Borrower, whose	names, titles and signatures are below	, may act on behalf of Borrower:
RESOLVED FURTHER, that any one of the persons designated above with a checked box beside his or her name may, from time to time, add or remove an individuals to and from the above list of persons authorized to act on behalf of Borrower.  RESOLVED FURTHER, that such individuals may, on behalf of Borrower:  Borrow Money. Borrow money from the Lenders.  Execute Loan Documents. Execute any loan documents any Lender requires.  Grant Security. Grant Collateral Agent a security interest in any of Borrower's assets.  Negotiate Items. Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receiv cash or otherwise use the proceeds.  Further Acts. Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.  Resolved Furthera, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.	<u>Name</u>	<u>Title</u>	<u>Signature</u>	Add or Remove
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[Balance of Page Intentionally Left Blank]	Grant Security. Grant Collateral Agent a Negotiate Items. Negotiate or discount all cash or otherwise use the proceeds. Further Acts. Designate other individual agreement that waive Borrower's right to a	security interest in any of Borrower's as I drafts, trade acceptances, promissory no Is to request advances, pay fees and cos I jury trial) they believe to be necessary to	otes, or other indebtedness in which Bots and execute other documents or ago o effectuate such resolutions.	
		[Balance of Page Intention	nally Left Blank]	

		By:	
		Title	
*** If the Secretary, Assistan authorized signing officers, th	t Secretary or other certifying officer executi is Certificate must also be signed by a second	ng above is designated by the resolutio d authorized officer or director of Borro	ns set forth in paragraph 4 as one of th wer.
I, the forth above.	of Borrower, hereby certify as to pa	aragraphs 1 through 5 above, as	[print title] of the date se
		Ву:	
		Name:	
		Title:	
	[Signature Page to Corp	porate Borrowing Certificate]	

The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

5.

### **EXHIBIT A**

### **Certificate of Incorporation (including amendments)**

### EXHIBIT B

### **Bylaws**

DEBTOR: OBSEVA SA
SECURED PARTY: OXFORD FINANCE LLC,

as Collateral Agent

#### EXHIBIT A TO UCC FINANCING STATEMENT

#### **Description of Collateral**

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (including all Intellectual Property), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Debtor's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessories, accessories and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral"; (ii) any Excluded Accounts; or (iii) any "intent to use" application for registration of a Trademark filed pursuant to Section 1(b) of the Lanham Act, 15 U.S.C. § 1051, prior to the filing of a "Statement of Use" pursuant to Section 1(d) of the Lanham Act or an "Amendment to Allege Use" pursuant to Section 1(c) of the Lanham Act with respect thereto, to the extent that, and during the period in which, the grant of a security interest therein would impair the validity or enforceability of any registration that issues from such intent-to-use application under applicable federal law.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of New York as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).

DEBTOR: OBSEVA USA INC.

SECURED PARTY: OXFORD FINANCE LLC,
as Collateral Agent

#### EXHIBIT A TO UCC FINANCING STATEMENT

#### **Description of Collateral**

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (including all Intellectual Property), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Debtor's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral"; (ii) any Excluded Accounts; or (iii) any "intent to use" application for registration of a Trademark filed pursuant to Section 1(b) of the Lanham Act, 15 U.S.C. § 1051, prior to the filing of a "Statement of Use" pursuant to Section 1(d) of the Lanham Act or an "Amendment to Allege Use" pursuant to Section 1(c) of the Lanham Act with respect thereto, to the extent that, and during the period in which, the grant of a security interest therein would impair the validity or enforceability of any registration that issues from such intent-to-use application under applicable federal law.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of New York as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).

#### FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **FIRST AMENDMENT** to Loan and Security Agreement (this "**Amendment**") is entered into as of December 6, 2019, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on <u>Schedule 1.1</u> hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and OBSEVA SA, a stock corporation organized under the laws of Switzerland with offices located at chemin des Aulx, 12, 1228 Plan-les-Ouates, Switzerland and registered with the commercial register of the Canton of Geneva with the registration number CHE-253.914.856 ("**Parent**") and OBSEVA USA INC., a Delaware corporation with offices located at 1 Financial Center, 24th Floor, Boston, Ma 02111 ("**ObsEva USA**", Parent and ObsEva USA, individually and collectively, jointly and severally, "**Borrower**").

