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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to_____

Commission File Number: 001-37993

OBSEVA SA

(Exact name of registrant as specified in its charter)

Switzerland **(State or other jurisdiction of incorporation or organization)**	**Not Applicable** **(I.R.S. Employer Identification No.)**
Chemin des Aulx, 12, Plan-les-Ouates, Geneva Switzerland **(Address of principal executive offices)**	**1228** **(Zip Code)**

Registrant's telephone number, including area code

+ 41 22 552 38 40

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common shares, par value CHF 1/13 per share	OBSVF	*

*The registrant's common shares began trading on the OTC Pink Marketplace on March 23, 2023 under the symbol "OBSVF".

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data file required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☐ No ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. Yes ☐ No ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). Yes ☐ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of voting and non-voting common equity held by non-affiliates, based upon the closing price of the registrant's common shares reported on The Nasdaq Stock Market on June 30, 2022, was approximately $136.0 million.

As of March 24, 2023, there were 113,177,287 shares of the registrant's common shares, CHF 1/13 par value per share, outstanding, excluding 33,741,950 treasury shares.

OBSEVA SA

ANNUAL REPORT ON FORM 10-K

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended December 31, 2022 (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Private Securities Litigation Reform Act of 1995. Written or oral statements that constitute forward-looking statements may be made by us or on our behalf. Words such as "expect," "anticipate," "intend," "plan," "believe," "estimate," "may," "will," "should," "could," "target," "strategy," "intend," "project," "guidance," "likely," "usually," "potential," or the negative of these words or variations of such words, similar expressions, or comparable terminology are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. These forward-looking statements are based on current expectations, estimates, forecasts, and projections about the industry and markets in which we operate, and management's beliefs and assumptions. These statements are not guarantees of future performance and involve certain risks, uncertainties, and assumptions that are difficult to predict and may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by any forward-looking statements. These risks, uncertainties and other factors include, but are not limited to, risks associated with the following:

- the impact of our delisting from the Nasdaq Stock Market ("Nasdaq") on our shareholders, including the impact on the trading price and volatility of our common shares;
- the impact of our reorganization as a Swiss only company and transition of our management and board of directors;
- the success, cost, timing and potential indications of our product candidate's development activities and clinical trials, including ongoing and future trials of nolasiban;
- the reliability of the results of the studies relating to human safety and possible adverse effects resulting from the administration of our product candidate;
- our or our partners' ability to obtain and maintain regulatory approval of our product candidates in any of the indications for which we or our partners plan to develop them, and any related restrictions, limitations or warnings in the label of an approved product;
- our ability to continue as a going concern and to obtain funding for our operations, and the terms on which we are able to raise that additional capital;
- our plans to research, develop and commercialize our product candidate;
- the timing of our regulatory filings for our product candidate;
- the clinical utility of our product candidate;
- the size and growth potential of the markets for our product candidate;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidate 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 or that we may receive under our license or acquisition 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;
- 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 or other geopolitical and macroeconomic events;
- regulatory developments in the United States and foreign countries; and
- risks detailed under the caption "Risk Factors" in this Annual Report and in our other reports filed with the U.S. Securities and Exchange Commission (the "SEC"), from time to time hereafter.

We have based the forward-looking statements included in this Annual Report on information available to us on the date of this Annual Report. Except as required by law we undertake no obligation to revise or update any forward-looking statements, whether as a result of new information, future events or otherwise. You are advised to consult any additional disclosures that we may make in reports that we, in the future, may file with the SEC.

All forward-looking statements included herein are expressly qualified in their entirety by the foregoing cautionary statements. Unless otherwise indicated, the information in this Annual Report is as of December 31, 2022.

SUMMARY OF RISK FACTORS

The risk factors detailed in Item 1A entitled "Risk Factors" in this Annual Report on Form 10-K are the risks that we believe are material to our investors and a reader should carefully consider them. Those risks are not all of the risks we face and other factors not presently known to us or that we currently believe are immaterial may also affect our business if they occur. The following is a summary of the risk factors detailed in Item 1A:

- We are consolidating our operations in Switzerland, where our headquarters are located, and may experience disruption in our operations;
- In connection with our reorganization, the composition of our executive management team and board of directors will change significantly;
- 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;
- Our recurring losses, negative cash flows and significant accumulated deficit have raised substantial doubt regarding our ability to continue as a going concern;
- 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 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;
- 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;
- Fluctuations in exchange rates may adversely affect our results of operations;
- If we do not obtain regulatory approval for and successfully commercialize our product candidate or experience significant delays in doing so, we may never become profitable;
- We will depend on Organon for the development and commercialization of ebopiprant;
- 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 U.S Food and Drug Administration ("FDA"), European Medicines Agency ("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 our product candidate;
- Our clinical trials may fail to demonstrate the safety and efficacy of our product candidate, or serious adverse or unacceptable side effects may be identified during the development of our product candidate, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of our product candidate;
- 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;
- 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 candidate, if approved, could limit our ability to market such product and decrease our ability to generate revenue;
- Even if any of our current or future product candidates, including nolasiban receive regulatory approval, or if ebopiprant receives regulatory approval, they will remain subject to ongoing regulatory oversight;
- Off-label use is common in the indications for which our product candidate is 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 candidate 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 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 candidate 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 candidate and may affect the prices we may set;
- If we are unable to comply, or have not fully complied, with applicable federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations, we could face substantial penalties;
- 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;
- 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 may be negatively impacted by volatility in the political and economic environment, such as the ongoing crisis in Ukraine, economic downturns and increases in interest rates, recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures and a period of sustained inflation across the markets in which we operate could result in higher operating costs and may negatively impact our business and financial performance;
- Our common shares were delisted from The Nasdaq Capital Market and are currently traded on the over-the-counter ("OTC") market. There is currently a limited and sporadic trading market for our common shares, and

liquidity of the common shares is limited. Subsequently, we also expect to deregister our common shares under the Exchange Act;

- 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;
- 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; and
- 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.

PART I

Item 1. Business

Overview

We are a biopharmaceutical company focused on the development of novel therapies to improve women's reproductive health. We are advancing a development program for Nolasiban, an oral oxytocin receptor agonist, focused on improving clinical pregnancy and live birth rates in women undergoing in-vitro fertilization ("IVF").

We in-licensed nolasiban from Ares Trading S.A., an affiliate of Merck Serono ("Merck Serono"), in August 2013. We currently have worldwide, exclusive, commercial rights for nolasiban, except for the People's Republic of China, where it has been sub-licensed to Yuyuan BioScience ("Yuyuan") in January 2020. In October 2022, we announced that Yuyuan's Investigational New Drug ("IND") application for a Phase 1 clinical trial of nolasiban has been accepted by the Center for Drug Evaluation at the Chinese National Medical Products Administration. Yuyuan plans to initiate a single-center, randomized, double-blind, placebo-controlled Phase 1 clinical trial in China to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic characteristics of nolasiban in healthy adult female subjects.

In February 2023, our Board of Directors approved a reorganization plan (the "Reorganization Plan"), to, among other things, consolidate our operations in Switzerland, where our headquarters are located. Following the Reorganization Plan, we notified The Nasdaq Stock Market LLC ("Nasdaq") of our inability to comply with the Nasdaq minimum bid price. On March 14, 2023, Nasdaq notified us that our common shares were to be delisted from The Nasdaq Capital Market and suspended at the opening of business on March 23, 2023. Our common shares began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF." On March 28, 2023, we filed a post-effective amendment to various outstanding registration statements on Form F-3, which amendment was declared effective by the United States Securities and Exchange Commission (the "SEC") on March 29, 2023, and a post-effective amendment to various outstanding registration statements on Form S-8, which amendment became effective immediately upon filing, each to remove and withdraw from registration the shares that were registered but remained unsold thereunder. We intend to file with the SEC a Form 15 requesting the deregistration of our common shares under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the suspension of our reporting obligations under Section 13 and Section 15(d) of the Exchange Act, subject to meeting certain conditions to deregistration, including the condition that we have fewer than 300 record holders of our common shares.

At June 30, 2022, the last business day of our second quarter, we determined that we no longer qualified as a foreign private issuer under Rule 3b-4(c) of the Exchange Act. As a result, beginning January 1, 2023, we are required to report with the SEC on domestic forms and comply with domestic company rules in the United States. The transition to generally accepted accounting principles in the United States ("U.S. GAAP") from International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS") was made retrospectively for all periods from our inception.

Recent Developments

In July 2022, we initiated a corporate restructuring and refocusing of our development and commercialization strategies following the receipt of a notice from the U.S. Food and Drug Administration ("FDA") of review issues regarding deficiencies in our New Drug Application ("NDA") for linzagolix, a prior product candidate developed for the potential treatment of uterine fibroids. These review issues precluded discussion of labeling and post-marketing commitments. As a result, we undertook the following actions in July 2022: (i) gave notice of termination of our license agreement (the "Kissei License Agreement") with Kissei Pharmaceutical Co., Ltd ("Kissei") for the development and commercialization of linzagolix; (ii) commenced a corporate restructuring to resize the company to be able to meet our license obligations; and (iii) filed an application to the competent court in Geneva, Switzerland for a court-sanctioned moratorium to facilitate the planned restructuring.

As a result of the termination of the Kissei License Agreement, our licensing agreement with Theramex HQ UK Limited ("Theramex") for the commercialization and further development of linzagolix across global markets outside of the U.S.,

Canada and Asia (the "Theramex License Agreement") was automatically assigned to Kissei and we have no further rights or obligations under the Kissei License Agreement or the Theramex License Agreement. In addition, we assigned to Kissei substantially all of our clinical, manufacturing, and scientific contracts related to the development of linzagolix representing approximately $4.9 million in transferred obligations to Kissei.

In September 2022, following a consultation process with our employees, the Board of Directors authorized the termination of approximately 70% of employees. We completed the terminations during the fourth quarter of 2022, saving approximately $7.6 million, on an annual basis, of cash compensation related to salary, bonus, and benefits to affected employees. In February 2023, as part of the Reorganization Plan, we further reduced our overall workforce by approximately 57%, including downsizing our US-based executive management team. We also expect to propose a reduced Board of Directors at our next Annual General Meeting of Shareholders. We expect to incur restructuring charges of approximately $1.2 million attributable to cash payments primarily for notice period payments, including healthcare coverage to employees with respect to eliminated positions and to realize annual savings of approximately $3.5 million. Such restructuring charges are expected to be incurred and recorded in the first quarter of 2023.