#### RECITALS

- **A.** Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of August 7, 2019 (as amended from time to time, the "**Loan Agreement**").
  - **B.** Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.
- **C.** Borrower is seeking to (i) exclude an additional Collateral Account that will be used for collecting the par value for subscriptions of capital stock of Parent, and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.
- **D.** Collateral Agent and Lenders have agreed to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

#### AGREEMENT

Now, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

- **14.** <u>DEFINITIONS.</u> Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.
- **15.** <u>AMENDMENTS TO LOAN AGREEMENT.</u>
- **15.1 Section 13.1 (Definitions).** The following term and its definition in Section 13.1 of the Loan Agreement hereby are amended and restated as follows:

"Excluded Accounts" are (a) deposit accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates delivered on the Effective Date, (b) the deposit accounts (i) with the account numbers ending in [\*\*\*] at Credit Suisse providing cash collateral to certain lessors, and (ii) ending in [\*\*\*] at Silicon Valley Bank providing cash collateral to Silicon Valley Bank for a letter of credit provided by Silicon Valley Bank to the landlord for ObsEva USA's leased office space at 1 Financial Center, 24th Floor, Boston, Massachusetts, provided that the aggregate amount in all such accounts in respect of this clause (b) does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time, and (c) the deposit account with the account number ending in [\*\*\*] maintained by Parent at UBS Switzerland AG for collecting the par value for subscriptions of capital stock of Parent in connection with the issuance of such shares, provided that (i) such account will be closed on or before the date that is thirty (30) days after the First Amendment Effective Date and all amounts in such account shall be transferred to a deposit account that is subject to a Control Agreement, and (ii) at no time shall the amount in such account exceed Eight Hundred Thousand Swiss Francs (CHF800,000.00).

**15.2 Section 13.1 (Definitions).** The following term and its definition hereby are added to Section 13.1 of the Loan Agreement as follows:

"First Amendment Effective Date" means December 6, 2019.

#### **16.** LIMITATION OF AMENDMENT.

- 16.1 The amendments set forth in Section 2 above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.
- 16.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.
- **17.** <u>REPRESENTATIONS AND WARRANTIES.</u> To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:
- 17.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;
- 17.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;
- 17.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect:
- 17.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;
- 17.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;
- 17.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and
- 17.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.
- **18.** <u>COUNTERPARTS</u>. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

<b>19.</b> Lenders of (i) this An	<u>EFFECTIVENESS</u> . This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and nendment by each party hereto, and (ii) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment.		
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BORROWER:					
OBSEVA SA					
Name:					
OBSEVA USA INC.					
Name:					
COLLATERAL AGEN					
Name:					
	[Signature Po	nge to First Amendment	to Loan and Security A	Agreement]	

In Witness Whereof, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written above.

## SECOND AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS **SECOND AMENDMENT** to Loan and Security Agreement (this "**Amendment**") is entered into as of February 18, 2020, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on <u>Schedule 1.1</u> hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and OBSEVA SA, a stock corporation organized under the laws of Switzerland with offices located at chemin des Aulx, 12, 1228 Plan-les-Ouates, Switzerland and registered with the commercial register of the Canton of Geneva with the registration number CHE-253.914.856 ("**Parent**") and OBSEVA USA INC., a Delaware corporation with offices located at 1 Financial Center, 24th Floor, Boston, Ma 02111 ("**ObsEva USA**", Parent and ObsEva USA, individually and collectively, jointly and severally, "**Borrower**").

#### RECITALS

- **A.** Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of August 7, 2019, as amended by that certain First Amendment to Loan and Security Agreement dated as of December 6, 2019 (as amended further from time to time, the "**Loan Agreement**").
  - **B.** Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.
- **C.** Borrower is seeking to (i) exclude additional Collateral Accounts that will be used for collecting the par value for subscriptions of capital stock of Parent, and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein.
- **D.** Collateral Agent and Lenders have agreed to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

#### AGREEMENT

**Now, THEREFORE,** in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

- **20.** <u>DEFINITIONS.</u> Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.
- 21. <u>AMENDMENTS TO LOAN AGREEMENT.</u>
- 21.1 Section 13.1 (Definitions). The following term and its definition in Section 13.1 of the Loan Agreement hereby are amended and restated as follows:

"Excluded Accounts" are (a) deposit accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates delivered on the Effective Date, (b) the deposit accounts (i) with the account numbers ending in [\*\*\*] at Credit Suisse providing cash collateral to certain lessors, and (ii) ending in [\*\*\*] at Silicon Valley Bank providing cash collateral to Silicon Valley Bank for a letter of credit provided by Silicon Valley Bank to the landlord for ObsEva USA's leased office space at 1 Financial Center, 24th Floor, Boston, Massachusetts, provided that the aggregate amount in all such accounts in respect of this clause (b) does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time, and (c) deposit accounts opened and maintained by Parent at UBS Switzerland AG (including account number ending in [\*\*\*]) for the limited purpose of issuing shares of the Parent to investors, including receiving par value for subscriptions of capital stock of Parent from such investors for the issuance of such shares, provided that (i) Parent shall not have more than one such account open at any time, (ii) the aggregate amount that Parent and its Subsidiaries may transfer into all such accounts from and

after the Second Amendment Effective Date shall not exceed Five Hundred Thousand Swiss Francs (CHF500,000.00), (iii) within thirty (30) days after par value amounts are deposited into such open account, such amounts shall be transferred to a deposit account that is subject to a Control Agreement, and (iv) at no time shall the amount in such open account exceed Two Million Five Hundred Thousand Swiss Francs (CHF2,500,000.00).

**21.2 Section 13.1 (Definitions).** The term "First Amendment Effective Date" and its definition hereby are deleted from Section 13.1 of the Loan Agreement. The following term and its definition hereby are added to Section 13.1 of the Loan Agreement as follows:

"Second Amendment Effective Date" means February 18, 2020.

#### 22. <u>LIMITATION OF AMENDMENT.</u>

- 22.1 The amendments set forth in Section 2 above, are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.
- 22.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.
- **23.** <u>REPRESENTATIONS AND WARRANTIES</u>. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:
- 23.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;
- 23.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;
- 23.3 The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect:
- 23.4 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;
- 23.5 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;
- 23.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and
- 23.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may

be limited by bankruptcy, insolvency, re	eorganization, liquidation	, moratorium or other	similar laws of general	application and equitab	le principles relating
to or affecting creditors' rights.					

- **24.** <u>COUNTERPARTS.</u> This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.
- **25.** <u>EFFECTIVENESS</u>. This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, and (ii) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment.

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In WITNESS	Whereof, the parties hereto have caused this Amendment to be dul	y executed and delivered as of the date first written above.
BORROWI	ER:	
OBSEVA SA	A	
3. T		
OBSEVA U	JSA INC.	
By Name: Title:		
COLLATE	ERAL AGENT AND LENDER:	
OXFORD F	FINANCE LLC	
	[Signature Page to Second Amendme	nt to Loan and Security Agreement]

#### THIRD AMENDMENT TO LOAN AND SECURITY AGREEMENT

**THIS THIRD AMENDMENT** to Loan and Security Agreement (this "Amendment") is entered into as of April 7, 2020, by and between **OXFORD FINANCE LLC**, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on <u>Schedule 1.1</u> hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and OBSEVA SA, a stock corporation organized under the laws of Switzerland with offices located at chemin des Aulx, 12, 1228 Plan-les- Ouates, Switzerland and registered with the commercial register of the Canton of Geneva with the registration number CHE-253.914.856 ("**Parent**") and OBSEVA USA INC., a Delaware corporation with offices located at 1 Financial Center, 24th Floor, Boston, MA 02111 ("**ObsEva USA**", Parent and ObsEva USA, individually and collectively, jointly and severally, "**Borrower**").