In November 2022, we entered into an IP Acquisition Agreement (the "IP Acquisition Agreement") with XOMA Corporation ("XOMA") for the sale of all of our rights to ebopiprant, a prior product candidate developed for the treatment of preterm labor by reducing inflammation and uterine contractions. Under the terms of the IP Acquisition Agreement, we sold to XOMA all of our rights to ebopiprant, including through the assignments to XOMA of (i) our July 2021 license agreement (the "Organon License Agreement") with Organon & Co. ("Organon"), (ii) our June 2015 license agreement with Merck KGaA, Darmstadt, Germany and (iii) the intellectual property estate related to ebopiprant. As consideration for the sale of all of our rights to ebopiprant under the IP Acquisition Agreement, we received an upfront cash payment from XOMA of $15.0 million upon the closing of the transaction, and we are eligible to receive up to approximately $98 million from XOMA upon the achievement of certain development and regulatory milestones and sales milestones under the Organon License Agreement that was assigned to XOMA in the transaction.

Proceeds from the IP Acquisition Agreement with XOMA resolved our overindebted position and positioned us to apply to the Swiss courts for the dismissal of the moratorium proceedings, which was granted by the courts on December 15, 2022, and to regain compliance with the Nasdaq Global Market's stockholders' equity requirement for continued listing in December 2022. On January 12, 2023, we received notice from Nasdaq that our application to transfer listing of our common shares from the Nasdaq Global Select Market to the Nasdaq Capital Market had been approved. The transfer was effective at the opening of business on January 17, 2023. On March 14, 2023, we received a delisting notice from Nasdaq notifying us that our common shares were scheduled for delisting from the Nasdaq Capital Market on March 23, 2023 due to our failure to regain compliance with Nasdaq Listing Rule 5450(a)(1) because the bid price of our common shares has not closed at or above $1.00 per share for a minimum of ten consecutive business days. As described above, our common shares began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF." See the risk factor in Part I. Item 1A. Risk Factors of this Annual Report titled "*Our common shares were delisted from The Nasdaq Capital Market and are currently traded on the over-the-counter ("OTC") market. There is currently a limited and sporadic trading market for our common shares, and liquidity of the common shares is limited. Subsequently, we also expect to deregister our common shares under the Exchange Act.*" for further information.

Also in November 2022, we and certain funds and accounts managed by JGB Management Inc. ("JGB") entered into a Consent and Amendment Agreement (the "Consent"), whereby JGB consented to our transaction with XOMA. Pursuant to the Consent and in connection with certain outstanding convertible notes issued to JGB, we agreed to maintain in a control account in favor of JGB a minimum cash balance of $6.7 million, representing the aggregate principal balance under the outstanding convertible notes as of the date of the Consent, provided such minimum cash balance shall be correspondingly reduced upon any conversion of the outstanding balance or payoff of the outstanding notes. In addition, pursuant to the terms of the Consent, the maturity date for each outstanding note was amended to December 31, 2023. See Note 5 for further information regarding our convertible notes and agreements with JGB. As of December 31, 2022, JGB had approximately $6.5 million in outstanding principal under the outstanding notes.

In February 2023, pursuant to a Payoff and Termination Agreement (the "Payoff Agreement"), we paid off the outstanding notes in full satisfaction of our obligations under the outstanding notes and under the related securities purchase agreement with JGB. Under the Payoff Agreement, JGB agreed to accept a reduced prepayment premium of (i)

approximately $0.6 million in cash and (ii) approximately $0.3 million in the form of 1,470,588 common shares of our company as prepayment for the outstanding notes.

Our Strategy

Key elements of our strategy include the following:

- Continue to advance the development program for nolasiban for the improvement of clinical pregnancy and live birth rates in women undergoing IVF;
- Strategically partner or out-license certain product candidates at later stages of development to focus our efforts on early to mid-stage product development; and
- In-license or acquire complementary immunotherapeutic technologies and product candidates that are either synergistic or complementary to our capabilities to expand our pipeline.

Nolasiban in IVF

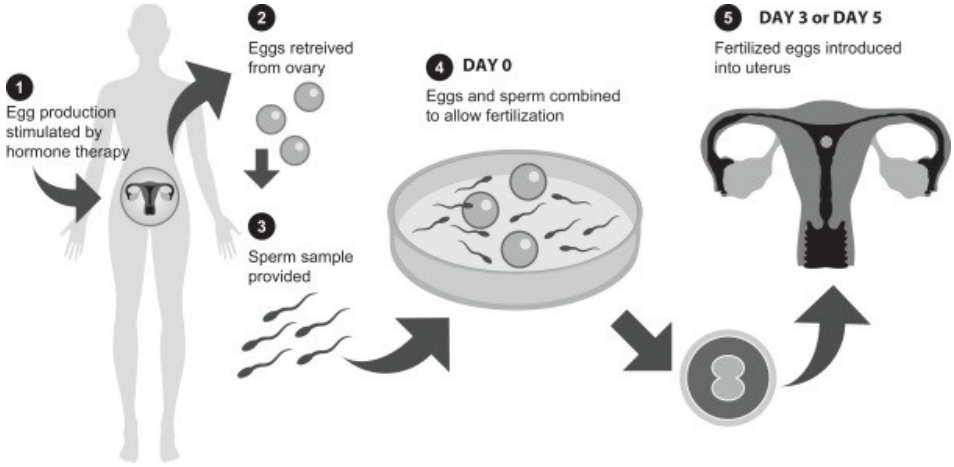
Nolasiban is an oral oxytocin receptor antagonist that is being developed to improve clinical pregnancy and live birth rates in women undergoing embryo transfer following IVF, including intracytoplasmic sperm injection, or ICSI. The mechanism of action of nolasiban supports its potential to improve uterine receptivity by decreasing uterine contractions, improve uterine blood flow and enhance the receptivity of the endometrium to embryo implantation. We in-licensed 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.

Assisted Reproductive Technology, or 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.

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:

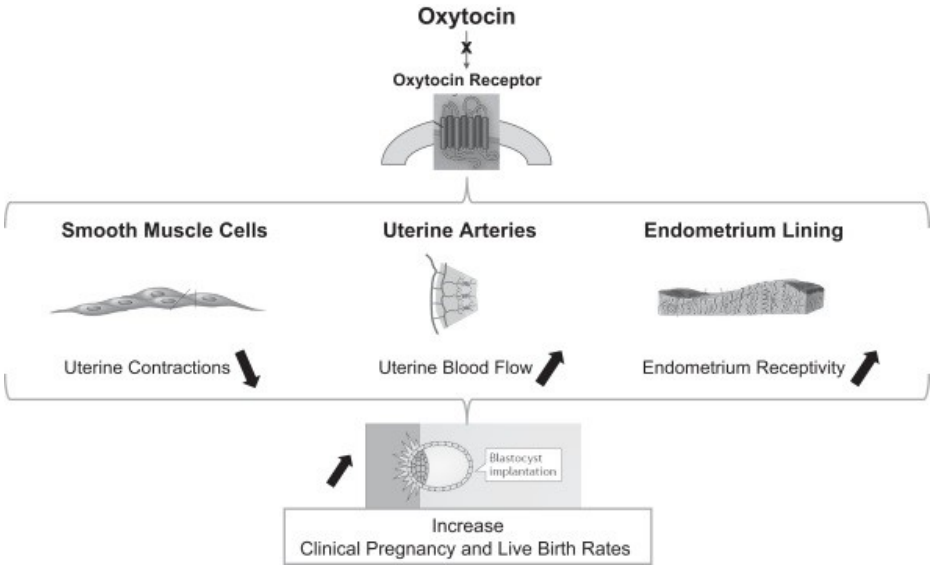


The cost of one IVF cycle varies between $8,000 to $15,000 in the United States, EUR 2,000 to EUR 10,000 in Europe and $3,000 to $6,000 in Japan. As of 2006, fertility drugs account for more than $2,000 of the cost of a treatment cycle. Most patients require multiple fertility treatment cycles. Data 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 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 or ET, were observed, based on three-dimensional power Doppler ultrasound, to have improved characteristics for uterine receptivity, including enhanced endometrial blood flow.

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 embryo transfer. 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.

In November 2018, we initiated an additional Phase 3 trial primarily in Europe, with some additional sites in Canada and Russia, also known as the IMPLANT 4 trial. In addition, we announced the clearance of our investigational new drug (IND) in October 2019 for the U.S. Phase 3 clinical trial of nolasiban, known as IMPLANT 3.

In November 2019, we announced that the IMPLANT 4 trial did not meet the primary endpoint of an increase in ongoing pregnancy rate at 10 weeks, (39.1 % placebo vs 40.5 % nolasiban) (p = 0.745). As these results did not confirm the prior positive Phase 3 IMPLANT 2 trial findings, we discontinued our previously ongoing development of nolasiban for IVF, and are exploring potential re-evaluating the compound, specifically through higher dose levels and longer exposure of nolasiban. 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 were published in the peer reviewed journal, *Human Reproduction*. A mechanism of study in health volunteers suggested 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 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, or 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 2021 with steering committee meetings to define the development plan for nolasiban in China for women undergoing ET following IVF.

In October 2022, we announced that Yuyuan Bioscience's (Yuyuan) IND application for a Phase 1 clinical trial of nolasiban was accepted by the Center for Drug Evaluation at the Chinese National Medical Products Administration. Yuyuan plans to initiate a single-center, randomized, double-blind, placebo-controlled Phase 1 clinical trial in China to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic characteristics of nolasiban in healthy adult female subjects.

Intellectual Property

We have filed numerous patent applications and have licensed numerous issued patents and patent applications pertaining to our product candidate, Nolasiban, and methods of manufacture and clinical use of the same. 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." 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, 2022, our patent portfolio as it pertains to our nolasiban product candidate included:

- nine United States (U.S.) patents, projected to expire between 2034 and 2035, two U.S. patent applications, which, if granted, project to expire between 2034 and 2035, 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 ("ART"); and

- three U.S. patent applications, which, if granted, project to expire between 2037 and 2041, as well as corresponding patents and patent applications internationally, directed to nolasiban dosing regimens, patient selection, and various other medical uses of nolasiban in the ART field.

As of December 31, 2022, our in-licensed patent portfolio as it pertains to our nolasiban product candidate 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.

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, and we license from third parties, issued patents in Europe that pertain to certain aspects of our nolasiban product candidate 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 candidate and methods of using or manufacturing the same. Moreover, we may be unable to obtain patent protection for certain aspects of our product candidate 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.

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 $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 digits, 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.

Agreements Related to Ebopiprant

In June 2015, we entered into a second license agreement with Merck Serono (the "2015 License Agreement"), which was amended in July 2016, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize ebopiprant. In July 2021, we entered into the Organon License Agreement, whereby Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant.

In November 2022, we entered into the IP Acquisition Agreement with XOMA for the sale of all of our rights to ebopiprant, which included the assignment to XOMA of the 2015 License Agreement and the Organon License Agreement. Pursuant to the IP Acquisition Agreement, we received an upfront payment of $15.0 million and are eligible to receive future milestone payments of up to approximately $98.0 million upon the achievement of certain development and regulatory milestones and sales milestones under the Organon License Agreement.

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. Large and established companies compete in the same market as our product candidate. These companies compete with us with their greater experience and resources to support their research and development efforts, conduct testing and clinical trials, obtain regulatory approvals to market products, manufacture such products on a broad scale and market approved products. These companies also compete with us by having significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the products that we develop obsolete. We also face competition from smaller companies who, like us, rely on investors to fund research and development and compete for co-development and licensing opportunities from large and established pharmaceutical companies.

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 and/or our ability to collect royalties or milestone payments 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 nolasiban or any other product candidate that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidate 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 nolasiban or any of our future product candidates less competitive.

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 chemistry, manufacturing and control ("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 institutional review board ("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 drug-drug interaction ("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 exists.

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 a risk evaluation and mitigation strategy ("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 Centers for Medicare & Medicaid Services ("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". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Prior to the Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period that remained open from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and additional 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 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

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. Moreover, Congress is considering additional health reform measures. For example, at the federal level, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services ("HHS") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. 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. 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.The full impact to overall physician reimbursement under the Medicare program as a result of the introduction of the Quality Payment Program remains unclear. 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 Regulation

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 below.

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), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Further, there are an increasing number of state laws that affect our business operations. Some state and local laws require manufacturers to make reports 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 does not ensure regulatory approval in another, but a failure or delay in obtaining 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 Committee for Medicinal Products for Human Use, or CHMP, of 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 the European Commission 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 data 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.

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities.

Manufacturing and Source of Supply

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 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. 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.

Employees and Human Capital Management

As of December 31, 2022, we had 15 full-time employees, 3 of whom hold Ph.D. degrees and 6 of whom hold other advanced degrees. Of our total workforce, 7 are engaged primarily in research and development activities and 8 are engaged primarily in executive, finance and accounting, and administrative functions. As of December 31, 2022, 5

employees are in the United States, 9 employees are in Switzerland, and one employee in the United Kingdom. In light of the Reorganization Plan and as of March 24, 2023, we had 6 full time employees. None are represented by labor unions or covered by collective bargaining agreements. We consider our relations with our employees to be good.

Compensation and Benefits Program

Our compensation program is designed to attract and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create long-term value for our shareholders. We provide employees with what we consider to be a very competitive mix of compensation and insurance benefits for all our employees, as well as participation in our equity programs.

Diversity and Inclusion

We believe that an equitable and inclusive environment with diverse teams produces more creative solutions, results in better, more innovative products and services and is crucial to our efforts to attract and retain key talent.

Available Information

Our common shares are currently trading on the OTC Pink Sheets Marketplace under the symbol "OBSF" and on SIX Swiss Exchange ("SIX") under the symbol "OBSN". Prior to March 23, 2023, our common shares were traded on The Nasdaq Capital Market under the symbol "OBSV". Our principal executive offices located at Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland. Our telephone number is + 41 22 552 38 40, and our Internet website is www.obseva.com and our investor relations website is located under the "Investors" tab. The information on, or that can be accessed through, our website is not part of this Annual Report and is not incorporated by reference herein.

We make available our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K, and amendments to these reports, free of charge through our website (www.obseva.com) as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We also make available on our website reports filed by our executive officers and Directors on Forms 3, 4, and 5 regarding their ownership of our securities. Our Code of Ethics, and any amendments to our Code of Ethics, are also available on our website under the "Investors" tab.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors

Investing in our common shares involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common shares. These risk factors and other uncertainties may cause our actual future results or performance to differ materially from any future results or performance expressed or implied in the forward-looking statements contained in this report and in other public statements we make. In addition, because of these risks and uncertainties, as well as other variables affecting our operating results, our past financial performance is not necessarily indicative of future performance. See "Special Note regarding Forward-Looking Statements" in this Annual Report.

Risks Related to Our Reorganization

We are consolidating our operations in Switzerland, where our headquarters are located and may experience disruption in our operations

On February 23, 2023, our board of directors approved a reorganization plan, to, among other things, consolidate our operations in Switzerland, where our headquarters are located. As part of the reorganization, we reduced our overall

workforce by approximately 57%, including downsizing our US-based executive management team and we expect to similarly propose a reduced board at our next Annual General Meeting of Shareholders (the "AGM"). We expect to incur restructuring charges of approximately $1.2 million attributable to cash payments primarily for notice period payments, including healthcare coverage to employees with respect to eliminated positions and to realize annual savings of approximately $3.5 million. Such restructuring charges are expected to be incurred and recorded in the first quarter of 2023. However, we may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur as a result of, or in connection with, the reorganization plan and reduction in workforce. Such charges, costs, cash expenditures or impairments could have a material adverse impact on our results of operations and financial condition.

In addition, the consolidation of our operations in Switzerland may have an impact on our operations and relationships with medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, as our reorganization may be disruptive to our day-to-day operations. This may result in 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, which could materially adversely impact our business and operations.

Furthermore, our common shares were delisted from The Nasdaq Capital Market in the United States. See the risk factor titled "*Our common shares were delisted from The Nasdaq Capital Market and are currently traded on the over-the-counter ("OTC") market. There is currently a limited and sporadic trading market for our common shares, and liquidity of the common shares is limited. Subsequently, we also expect to deregister our common shares under the Exchange Act.*" below for more information.

In connection with our reorganization, the composition of our executive management team and board of directors will change significantly.

In connection with our reorganization the composition of our board of directors will change significantly following our AGM. Currently only the Company's founder, Dr. Ernest Loumaye and Catarina Edfjäll will stand for re-election at our AGM. On March 10, 2023, Annette Clancy, chair of our board of directors, resigned as a director, with Dr. Loumaye succeeding Ms. Clancy and serving as interim chair of the board of directors, effective March 13, 2023 and until the AGM at which time he is expected to be nominated for this position for the upcoming year. In addition, as part of our reorganization our prior Chief Executive Officer, Brian O'Callaghan stepped down from his position effective February 23, 2023 and Will Brown our Chief Financial Officer is serving as interim Chief Executive Officer. On March 13, 2023, we announced that Fabien de Ladonchamps, currently Vice President, Corporate Affairs and Finance of our company, will be appointed as our Chief Executive Officer with an anticipated effective date of May 1, 2023. Additionally, Clive Bertram, former Chief Commercial Officer, Brandi Howard, former Chief Clinical Officer, and Luigi Marro, former Chief Transformation Officer also departed the Company effective February 23, 2023. While we expect to engage in an orderly transition process as we integrate newly appointed board members and new executives, our new board of directors and executive management team may change views on strategic initiatives and a range of issues that will determine the future of the Company. As a result, our future strategy and plans may differ materially from those of the past. See also the risk factor titled "*Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel*" below for more information.

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 $29.9 million and $53.0 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $472.8 million. 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 prior and current product candidates, as well as capital raising, and building our management team. We may be unable to commercialize our current product

candidate, nolasiban, 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 nolasiban;
- initiate preclinical studies and clinical trials for any additional indications for our current product candidate 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 and as a domestic issuer.

To become and remain profitable, we must develop and eventually commercialize one or more product candidates with significant market potential. This will require us or our licensees to be successful in a range of challenging activities, including completing clinical trials of nolasiban, or any other future product candidates that we may pursue, 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 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 our product candidate. If we are required by the U.S. Food and Drug Administration ("FDA") or other regulatory authorities such as the European Medicines Agency ("EMA"), to perform additional studies and trials, 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.

Our recurring losses, negative cash flows and significant accumulated deficit have raised substantial doubt regarding our ability to continue as a going concern.

We have incurred recurring losses since inception, including net losses of $29.9 million for the year ended December 31, 2022. As of December 31, 2022, we had an accumulated deficit of $472.8 million. We expect to continue to generate operating losses for the foreseeable future. As of December 31, 2022, we had cash and cash equivalents of $8.4. We

have prepared our consolidated financial statements assuming that we will continue as a going concern which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business.