#### RECITALS

- **A.** Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of August 7, 2019, as amended by that certain First Amendment to Loan and Security Agreement dated as of December 6, 2019, as amended further by that certain Second Amendment to Loan and Security Agreement dated as of February 18, 2020 (as amended further from time to time, the "**Loan Agreement**").
  - **B.** Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.
- **C.** Borrower has requested that Collateral Agent and Lenders (i) modify certain Term C Loan provisions and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein. Collateral Agent and Lenders have agreed to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

#### **AGREEMENT**

**NOW, THEREFORE,** in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

**1. Definitions.** Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

#### 2. AMENDMENTS TO LOAN AGREEMENT.

**2.1 Section 2.2(a) (Term C Loan).** Section 2.2(a)(iii) of the Loan Agreement hereby is amended and restated as follows:

"(iii) Subject to the terms and conditions of this Agreement, at any time after the Third Amendment Effective Date upon request by Borrower, the Lenders may, in their sole discretion, agree to make term loans to Borrower (but in a single disbursement) in an aggregate amount of up to Twenty-Five Million Dollars (\$25,000,000.00), and, when made, according to a commitment schedule to be provided by Lenders prior to the Funding Date of such term loans (such term loans are hereinafter referred to singly as a "**Term C Loan**", and collectively as the "**Term C Loans**"; each Term A Loan, Term B Loan or Term C Loan is hereinafter referred to singly as a "**Term Loan**" and the Term A Loan, the Term B Loans and the Term C Loans are hereinafter referred to collectively as the "**Term Loans**"). After repayment, no Term C Loan may be re-borrowed."

- **2.2 Section 2.5(a) (Facility Fee).** Section 2.5(a) of the Loan Agreement hereby is amended and restated as follows:
- "(a) <u>Facility Fee</u>. A fully earned, non-refundable facility fee of [\*\*\*]

(the "Facility Fee") to be shared between the Lenders in accordance with their respective Commitment Percentages payable as follows: (i) [\*\*\*] of the Facility Fee shall be due and payable on the Effective Date, (ii) [\*\*\*] of the Facility Fee shall be due and payable on the earliest of (x) the Funding Date of the Term B Loans, (y) the date of the expiration of the Second Draw Period (whether or not the Second Draw Period commenced), and (z) the acceleration of any Term Loan or the prepayment of any Term Loan pursuant to Section 2.2(c) or (d), and (iii) [\*\*\*] of the Facility Fee shall be due and payable on the Funding Date of the Term C Loans;."

- **2.3 Section 5.8 (Tax Returns and Payments; Pension Contributions).** Section 5.8 of the Loan Agreement hereby is amended by replacing "Six Hundred Fifty Thousand Dollars (\$650,000.00)" in clause (c) of the first sentence thereof with "One Million Five Hundred Thousand Dollars (\$1,500,000.00)."
  - **Section 7.7 (Distributions).** Section 7.7(a)(iii) of the Loan Agreement hereby is amended and restated as follows:

"(iii) in accordance with Borrower's historical business practice, purchases by Borrower consisting of subscriptions for capital stock of Parent or options to acquire capital stock of Parent at par value for the purchase of acquiring treasury stock in connection with a substantially concurrent issuance, or in anticipation of an issuance, of capital stock or convertible securities, provided that from and after the Second Amendment Effective Date such purchases by Borrower do not exceed Five Hundred Thousand Swiss Francs (CHF500,000.00), or."

**2.5 Section 13.1 (Definitions).** The following terms and their respective definitions hereby are deleted from Section 13.1 of the Loan Agreement: "Term C Milestone I", "Term C Milestone III" and "Third Draw Period." The following term and its definition hereby are added to Section 13.1 of the Loan Agreement as follows:

"Third Amendment Effective Date" means April 7, 2020.

**2.6 Schedule 1.1 (Lenders and Commitments).** <u>Schedule 1.1</u> of the Loan Agreementhereby is amended and restated in the form attached hereto as <u>Exhibit A</u>.