To date, we have funded our operations through equity and debt offerings, through payments from licensors and through the sale of our rights to ebopiprant. We believe that our current cash and cash equivalents are only sufficient to fund our operating expenses into the fourth quarter of 2023 and this raises substantial doubt about our ability to continue as a going concern within one year from the date of the issuance of the consolidated financial statements appearing elsewhere in this Annual Report. Our future viability is dependent on our ability to raise additional capital to finance our future operations. We can potentially raise funds through equity or debt offerings. 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 our ability to pay dividends or make other distributions to shareholders. We may receive future milestone payments from licensors or pursuant to the IP Acquisition Agreement, but that is dependent on achieving certain regulatory or commercial milestones that may never happen. We may seek additional funding through public or private financings, debt financing or collaboration agreements. On March 14, 2023, we received a delisting notice from The Nasdaq Stock Market LLC ("Nasdaq") notifying us that our common shares were scheduled for delisting from the Nasdaq Capital Market on March 23, 2023 due to our failure to regain compliance with Nasdaq Listing Rule 5450(a)(1) because the bid price of our common shares has not closed at or above $1.00 per share for a minimum of ten consecutive business days. As a result, our common shares were delisted from The Nasdaq Capital Market and began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF." In addition, on March 28, 2023, we filed a post-effective amendment to various outstanding registration statements on Form F-3, which amendment was declared effective by the United States Securities and Exchange Commission (the "SEC") on March 29, 2023, and a post-effective amendment to various outstanding registration statements on Form S-8, which amendment became effective immediately upon filing, each to remove and withdraw from registration the shares that were registered but remained unsold thereunder. See the risk factor titled "*Our common shares were delisted from The Nasdaq Capital Market and are currently traded on the over-the-counter ("OTC") market. There is currently a limited and sporadic trading market for our common shares, and liquidity of the common shares is limited. Subsequently, we also expect to deregister our common shares under the Exchange Act.*" for more information. We expect that our delisting and deregistration will also impact our ability to obtain funding. The inability to obtain funding, as and when needed, would have a negative impact on our operations, financial condition and ability to pursue our business strategies. If we are unable to obtain the required funding to run our operations and to develop and commercialize our product candidate, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Management continues to explore all potential options to obtain additional funding. However, there is no assurance that we will be successful in raising funds, closing a collaboration agreement, obtaining sufficient funding on terms acceptable to us, or if at all, which could have a material adverse effect on our business, results of operations and financial conditions.

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 current and prior 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 candidate 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 candidate. Our expenses could increase beyond our current expectations if the FDA, EMA or other foreign regulatory agencies require us to perform additional clinical trials and other studies. In addition, our current and future 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 current and future 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, 2022, our cash and cash equivalents was $8.4 million.

We expect our current cash and cash equivalents will be sufficient to fund our operations through the fourth quarter of 2023. 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 nolasiban and any other future product candidates;
- the timing and amount of milestone payments we are required to make or that we may receive under our license or acquisition 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 current or any future product candidates;
- the continuing impact of the COVID-19 pandemic, including due to emerging variant strains of the virus with varying degrees of vaccine resistance, and the impact of the COVID-19 pandemic on our operations and the impact of macroeconomic conditions such as inflation, increasing interest rates, and recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures on global capital markets, which may affect our ability to conduct offerings;
- the costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for our current or any future 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 candidate 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 our product candidate, 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.

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. Following the payoff of the outstanding notes held by JGB, 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 or pursuant to the IP Acquisition Agreement. 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. We do currently hedge against certain currency risks, see "Item 7A— 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 Candidate

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 to nolasiban, and as a result, our business currently depends heavily on the successful development, regulatory approval and commercialization of this product candidate. We cannot be certain that our product candidate 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 candidate 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 candidate in the United States, the European Union or other jurisdictions will prevent us from commercializing and marketing our product candidate. The success of our product candidate 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 candidate;
- acceptance of our product candidate 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 candidate;
- competing effectively with other therapies, including with respect to the sales and marketing of our product candidate, 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 candidate 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 candidate, which would harm our business, financial condition and results of operations.

We will depend on Organon for the development and commercialization of ebopiprant.

We sold all of our rights to ebopiprant, a prior product candidate developed for the potential treatment for preterm labor, to XOMA in November 2022 pursuant to the IP Acquisition Agreement. Under the terms of the IP Acquisition Agreement, we are eligible to receive up to approximately $98.0 million from XOMA upon the achievement of certain development and regulatory milestones and sales milestones under our July 2021 license agreement (the "Organon License Agreement") with Organon & Co. ("Organon"), which was assigned to XOMA in the transaction. Under the terms of the Organon License Agreement, Organon is responsible for the development and commercialization of ebopiprant. The timing and amount of any milestone and royalty payments we may receive under the IP Acquisition Agreement with XOMA depends in part on the efforts and successful commercialization of ebopiprant by Organon. We do not control the individual efforts of Organon, and any failure by Organon to devote sufficient time and effort to the development and commercialization of ebopiprant; to meet its obligations to us, including for future milestone and royalty payments; to adequately deploy business continuity plans in the event of a crisis; or to satisfactorily resolve significant disagreements with us could each have an adverse impact on our financial results and operations. We also depend on Organon to comply with all applicable laws relative to the development and commercialization of ebopiprant. If Organon were to violate, or was alleged to have violated, any laws or regulations during the performance of its obligations for us, it is possible that we could suffer financial and reputational harm or other negative outcomes, including possible legal consequences.

Any termination, breach or expiration of the Organon License Agreement or IP Acquisition Agreement could have a material adverse effect on our financial position by reducing or eliminating the potential for us to receive milestones and royalties.

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 candidate is high. It is impossible to predict when or if our product candidate will prove effective or safe in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell our product candidate, we must demonstrate through extensive preclinical studies and clinical trials that our product candidate is 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 candidate 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 ebopiprant and nolasiban from Ares Trading S.A., an affiliate of Merck Serono, we were not involved in and had no control over its preclinical and clinical development prior to entering into the in-license agreement. In addition, we are relying on 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 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 this product candidate.

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 candidate.

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.

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 candidate, 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.

If we experience delays in the completion, or termination, of any clinical trial of our product candidate, the commercial prospects of our product candidate 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 candidate. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidate or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidate.

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 our product candidate. 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 our existing product candidate 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 our product candidate 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 candidate 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 candidate;
- our inability to demonstrate to the satisfaction of the FDA, EMA or the applicable foreign regulatory agency that our product candidate 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 candidate 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 candidate;
- 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 candidate.

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 candidate, 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 candidate 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.

We generally plan to seek regulatory approval to commercialize our product candidate in the United States, the European Union and other key global markets. With regard to our product candidate, 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 candidate. 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 candidate will result in the inability to market and sell such product. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidate could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidate 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 candidate, 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 candidate, or serious adverse or unacceptable side effects may be identified during the development of our product candidate, 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 candidate.

Before obtaining regulatory approvals for the commercial sale of our product candidate, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidate is 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 candidate 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.

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 candidate 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 candidate 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 candidate. 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 candidate 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, or as a result of geopolitical tensions or conflicts; 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 candidate, 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.

Delays in the completion of any clinical trial of our product candidate 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 candidate.

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, we have expended substantial efforts and expenses 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 candidate 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 candidate or any prospects for commercialization of our product candidate, 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 our product candidate 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 candidate.

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 Candidate

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 candidate and undertaking preclinical studies and clinical trials of our product candidate. We currently have no sales force, marketing or distribution capabilities. If our product candidate is approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidate, or

to outsource these functions to a third party. Either of these options could be expensive, time-consuming and delay launch of our product candidate, and these costs may be incurred in advance of any approval of our product candidate. 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. While we have a Chief Commercial Officer and Chief Transformation 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.

Entering into collaboration agreements with respect to marketing, sales or distribution may cause our product revenue to 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 such arrangements on acceptable terms, 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.

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 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 United States 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. Under the terms of the IP Acquisition Agreement, we are eligible to receive up to approximately $98.0 million from XOMA upon the achievement of certain development and regulatory milestones and sales milestones under the Organon License Agreement which was assigned to XOMA in the transaction.

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 candidate 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 candidate 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 candidate, 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 candidate, 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 candidate. Coverage under certain government programs, such as Medicare, Medicaid and Tricare, may not be available for our product candidate. 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 candidate 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 candidate, pricing of existing drugs may limit the amount we will be able to charge for our product candidate. 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 candidate 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 candidate.

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 candidate. 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 candidate. 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 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 candidate. We expect to experience pricing pressures in connection with the sale of any of our product candidate 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 any of our current or future product candidates, including nolasiban receive regulatory approval, or if ebopiprant, receives regulatory approval, they will remain subject to ongoing regulatory oversight.

Even if our current or future product candidates, including nolasiban, receive regulatory approval, or if ebopiprant receives regulatory approval, 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 the ability to commercialize such products. In addition, any potential regulatory approvals received for our product candidate 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 candidate, 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 candidate. 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 and generate revenue 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 candidate is 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. Nolasiban is 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. To the extent the price of our product candidate, 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 our product candidate is 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 candidate, 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 candidate, 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 candidate 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 candidate may require significant resources and may not be successful. If nolasiban or ebopiprant 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 or receive any earnout payments under the IP Acquisition Agreement. The degree of market acceptance of 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 candidate. Because we expect sales of our product candidate, if approved, to generate substantially all of our product revenue for the foreseeable future, the failure of our product candidate to find market acceptance would harm our business and could require us to seek additional financing.

In addition, the potential market opportunity for 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 nolasiban or our future product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for 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 or royalty payments from product sales may be limited and we may be unable to achieve or maintain profitability.

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 a license agreement with Merck Serono, pursuant to which we were granted exclusive worldwide licenses relating to nolasiban. We may enter into additional license agreements in the future. Our license agreement imposes, 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 nolasiban or any future product candidates. See "Item 1—Business Overview" for a more detailed description of our current license and acquisition agreements.

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 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 nolasiban or any future product candidates;
- lose patent protection for nolasiban or any future product candidates;
- experience significant delays in the development or commercialization of 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 candidate 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 our product candidate 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 candidate. The inability to obtain supply of the materials for our product candidate 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 candidate and, if approved, our commercial supply. 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 candidate 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 contract development manufacturing organizations, or CDMOs, with whom we currently work will need to increase scale of production, or we will need to secure alternate suppliers. For nolasiban, we obtain supply on a purchase order basis from a single source. However, we believe that there are multiple potential sources for our contract manufacturing for 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 candidate on a timely basis.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidate 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 candidate 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 candidate. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidate, the commercial launch of our product candidate 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 candidate.

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 candidate, 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 candidate 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 candidate, 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 candidate 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 candidate means that we are subject to the risk that our product candidate 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 have, and may in the future, enter into collaborations with third parties to develop our product candidate. If these collaborations are not successful, our business could be harmed.

In January 2020, we and 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 (the "PRC"). We may potentially enter into other collaborations with third parties in the future, and we will face, to the extent that we decide to enter into future 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. In addition, the terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any current or 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 candidate 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 candidate;
- a collaborator with marketing and distribution rights to our product candidate 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 current or potential future collaborations do not result in the successful development and commercialization of product candidates, or if a collaborator terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. If we do not receive the funding we expect under these agreements, the development of our product candidate could be delayed and we may need additional resources to develop our product candidate. In addition, if a collaborator 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 candidate will require substantial additional capital to fund expenses. For our product candidate, we may decide to collaborate with pharmaceutical and biotechnology companies for the future development and potential commercialization of those product candidates. 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 PRC. Under the terms of the sublicense agreement, Yuyuan has the exclusive rights to develop and commercialize nolasiban in the PRC. 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 collaborators' resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborators' 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 candidate 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 candidate, 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 candidate 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 changed 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. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, included 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". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period that remained open from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such additional challenges and 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, will remain in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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, the full impact to overall physician reimbursement under the Medicare program as a result of the introduction of the Quality Payment Program remains unclear. 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 Presidential executive orders, 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. For example, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, Congress is considering additional health reform measures. Additionally, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report within ninety (90) days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. However, 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 candidate 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 our product candidate, 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 candidate, 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 significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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 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 candidate 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) other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members.

- 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 a license agreement 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 candidate and rely on our licensor, Merck Serono, to prosecute and maintain other relevant patent rights for 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 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 candidate, 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 candidate, 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 licensor, have filed several patent applications covering various aspects of our product candidate. 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 candidate.

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 candidate 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 candidate 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 candidate or the use of our product candidate. 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 candidate. We may incorrectly determine that our product candidate is 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 candidate. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidate.

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 our product candidate 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 candidate 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 candidate 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 nolasiban or any future product candidates 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 candidate, 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 nolasiban formulations that are similar to 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 candidate 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 candidate.

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 current or future collaborators, to develop, manufacture, market and sell 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 candidate 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 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 candidate, 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 our product candidate 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 our product candidate, 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 agreement with Merck Serono gives 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 licensor 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 agreement with Merck Serono gives 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 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 candidate, 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 candidate. 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 candidate 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 candidate. 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

Litigation or legal proceedings could expose us to significant liabilities and have a negative impact on our reputation or business.

We are, and may in the future become, party to various claims and litigation proceedings, including pursuant to disputes under agreements we have previously assigned. We evaluate these claims and litigation proceedings to assess the likelihood of unfavorable outcomes and to estimate, if possible, the amount of potential losses. Based on these assessments and estimates, we may establish reserves, as appropriate. These assessments and estimates are based on the information available to management at the time and involve a significant amount of management judgment. Actual outcomes or losses may differ materially from our assessments and estimates.

Even when not merited, the defense of these lawsuits may divert our management's attention, and we may incur significant expenses in defending these lawsuits. The results of litigation and other legal proceedings are inherently uncertain, and adverse judgments or settlements in some of these legal disputes may result in adverse monetary damages, penalties or injunctive relief against us, which could have an adverse effect on our business, financial condition, results of operations and prospects. Any claims or litigation, even if fully indemnified or insured, could damage our reputation and make it more difficult to compete effectively or to obtain adequate insurance in the future.

Furthermore, while we maintain insurance for certain potential liabilities, such insurance does not cover all types and amounts of potential liabilities and is subject to various exclusions as well as caps on amounts recoverable. Even if we believe a claim is covered by insurance, insurers may dispute our entitlement to recovery for a variety of potential reasons, which may affect the timing and, if the insurers prevail, the amount of our recovery.

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 our principal executives and officers. 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 candidate in markets outside of the United States and the European Union. If we commercialize our product candidate 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.

If our information technology systems or sensitive information, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including, but not limited to, regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits, and other adverse consequences.

In the ordinary course of our business, we may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property, and trade secrets (collectively, sensitive information).We may share or receive sensitive information with or from third-party service providers and rely upon third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third-party providers of cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to cyberattacks, malicious internet-based activity and online and offline fraud. These threats are prevalent, continue to increase, and are becoming increasingly difficult to detect. These threats include, but are not limited to, malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), natural disasters, terrorism, war, telecommunication and electrical failures, social engineering attacks (including through phishing attacks), personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us. Additionally, the COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

These threats come from a wide variety of sources, including threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. These parties are expected to continue to engage in cyber-attacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. For example, we may have operations and third parties upon which we rely to support our business located in unstable regions and regions experiencing (or expected to experience) geopolitical or other conflicts, including Ukraine, including through the use of cyber-attacks.

Any of the previously identified or similar threats could cause a security incident or other interruption. 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.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be

detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may negatively impact our ability to grow and operate our business, including delaying the further development of our product candidate.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

If we fail or are perceived to have failed 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.

In the ordinary course of business, we process personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

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, govern the collection, use, disclosure, and protection of health-related and other personal data. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. 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 HIPAA. 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.

Additionally, the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, imposes obligations on covered businesses. The CCPA gives California residents expanded rights to access and delete their personal data, opt out of certain personal data sharing, and receive detailed information about how their personal data is used. The CCPA provides for civil penalties for violations (up to $7,500 per violation), as well as a private right of action for certain data breaches that is expected to increase data breach litigation. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase our compliance costs and potential liability with respect to other personal data we maintain about California residents. It is anticipated that the California Privacy Rights Act of 2020, or CPRA, effective January 1, 2023, will expand the CCPA. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws as well. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. Several states and localities have also enacted statutes banning or restricting the collection of biometric information. Additionally, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law, or PIPL, impose strict requirements for processing personal data. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data. The GDPR also imposes heightened restrictions on processing of special categories of personal data, such as health and genetic personal data.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts 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. The European Commission released a set of "Standard Contractual Clauses," or SCCs, that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries such as the United States that do not provide an adequate level of personal data protection, and certain countries outside Europe (e.g. Russia, China, Brazil) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders, any of which could increase the cost and complexity of doing business. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or other.

If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of 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 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.

We may be negatively impacted by volatility in the political and economic environment, such as the ongoing crisis in Ukraine, economic downturns and increases in interest rates, recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures and a period of sustained inflation across the markets in which we operate could result in higher operating costs and may negatively impact our business and financial performance.

Trade, monetary and fiscal policies, and political and economic conditions may substantially change, and credit markets may experience periods of constriction and variability. These conditions may impact our business. Furthermore, rising inflation may negatively impact our business, increase costs and reduce profitability. The COVID-19 pandemic has also resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. While we would take actions, wherever possible, to mitigate the impact of the effects of inflation, in the case of sustained inflation across several of the markets in which we operate, it could become increasingly difficult to effectively mitigate the increases to our costs. If we are unable to take actions to effectively mitigate the effect of the resulting higher costs, our profitability and financial position could be negatively impacted.

The U.S. Federal Reserve has recently raised interest rates multiple times in response to concerns about inflation among other things, and it may raise them again. In fact, it has indicated its intention to continue to raise interest rates. Higher interest rates, coupled with reduced government spending and volatility in financial markets may increase economic uncertainty. Similarly, the ongoing military conflict between Russia and Ukraine as well as recent and potential future disruptions in access to bank deposits and lending commitments due to bank failure has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including disruptions of the global supply chain and energy markets. Any such volatility and disruptions may adversely affect our business or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. Increased inflation rates can adversely affect us by increasing our costs, including labor and

employee benefit costs. In addition, higher inflation and macro turmoil and uncertainty could also adversely affect our customers, which could reduce demand for our products.

Risks Related to Our Common Shares

Our common shares were delisted from The Nasdaq Capital Market and are currently traded on the over-the-counter ("OTC") market. There is currently a limited and sporadic trading market for our common shares, and liquidity of the common shares is limited. We also expect to deregister our common shares under the Exchange Act.

As previously disclosed, our common shares were delisted from The Nasdaq Capital Market and began trading on the OTC market on March 23, 2023 under the symbol "OBSVF." In addition, on March 28, 2023, we filed a post-effective amendment to various outstanding registration statements on Form F-3, which amendment was declared effective by the United States Securities and Exchange Commission (the "SEC") on March 29, 2023, and a post-effective amendment to various outstanding registration statements on Form S-8, which amendment became effective immediately upon filing, each to remove and withdraw from registration the shares that were registered but remained unsold thereunder. We can provide no assurance that our common shares will continue to trade on the OTC market, whether broker-dealers will continue to provide public quotes of our common shares on this market, whether the trading volume of our common shares will be sufficient to provide for an efficient trading market or whether quotes for our common shares will continue on this market in the future, which could result in significantly lower trading volumes and reduced liquidity for investors seeking to buy or sell our common shares. Furthermore, because of the limited market and generally low volume of trading in our common shares, the price of our common shares could be more likely to be affected by broad market fluctuations, general market conditions, and changes in the markets' perception of our common shares.

We intend to file a Form 15 with the SEC, at which time we anticipate that our obligation to file periodic reports under the Exchange Act, including annual reports on Form 10-K, quarterly reports on Form 10-Q, and current reports on Form 8-K will be suspended, and that all requirements associated with being an Exchange Act-registered company, including the requirement to file current and periodic reports, will terminate 90 days thereafter. Accordingly, there will be significantly less information regarding us available to shareholders and potential investors.

Following delisting and deregistration, it could become more difficult to dispose of, or obtain accurate price quotations for, our common shares, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common shares to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major American exchange.

"Penny stock" rules may make buying or selling our securities difficult which may make our common shares less liquid and make it harder for investors to buy and sell our securities.

Trading in our securities is subject to the "penny stock" rules of the SEC and it is anticipated that trading in our securities will continue to be subject to the penny stock rules for the foreseeable future. The SEC has adopted regulations that generally define a penny stock to be any equity security that has a market price of less than $5.00 per share, subject to certain exceptions. These rules require that any broker-dealer who recommends our securities to persons other than prior customers and accredited investors must, prior to the sale, make a special written suitability determination for the purchaser and receive the purchaser's written agreement to execute the transaction. Unless an exception is available, the regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated with trading in the penny stock market. In addition, broker-dealers must disclose commissions payable to both the broker-dealer and the registered representative and current quotations for the securities they offer. The additional burdens imposed upon broker-dealers by these requirements may discourage broker-dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities.

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. In addition, our common shares have been delisted from Nasdaq and now trades on the OTC market. See also the risk factor titled "*Our common shares were delisted from The Nasdaq Capital Market and are currently traded on the over-the-counter ("OTC") market. There is currently a limited and sporadic trading market for our common shares, and liquidity of the common shares is limited. Subsequently, we also expect to deregister our common shares under the Exchange Act.*" above.