#### 3. <u>LIMITATION OF AMENDMENT.</u>

- 3.1 The amendments set forth in **Section 2** are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.
- 3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.
- **4. Representations and Warranties.** To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:
- **4.1** Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;
- **4.2** Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

- **4.3** The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;
- **4.4** The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;
- **4.5** The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene
- (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;
- 4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and
- 4.7 This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

#### 5. <u>RELEASE BY BORROWER.</u>

- 5.1 FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Collateral Agent and each Lender and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of this Amendment (collectively "Released Claims"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.
- 5.2 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any representation or statement made by Collateral Agent or any Lender with respect to the facts underlying this release or with regard to any of such party's rights or asserted rights.
- 5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and Lenders to enter into this Amendment, and that Collateral Agent and Lenders would not have done so but for Collateral Agent's and Lenders' expectation that such release is valid and enforceable in all events.

6.	Counterparts. This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be	рe
deemed to constitute of	one and the same instrument and a pdf copy of a counterpart shall be deemed an original.	

7. **Effectiveness.** This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, and (ii) Borrower's payment of all Lenders' Expenses incurred through the date of this Amendment.

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above.	
BORROWER:	
OBSEVA SA	
n.	
ByName:	
Title	
ODGOVA VICA INC	
OBSEVA USA INC.	
Ву	
Name:	
Title:	
COLLATERAL AGENT AND LENDER:  OXFORD FINANCE LLC	
Ву	
Name:	
Title:	
[Signature Page to Third Amendme	nt to Loan and Security Agreement]
1	4

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written

### Exhibit A

### **SCHEDULE 1.1**

### **Lenders and Commitments**

### Term A Loan

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$25,000,000.00	100.00%
TOTAL	\$25,000,000.00	100.00%

### TERM B LOANS

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$25,000,000.00	100.00%
TOTAL	\$25,000,000.00	100.00%

### Aggregate (all Term Loans)

Lender	Term Loan Commitment	Commitment Percentage
OXFORD FINANCE LLC	\$50,000,000.00	100.00%
TOTAL	\$50,000,000.00	100.00%

# FOURTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FOURTH AMENDMENT to Loan and Security Agreement (this "Amendment") is entered into as of January 26, 2021, by and between OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 115 South Union Street, Suite 300, Alexandria, Virginia 22314 ("Oxford"), as collateral agent (in such capacity, "Collateral Agent"), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a "Lender" and collectively, the "Lenders"), and OBSEVA SA, a stock corporation organized under the laws of Switzerland with offices located at chemin des Aulx, 12, 1228 Plan- les-Ouates, Switzerland and registered with the commercial register of the Canton of Geneva with the registration number CHE-253.914.856 ("Parent") and OBSEVA USA INC., a Delaware corporation with offices located at 1 Financial Center, 24th Floor, Boston, MA 02111 ("ObsEva USA", Parent and ObsEva USA, individually and collectively, jointly and severally, "Borrower").

#### RECITALS

- **A.** Collateral Agent, Lenders and Borrower have entered into that certain Loan and Security Agreement dated as of August 7, 2019, as amended by that certain First Amendment to Loan and Security Agreement dated as of December 6, 2019, as amended further by that certain Second Amendment to Loan and Security Agreement dated as of February 18, 2020, as amended further by that certain Third Amendment to Loan and Security Agreement dated as of April 7, 2020 (as amended further from time to time, the "**Loan Agreement**").
  - B. Lenders have extended credit to Borrower for the purposes permitted in the Loan Agreement.
- **C.** Borrower has requested that Collateral Agent and Lenders (i) modify Section 7.7 and the defined term "Excluded Accounts" and (ii) make certain other revisions to the Loan Agreement as more fully set forth herein. Collateral Agent and Lenders have agreed to amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

#### **AGREEMENT**

**NOW, THEREFORE,** in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

**1. Definitions.** Capitalized terms used but not defined in this Amendment shall have the meanings given to them in the Loan Agreement.

#### 2. AMENDMENTS TO LOAN AGREEMENT.

**Section 7.7 (Distributions).** Section 7.7(a)(iii) of the Loan Agreement hereby is amended and restated as follows:

"(iii) in accordance with Borrower's historical business practice, purchases by Borrower consisting of subscriptions for capital stock of Parent or options to acquire capital stock of Parent at par value for the purchase of acquiring treasury stock in connection with a substantially concurrent issuance, or in anticipation of an issuance, of capital stock or convertible securities, provided that from and after the Second Amendment Effective Date such purchases by Borrower do not exceed Two Million Swiss Francs (CHF2,000,000.00), or."

**2.2 Section 13.1 (Definitions).** The following term and its definition in Section 13.1 of the Loan Agreement hereby are amended and restated as follows:

"Excluded Accounts" are (a) deposit accounts exclusively used for payroll, payroll Taxes and other employee wage and benefit payments to or for the benefit of Borrower's, or any of its Subsidiaries', employees and identified to Collateral Agent by Borrower as such in the Perfection Certificates delivered on the Effective Date, (b) the deposit accounts (i) with the account numbers ending in [\*\*\*] at Credit Suisse providing cash collateral to certain lessors, and (ii) ending in [\*\*\*] at Silicon Valley Bank providing cash collateral to Silicon

Valley Bank for a letter of credit provided by Silicon Valley Bank to the landlord for ObsEva USA's leased office space at 1 Financial Center, 24th Floor, Boston, Massachusetts, provided that the aggregate amount in all such accounts in respect of this clause (b) does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time, and

(c) deposit accounts opened and maintained by Parent at UBS Switzerland AG (including account number ending in [\*\*\*]) for the limited purpose of issuing shares of the Parent to investors, including receiving par value for subscriptions of capital stock of Parent from such investors for the issuance of such shares, provided that (i) Parent shall not have more than one such account open at any time, (ii) the aggregate amount that Parent and its Subsidiaries may transfer into all such accounts from and after the Second Amendment Effective Date shall not exceed Two Million Swiss Francs (CHF2,000,000.00), (iii) within thirty (30) days after par value amounts are deposited into such open account, such amounts shall be transferred to a deposit account that is subject to a Control Agreement, and (iv) at no time shall the amount in such open account exceed Two Million Five Hundred Thousand Swiss Francs (CHF2,500,000.00).

2.3 Section 10 (Notices). Section 10 of the Loan Agreement is hereby amended by replacing the notice information for Collateral Agent with the following:

"If to Collateral Agent: OXFORD

FINANCE LLC 115 South Union Street Suite 300

Alexandria, VA 22314 Attention: Legal Department Fax: (703) 519-5225

Email: [\*\*\*]

with a copy (which shall not constitute notice) to:

DLA Piper LLP (US)

500 8th Street, NW Washington, DC 20004 Attention: Eric Eisenberg Fax: (202) 799-5211

Email: [\*\*\*]"

#### 3. LIMITATION OF AMENDMENT.

3.1 The amendments set forth in Section 2 are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Collateral Agent or any Lender may now have or may have in the future under or in connection with any Loan Document.

3.2 This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4.1 Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

4.2 Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the

Representations and Warranties. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby

- **4.2** Borrower has the power and authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;
- **4.3** The organizational documents of Borrower delivered to Collateral Agent and Lenders on the Effective Date, or subsequent thereto, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;
- **4.4** The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, have been duly authorized;
- **4.5** The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene
- (a) any law or regulation binding on or affecting Borrower, (b) any contractual restriction with a Person binding on Borrower, (c) any order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (d) the organizational documents of Borrower;
- 4.6 The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower; and
- **4.7** This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