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 our product candidate;
- 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 our product candidate 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.

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, 2022, 107,706,699 common shares were issued and outstanding. In addition, on February 23, 2023, we issued 1,470,588 common shares to JGB in connection with the payoff and termination agreement and on February 28, 2023, we entered into a share purchase agreement with Dr. Loumaye pursuant to which we sold 4,000,000 common shares. 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.

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. 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. 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 and are consolidating our operations in Switzerland as part of our reorganization. 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.

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, and situations may arise where greater flexibility would have provided benefits to our shareholders.

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

We have not determined our PFIC status for the year ended December 31, 2022. 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 relative to our total assets. 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, 2022 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 percentage (as determined under applicable Treasury Regulations) of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, if a non-U.S. corporation owns directly or indirectly at least 25% of the stock of another entity treated as a corporation or partnership for U.S. federal income tax purposes (or, in the case of a partnership, the non-U.S. corporation satisfies active partner tests with respect to the partnership), the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of such entity and as receiving directly its proportionate share of the other entity's income. 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 below) 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.

A "U.S. Holder" is a holder of our common stock who, for U.S. federal income tax purposes: 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 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.

If a U.S. Holder 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 shares (as determined for U.S. federal income tax purposes), 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 shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any 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 income is 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 informally titled the Tax Cuts and Jobs Act (the "Tax Act"); the Coronavirus Aid, Relief, and Economic Security Act; and the Inflation Reduction 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 such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to 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.

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

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal executive offices are located in Geneva, Switzerland, where we occupy approximately 11,711 square feet of office space. For additional information, see Note 8 to our consolidated financial statements.

Management believes that these facilities are suitable and adequate to meet our anticipated needs.

Item 3. Legal Proceedings

None.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common shares previously traded on The Nasdaq Capital Market under the symbol "OBSV." On March 23, 2023, our common shares were delisted from The Nasdaq Capital Market and began trading on the over-the-counter market under the symbol "OBSVF." Our common shares are also traded on SIX Swiss Exchange (SIX) under the symbol "OBSN".

Holders

As of March 24, 2023, we had 21 record holders of our common shares. The number of record holders is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividends

We have never declared or paid any cash dividends on our capital stock. We intend to retain future earnings, if any, to finance the operation and expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is contained in Part III, Item 12 of this Annual Report under the heading Equity Compensation Plans and is incorporated herein by reference.

Recent Sales of Unregistered Securities

In connection with certain transactions related to our securities purchase agreement with JGB during 2022 we had issued our common shares to JGB upon conversion of convertible notes, as described under Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Securities Purchase Agreement with JGB." Such issuances were pursuant to Section 4(a)(2) under the Securities Act of 1933, as amended.

Use of Proceeds

None.

Purchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis contains forward-looking statements that involve substantial risks and uncertainties. See "Forward-looking statements" in Part I of this Annual Report and the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report for a discussion of certain factors that could cause actual results or events to differ materially from the forward-looking statements that we make.

Overview

We are a biopharmaceutical company focused on the development of novel therapies to improve women's reproductive health. We are advancing a development program for nolasiban, an oral oxytocin receptor agonist, focused on improving clinical pregnancy and live birth rates in women undergoing in-vitro fertilization.

We in-licensed nolasiban from Ares Trading S.A., an affiliate of Merck Serono ("Merck Serono"), in August 2013. We currently have worldwide, exclusive, commercial rights for nolasiban, except for the People's Republic of China, where it has been sub-licensed to Yuyuan BioScience ("Yuyuan") in January 2020. In October 2022, we announced that Yuyuan's Investigational New Drug ("IND") application for a Phase 1 clinical trial of nolasiban has been accepted by the Center for Drug Evaluation at the Chinese National Medical Products Administration. Yuyuan plans to initiate a single-center, randomized, double-blind, placebo-controlled Phase 1 clinical trial in China to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic characteristics of nolasiban in healthy adult female subjects.

In February 2023, our Board of Directors approved a reorganization plan (the "Reorganization Plan"), to, among other things, consolidate our operations in Switzerland, where our headquarters are located. Following the Reorganization Plan, we notified The Nasdaq Stock Market LLC ("Nasdaq") of our inability to comply with the Nasdaq minimum bid price. On March 14, 2023, Nasdaq notified us that our common shares were to be delisted from The Nasdaq Capital Market and suspended at the opening of business on March 23, 2023. Our common shares began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF." On March 28, 2023, we filed a post-effective amendment to various outstanding registration statements on Form F-3, which amendment was declared effective by the United States Securities and Exchange Commission (the "SEC") on March 29, 2023, and a post-effective amendment to various outstanding registration statements on Form S-8, which amendment became effective immediately upon filing, each to remove and withdraw from registration the shares that were registered but remained unsold thereunder. We intend to file with the SEC a Form 15 requesting the deregistration of our common shares under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the suspension of our reporting obligations under Section 13 and Section 15(d) of the Exchange Act, subject to meeting certain conditions to deregistration, including the condition that we have fewer than 300 record holders of our common shares.

At June 30, 2022, the last business day of our second quarter, we determined that we no longer qualified as a foreign private issuer under Rule 3b-4(c) of the Exchange Act. As a result, beginning January 1, 2023, we are required to report with the SEC on domestic forms and comply with domestic company rules in the United States. The transition to generally accepted accounting principles in the United States (“U.S. GAAP”) from International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS") was made retrospectively for all periods from our inception.

We were founded in November 2012 and our operations to date have included organizing and staffing our company, raising capital, in-licensing rights to our portfolio 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 and debt. From inception through December 31, 2022, we raised an aggregate of $447.7 million of net proceeds from the sale of equity securities and $64.5 million from the issuance of debt instruments, of which $62.5 million has been repaid.

We have never been profitable and have incurred significant net losses in each period since our inception. Our net losses were $29.9 million and $53.0 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $472.8 million. We expect to continue to incur operating losses for the foreseeable future. We used $23.1 million and $50.4 million of cash in operations in the years ended December 31, 2022 and 2021, respectively.

We anticipate that our expenses will remain substantial in connection with our ongoing activities as we continue to invest in any clinical trials, nonclinical studies and pre-commercial activities that we may conduct for nolasiban. We will need substantial additional funding to support our operating activities as we advance our product candidate through clinical development, seek regulatory approval and prepare for and invest in future commercialization of this candidate, 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 development and commercialization of our product candidate, including through collaborations with third parties.

We have no manufacturing facilities, and all of our product manufacturing is contracted out to third parties. We currently utilize third-party contract research organizations, or CROs, to carry out our clinical development and trials.

Recent Developments

In July 2022, we initiated a corporate restructuring and refocusing of our development and commercialization strategies following the receipt of a notice from the U.S. Food and Drug Administration (“FDA”) of review issues regarding deficiencies in our New Drug Application (“NDA”) for linzagolix, a prior product candidate developed for the potential treatment of uterine fibroids. These review issues precluded discussion of labeling and post-marketing commitments. As a result, we undertook the following actions in July 2022: (i) gave notice of termination of our license agreement (the “Kissei License Agreement”) with Kissei Pharmaceutical Co., Ltd (“Kissei”) for the development and commercialization of linzagolix; (ii) commenced a corporate restructuring to resize the company to be able to meet our license obligations; and (iii) filed an application to the competent court in Geneva, Switzerland for a court-sanctioned moratorium to facilitate the planned restructuring.

As a result of the termination of the Kissei License Agreement, our licensing agreement with Theramex HQ UK Limited (“Theramex”) for the commercialization and further development of linzagolix across global markets outside of the U.S., Canada and Asia (the “Theramex License Agreement”), was automatically assigned to Kissei and we have no further rights or obligations under the Kissei License Agreement or the Theramex License Agreement. In addition, we assigned to Kissei substantially all of our clinical, manufacturing, and scientific contracts related to the development of linzagolix representing approximately $4.9 million in transferred obligations to Kissei.

In September 2022, following a consultation process with our employees, the Board of Directors authorized the termination of approximately 70% of employees. We completed the terminations during the fourth quarter of 2022, saving approximately $7.6 million, on an annual basis, of cash compensation related to salary, bonus, and benefits to affected employees. In February 2023, as part of the Reorganization Plan, we further reduced our overall workforce by

approximately 57%, including downsizing our US-based executive management team. We also expect to propose a reduced Board of Directors at our next Annual General Meeting of Shareholders. We expect to incur restructuring charges of approximately $1.2 million attributable to cash payments primarily for notice period payments, including healthcare coverage to employees with respect to eliminated positions and to realize annual savings of approximately $3.5 million. Such restructuring charges are expected to be incurred and recorded in the first quarter of 2023.

In November 2022, we entered into an IP Acquisition Agreement (the "IP Acquisition Agreement") with XOMA Corporation ("XOMA") for the sale of all of our rights to ebopiprant, a prior product candidate developed for the treatment of preterm labor by reducing inflammation and uterine contractions. Under the terms of the IP Acquisition Agreement, we sold to XOMA all of our rights to ebopiprant, including through the assignments to XOMA of (i) our July 2021 license agreement (the "Organon License Agreement") with Organon & Co. ("Organon"), (ii)our June 2015 license agreement with Merck KGaA, Darmstadt, Germany and (iii) the intellectual property estate related to ebopiprant. As consideration for the sale of all of our rights to ebopiprant under the IP Acquisition Agreement, we received an upfront cash payment from XOMA of $15.0 million upon the closing of the transaction, and we are eligible to receive up to approximately $98 million from XOMA upon the achievement of certain development and regulatory milestones and sales milestones under the Organon License Agreement that was assigned to XOMA in the transaction.