#### 5. RELEASE BY BORROWER.

- 5.1 FOR GOOD AND VALUABLE CONSIDERATION, Borrower hereby forever relieves, releases, and discharges Collateral Agent and each Lender and their respective present or former employees, officers, directors, agents, representatives, attorneys, and each of them, from any and all claims, debts, liabilities, demands, obligations, promises, acts, agreements, costs and expenses, actions and causes of action, of every type, kind, nature, description or character whatsoever, whether known or unknown, suspected or unsuspected, absolute or contingent, arising out of or in any manner whatsoever connected with or related to facts, circumstances, issues, controversies or claims existing or arising from the beginning of time through and including the date of this Amendment (collectively "Released Claims"). Without limiting the foregoing, the Released Claims shall include any and all liabilities or claims arising out of or in any manner whatsoever connected with or related to the Loan Documents, the Recitals hereto, any instruments, agreements or documents executed in connection with any of the foregoing or the origination, negotiation, administration, servicing and/or enforcement of any of the foregoing.
- 5.2 By entering into this release, Borrower recognizes that no facts or representations are ever absolutely certain and it may hereafter discover facts in addition to or different from those which it presently knows or believes to be true, but that it is the intention of Borrower hereby to fully, finally and forever settle and release all matters, disputes and differences, known or unknown, suspected or unsuspected; accordingly, if Borrower should subsequently discover that any fact that it relied upon in entering into this release was untrue, or that any understanding of the facts was incorrect, Borrower shall not be entitled to set aside this release by reason thereof, regardless of any claim of mistake of fact or law or any other circumstances whatsoever. Borrower acknowledges that it is not relying upon and has not relied upon any

representation or statement made by	Collateral Agent or any	Lender with respect to	the facts underlying t	his release or with	regard to any of	such party's
rights or asserted rights.						

- 5.3 This release may be pleaded as a full and complete defense and/or as a cross-complaint or counterclaim against any action, suit, or other proceeding that may be instituted, prosecuted or attempted in breach of this release. Borrower acknowledges that the release contained herein constitutes a material inducement to Collateral Agent and Lenders to enter into this Amendment, and that Collateral Agent and Lenders would not have done so but for Collateral Agent's and Lenders' expectation that such release is valid and enforceable in all events.
- **6. Counterparts.** This Amendment may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument and a pdf copy of a counterpart shall be deemed an original.
- 7. **Effectiveness.** This Amendment shall be deemed effective upon the due execution and delivery to Collateral Agent and Lenders of (i) this Amendment by each party hereto, and (ii) Borrower's payment of all Lenders' Expenses that have been invoiced through the date of this Amendment.

[Balance of Page Intentionally Left Blank]

above.	
BORROWER:	
OBSEVA SA	
By	
Name: Title:	
OBSEVA USA INC.	
Ву	
Name: Title:	
COLLATERAL AGENT AND LENDER:	
OXFORD FINANCE LLC	
By	
Name: Title:	

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed and delivered as of the date first written

[Signature Page to Fourth Amendment to Loan and Security Agreement]

#### Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

#### I, Brian O'Callaghan, certify that:

- 1. I have reviewed this annual report on Form 20-F of ObsEva SA;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
- 4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
- 5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 5, 2021

/s/ Brian O'Callaghan

Name: Brian O'Callaghan
Title: Chief Executive Officer
(Principal Executive Officer)

#### Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

#### I, David Renas, certify that:

- 1. I have reviewed this annual report on Form 20-F of ObsEva SA;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
- 4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
- 5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 5, 2021

/s/ David Renas

Name: David Renas

Title: Chief Financial Officer (Principal Financial Officer)

#### Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of ObsEva SA (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian O'Callaghan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2021

### /s/ Brian O'Callaghan

Name: Brian O'Callaghan

Title: Chief Executive Officer (Principal Executive Officer)

#### Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report of ObsEva SA (the "Company") on Form 20-F for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Renas, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 5, 2021

#### /s/ David Renas

Name: David Renas

Title: Chief Financial Officer

(Principal Financial Officer)

### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-249457, 333-231629 and 333-216170) and Form F-3 (Nos. 333-233069 and 333-221462) of ObsEva SA of our report dated March 5, 2021 relating to the financial statements, which appears in this Form 20-F.

/s/ PricewaterhouseCoopers SA

Geneva, Switzerland March 5, 2021