Proceeds from the IP Acquisition Agreement with XOMA resolved our overindebted position and positioned us to apply to the Swiss courts for the dismissal of the moratorium proceedings, which was granted by the courts on December 15, 2022, and to regain compliance with The Nasdaq Global Market's stockholders' equity requirement for continued listing in December 2022. On January 12, 2023, we received notice from Nasdaq that our application to transfer listing of our common shares from the Nasdaq Global Select Market to the Nasdaq Capital Market had been approved. The transfer was effective at the opening of business on January 17, 2023. On March 14, 2023, we received a delisting notice from Nasdaq notifying us that our common shares were scheduled for delisting from the Nasdaq Capital Market on March 23, 2023 due to our failure to regain compliance with Nasdaq Listing Rule 5450(a)(1) because the bid price of our common shares has not closed at or above $1.00 per share for a minimum of ten consecutive business days. As described above, our common shares began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF." See the risk factor in Part I. Item 1A. Risk Factors of this Annual Report titled "*Our common shares were delisted from The Nasdaq Capital Market and are currently traded on the over-the-counter ("OTC") market. There is currently a limited and sporadic trading market for our common shares, and liquidity of the common shares is limited. Subsequently, we also expect to deregister our common shares under the Exchange Act.*

Also in November 2022, we and certain funds and accounts managed by JGB Management Inc. ("JGB") entered into a Consent and Amendment Agreement (the "Consent"), whereby JGB consented to our transaction with XOMA. Pursuant to the Consent and in connection with certain outstanding convertible notes issued to JGB, we agreed to maintain in a control account in favor of JGB a minimum cash balance of $6.7 million, representing the aggregate principal balance under the outstanding convertible notes as of the date of the Consent, provided such minimum cash balance shall be correspondingly reduced upon any conversion of the outstanding balance or payoff of the outstanding notes. In addition, pursuant to the terms of the Consent, the maturity date for each outstanding note was amended to December 31, 2023. See Note 5 for further information regarding our convertible notes and agreements with JGB. As of December 31, 2022, JGB had approximately $6.5 million in outstanding principal under the outstanding notes. In February 2023, pursuant to a Payoff and Termination Agreement (the "Payoff Agreement"), we paid off the outstanding notes in full satisfaction of our obligations under the outstanding notes and under the related securities purchase agreement with JGB. Under the Payoff Agreement, JGB agreed to accept a reduced prepayment premium of (i) approximately $0.6 million in cash and (ii) approximately $0.3 million in the form of 1,470,588 common shares of our company as prepayment for the outstanding notes.

Macroeconomic Considerations

Unfavorable conditions in the economy in the United States and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, including the COVID-19 pandemic, rising inflation, the U.S. Federal Reserve raising interest rates, recent and potential future disruptions in access to bank deposits and lending commitments due to bank failures and the Russia-Ukraine war, have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If,

however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed. For further discussion of the potential impacts of macroeconomic events on our business, financial condition, and operating results, see the section titled "Risk Factors."

Strategic Licensing Agreements

Agreements to Nolasiban

Ares Trading

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 USD 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.

YuYuan

In January 2020, we entered into the YuYuan Sublicense Agreement with YuYan, 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 YuYuan 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 digits, 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.

Agreements Related to Ebopiprant

Merck Serono

In June 2015, we entered into the 2015 license agreement with Merck Serono (the "Merck Serono 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.

As a result of the IP Acquisition Agreement with XOMA, the Merck Serono License Agreement was automatically assigned to XOMA and we have no further rights or obligations under the agreement.

Organon

In July 2021, we entered into an agreement with Organon (the "Organon License Agreement"), pursuant to which we granted to Organon exclusive rights to develop, use, register, import, export, manufacture, market, promote, distribute, offer for sale and commercialize ebopiprant worldwide. In consideration for entering into the agreement, Organon has agreed to make up to $500 million in upfront and milestone payments, including $25 million that was paid at signing, up to $90 million in development and regulatory milestones and up to $385 million in sales-based milestones. In addition, Organon has agreed to pay us tiered double-digit royalties on annual net sales of all products, subject to specified reductions, until, on a country-by-country and product-by-product basis, the latest of (i) the expiration of the last valid

claim covering such product in such country, (ii) expiration of regulatory exclusivity for such product in such country, and (iii) ten years from the first commercial sale of such product in such country.

XOMA

In November 2022, we entered into the IP Acquisition Agreement with XOMA for the sale of all of our rights to ebopiprant, which included the assignment to XOMA of the Merck Serono License Agreement and the Organon License Agreement. Pursuant to the IP Acquisition Agreement, we received an upfront payment of $15.0 million and are eligible to receive future milestone payments of up to approximately $98 million upon the achievement of certain development and regulatory and sales milestones under the Organon License Agreement.

Financial Operations Overview

The consolidated financial information presented below includes the accounts of ObsEva SA, ObsEva USA, Inc., ObsEva Ireland Limited, and ObsEva Europe B.V. All intercompany accounts and transactions have been eliminated in consolidation.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and we do not expect to generate revenue unless and until we successfully complete development and obtain regulatory approval for our product candidate.

Revenue consists primarily of revenue from licensing arrangements and collaboration arrangements.

Our collaboration revenue consists of the full recognition of the upfront payment from the Theramex License Agreement that was triggered upon obtaining the marketing authorization from the European Commission in June 2022. We do not expect to earn collaboration revenue in future periods on the Theramex License Agreement as it was automatically assigned to Kissei upon the termination of the Kissei License Agreement. Accordingly, we have no further rights or obligations under the agreement.

Our license revenue consists of the recognition of the upfront payment we received from XOMA pursuant to the terms of the IP Acquisition Agreement. We are eligible to receive up to approximately $98.0 million in milestone and royalty payments from XOMA upon the achievement of certain development and regulatory milestones and sales milestones. The timing and amount of any milestone and royalty payments we may receive under the IP Acquisition Agreement with XOMA depends in part on the efforts and successful commercialization of ebopiprant by Organon.

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; 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.

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 candidate through clinical trials and regulatory submissions. We are also unable to predict when, if ever, material net cash inflows will commence from sales of our product candidate. This is due to the numerous risks and uncertainties associated with developing such product candidate, 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 candidate 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 candidate 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 expenses related to regulatory affairs and intellectual property, commercialization readiness costs, 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 decrease in the future as a result of our corporate restructuring. We also anticipate that we will continue spending material accounting, audit, legal, regulatory and compliance costs, as well as investor and public relations expenses, associated with operating as a public company.

Other income (expense), net

Other income (expense), net consists of interest expense associated with our lease liabilities and debt instruments, the loss associated with the early retirement of the outstanding convertible notes, the change in fair value of the warrant and derivative liabilities, and gains in foreign exchange.

Interest expense

Our interest expense consists primarily of interest expense pursuant to the Securities Purchase Agreement with JGB, which bears an interest rate at 9.5%. We anticipate that our interest expense will decrease in the future as the principal balance on the outstanding convertible notes held by JGB was early retired in February 2023.

Loss on debt extinguishment

Loss on debt extinguishment consists of the loss associated with the early retirement of the outstanding convertible notes under the Securities Purchase Agreement with JGB and represents the difference between the consideration paid and the carrying value of the Outstanding Notes upon extinguishment.

Change in fair value of warrant liability

Warrants to purchase common share issued in connection with the Securities Purchase Agreement with JGB are classified as a warrant liability and recorded at fair value. These warrants contain a feature that could require the potential transfer of cash in the event a change of control occurs and therefore, are classified as a liability in accordance with ASC 480, *Distinguishing Liabilities from Equity*.

The fair values of the warrants are estimated on the date of issuance, and each subsequent balance sheet date, using the Black-Scholes valuation model using the appropriate risk-free interest rate, expected term and volatility assumptions. This warrant liability is subject to remeasurement at each balance sheet date and we recognize any change in the fair value of the warrant liability in the consolidated statements of comprehensive loss. We will continue to adjust the carrying value of the warrants for changes in the estimated fair value until the earlier of the modification, exercise or expiration of the warrants. At that time, the liabilities will be reclassified to additional paid-in capital, a component of shareholders' equity. We anticipate that the value of the warrants could fluctuate from quarter to quarter and that such fluctuation could have a material impact on our financial statements from quarter to quarter and year to year.

Change in fair value of derivative liability

We determined that certain features under our convertible notes required bifurcation from the debt host agreement in accordance with ASC 815, *Derivatives and Hedging*. Accordingly, we recognized a derivative liability at fair value for this instrument in our consolidated balance sheets and adjusted the carrying value of the liability to fair value at each reporting period until the conversion option underlying the instrument was exercised or expired. The changes in fair value were assessed quarterly and recorded in our consolidated statements of operations and comprehensive loss.

Foreign exchange gain, net

Our foreign exchange gain, net for the year ended December 31, 2022, consists of the impact of changes in foreign currency exchange rates on our foreign exchange denominated liabilities, relative to the U.S. dollar. The impact of foreign currency exchange rates on our results of operations fluctuates period over period based on our foreign currency exposures resulting from changes in applicable exchange rates associated with our foreign denominated liabilities. Our primary foreign currency exposure has historically been the exchange rate between the Swiss franc and the U.S. dollar.

Taxation

We are subject to corporate taxation in Switzerland, Ireland, Netherlands 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, 2022, we had tax loss carryforwards totaling $x million. We have recorded a full valuation allowance against our deferred tax assets as we believe they are not more likely than not realizable.

Our Swiss, Irish and Dutch subsidiaries had no activity in 2022 or 2021. Our US subsidiary, as a service organization to the group under cost plus arrangement, was the only entity to generate income tax expenses during 2022 and 2021.

Results of Operations

Comparison of years ended December 31, 2022 and December 31, 2021:

(in thousands except percentages)	Year Ended December 31, 2022	2021	Increase (Decrease)	
Net revenues				
Revenue from licensing arrangements	$ 14,197	22,200	$ (8,003)	(36)%
Revenue from collaboration arrangements	5,440	—	5,440	100 %
Total net revenues	19,637	22,200	(2,563)	(12)%
Operating income (expense)				
Research and development	(10,710)	(53,894)	43,184	(80)%
General and administrative	(24,725)	(25,021)	296	(1)%
Other operating income	121	108	13	12 %
Total operating income (expense)	(35,314)	(78,807)	43,493	(55)%
Loss from operations	(15,677)	(56,607)	(46,056)	81 %
Other income (expense)				
Interest expense	(9,228)	(3,426)	(5,802)	169 %
Loss on debt extinguishment	(14,155)	(1,362)	(12,793)	939 %
Change in fair value of warrant liability	1,270	792	478	60 %
Change in fair value of derivative liability	6,940	7,743	(803)	(10)%
Foreign exchange gain, net	982	94	888	945 %
Total other (expense) income	(14,191)	3,841	(18,032)	(469)%
Net loss before income tax benefit	(29,868)	(52,766)	22,898	(43)%
Income tax expense	(11)	(213)	202	(95)%
Net loss	$ (29,879)	(52,979)	$ 23,100	(44)%

Revenue

The following is a summary of revenue for the years ended December 31, 2022 and 2021:

(in thousands except percentages)	Year Ended December 31, 2022	2021	Increase (Decrease)	
Net revenues				
Revenue from licensing arrangements	$ 14,197	22,200	$ (8,003)	100 %
Revenue from collaboration arrangements	5,440	—	5,440	100 %
Total net revenues	$ 19,637	22,200	$ (2,563)	(12)%

Revenue decreased by $2.6 million, or 12% for the year ended December 31, 2022 as compared to December 31, 2021. The decrease was primarily the result of:

- a decrease of $8.0 million in revenue from licensing arrangements resulting from the difference in net upfront proceeds received pursuant to the XOMA IP acquisition agreement of $14.2 million entered into in November 2022, as compared to the net upfront proceeds received pursuant to the Organon License Agreement of $22.2 million entered into in July 2021; offset by,

- an increase of $5.4 million in revenue from collaboration arrangements attributable to the net upfront proceeds received pursuant to the Theramex License Agreement.

Research and development expenses

The following is a summary of research and development expenses for the years ended December 31, 2022 and 2021:

(in thousands except percentages)	Year Ended December 31, 2022	2021	Increase (Decrease)	
Directly allocable research and development expenses	$ 905	38,692	$ (37,787)	(98)%
Unallocated expenses				
Staff costs	7,972	11,643	(3,671)	(32)%
Other research and development costs	1,833	3,559	(1,726)	(48)%
Total research and development expenses	$ 10,710	53,894	$ (43,184)	(80)%

Research and development expenses decreased by $43.2 million, or 80%, during the year ended December 31, 2022 as compared to 2021. The decreased expense was primarily due to:

- a decrease of $37.8 million in directly allocable research and development expenses due to lower expenditures in our linzagolix program resulting from the termination of the Kissei License Agreement and assignment of linzagolix contractual obligations related to the linzagolix program to Kissei; and
- a decrease of $3.7 million in unallocated staff costs due to lower salary, bonus, and share based compensation expenses as a result of our termination of approximately 70% of our employees as announced in September 2022, a majority of whom were responsible for research and development activities.

General and administrative expenses

The following is a summary of general and administrative expenses for the years ended December 31, 2022 and 2021:

(in thousands except percentages)	Year Ended December 31, 2022	2021	Increase (Decrease)	
Staff costs	$ 9,205	10,331	$ (1,126)	(11)%
Professional fees	10,171	10,464	(293)	(3)%
Other general and administrative costs	5,349	4,226	1,123	27 %
Total general and administrative expenses	$ 24,725	25,021	$ (296)	(1)%

General and administrative expenses decreased by $0.3 million, or 1%, during the year ended December 31, 2022 as compared to 2021. The decreased expense is primarily due to a decrease in personnel-related expenses such as salaries and bonuses.

Other income (expense), net

The following is a summary of Other income (expense), net for the years ended December 31, 2022 and 2021:

(in thousands except percentages)	Year Ended December 31, 2022	2021	Increase (Decrease)	
Interest expense	$ (9,228)	(3,426)	$ (5,802)	169 %
Loss on debt extinguishment	(14,155)	(1,362)	(12,793)	939 %
Change in fair value of warrant liability	1,270	792	478	60 %
Change in fair value of derivative liability	6,940	7,743	(803)	(10)%
Foreign exchange gain, net	982	94	888	945 %
Total other (expense) income	$ (14,191)	3,841	$ (18,032)	(469)%

Total other income (expense) decreased by $18.0 million, or 469%, during the year ended December 31, 2022 as compared to the year ended December 31, 2021. The net increase was primarily due to:

- the $5.8 million increase in interest expense associated with the debt instruments outstanding during the year; and,
- the $12.8 million increase in the loss on the debt extinguishment whereby we recognized a $14.2 million loss associated with the early retirement and conversion of the outstanding convertible notes under the Securities Purchase Agreement with JGB in 2022 as compared to the $1.4 million loss recognized on the extinguishment of our prior credit facility with the Oxford Finance LLC in 2021.

Liquidity and Capital Resources

Liquidity and Current Resources

Overview

Our primary sources of cash for the year ended December 31, 2022 were from equity transactions, the sale of our ebopiprant rights to XOMA, and cash received in connection with our sub-license to Theramex. Our cash and cash equivalents was $8.4 million at December 31, 2022. We believe, based on the operating cash requirements and capital expenditures expected for 2023, our cash on hand at December 31, 2022, are sufficient to fund operations through the fourth quarter of 2023 and this raises substantial doubt about our ability to continue as a going concern within one year from the date of the issuance of the consolidated financial statements appearing elsewhere in this Annual Report. See Part I, Item 1A. "Risk Factors – *Our recurring losses, negative cash flows and significant accumulated deficit have raised substantial doubt regarding our ability to continue as a going concern"*.

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 securities, issuance of debt instruments and license of our product candidates. From inception through December 31, 2022, we raised an aggregate of $447.7 million of net proceeds from the sale of equity securities, through public and private offerings and our at-the-market programs, and $64.5 million from the issuance of debt instruments, of which $62.5 million has been repaid. As of December 31, 2022, we had remaining outstanding principal of $6.5 million under our Securities Purchase Agreement with JGB, a portion of which was used to fully retire our prior credit facility with Oxford Finance LLC (the "Oxford Credit Facility") in October 2021. In July 2021, we received $25.0 million from Organon in connection with the licensing agreement for ebopiprant. In February 2022, we received EUR 5.0 million from Theramex in connection with the Theramax License Agreement.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by California and federal regulatory agencies. As a result of these actions, the Federal Deposit Insurance Corporation (FDIC) established Silicon Valley Bridge Bank, N.A. (the "Bridge Bank") as successor to SVB. We maintained a portion of our cash with SVB. On March 12, 2023, the U.S. Treasury, Federal Reserve and FDIC rolled out emergency measures to fully protect all depositors of SVB and, on March 13, 2023, we had full access to our cash on deposit with SVB. As a result, we do not anticipate any losses with respect to such balances.

On March 14, 2023, we received a delisting notice from Nasdaq notifying us that our common shares were scheduled for delisting from the Nasdaq Capital Market on March 23, 2023 due to our failure to regain compliance with Nasdaq Listing Rule 5450(a)(1) because the bid price of our common shares has not closed at or above $1.00 per share for a minimum of ten consecutive business days. As described above, our common shares began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF". Accordingly, it may be difficult for us to raise additional capital as we are no longer listed on a national stock exchange in the United States. In addition, on March 28, 2023, we filed a post-effective amendment to various outstanding registration statements on Form F-3, which amendment was declared effective by the SEC on March 29, 2023, and a post-effective amendment to various outstanding registration statements on Form S-8, which amendment became effective immediately upon filing, each to remove and withdraw from registration the shares that were registered but remained unsold thereunder.

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 the date the ATM program was terminated in March 2021, we generated gross proceeds of $75.0 million under the program.

In March 2021, we terminated our prior ATM program with Jefferies and entered into a new agreement, or the Sales Agreement, with SVB Leerink LLC, or the Agent, to sell treasury shares from time to time at our discretion under an ATM program, with aggregate gross sales proceeds of up to $50.0 million. The Sales Agreement provides that the commission payable to the Agent for sales of common shares with respect to which the Agent acts as sales agent shall be 3.0% of the gross sales price for such common shares sold pursuant to the Sales Agreement. The Sales Agreement contains customary representations and warranties of the parties and indemnification and contribution provisions under which the Company and the Agent have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act. We and the Agent have the right, by giving written notice as specified in the Sales Agreement, to terminate the Sales Agreement. During the year ended December 31, 2021, we sold a total of 15,933,420 treasury shares at an average price of $3.28 per share, as part of our ATM program. These multiple daily transactions generated total gross proceeds of $53.7 million. Directly related share issuance costs of $2.3 million were recorded as a deduction in equity. During the year ended December 31, 2021, 6,448,240 warrants were exercised at an average price of $3.43 per share, resulting in proceeds of $22.1 million.

Through the year ended December 31, 2022, we raised additional gross proceeds of $6.6 million under the Sales Agreement. Our ATM program expired during the year ended December 31, 2022.

Material Capital Requirements

Oxford Credit Facility

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 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 amended the Credit Facility Agreement pursuant to which the third tranche of $25.0 million was available to be drawn at any time between April 7, 2020 and August 1, 2024 upon our request and at Oxford's discretion. The credit facility was secured by substantially all of our assets, including our intellectual property. The loan bore a floating interest rate (partially based on thirty-day U.S. LIBOR rate) at 8.68% per year in total and was set mature to on August 1, 2024.

Securities Purchase Agreement with JGB

On October 12, 2021, we entered into the Securities Purchase Agreement with JGB, which was structured to provide up to $135.0 million in borrowing capacity, available in nine tranches. We received gross proceeds of $30.0 million at closing and used the proceeds to repay all amounts outstanding under a prior agreement with Oxford Finance. In conjunction with the closing, we also issued warrants to purchase 1,634,877 of our common shares at an exercise price of $3.67 per share On January 28, 2022, we entered into an amendment agreement and an amended and restated securities purchase agreement (the "Amendment Agreements"), with JGB regarding the second tranche under the Securities Purchase Agreement. In connection with the Amendment Agreements, we received proceeds of $10.5 million ($975 thousand of original issue discount) in the second tranche, funded on January 28, 2022, and the conversion price for the note issued in the second tranche was adjusted to a price of $1.66 per common share. In addition, as adjusted pursuant to the Amendment Agreements, we issued warrants to purchase 1,018,716 of our common shares at an exercise price of $1.87 per share.

On July 27, 2022, our announced application to the courts of competent jurisdiction of the Swiss canton of Geneva for a preliminary moratorium resulted in the Events of Default (the "Events of Default") under the outstanding notes issued to JGB (the "Outstanding Notes").

On July 31, 2022, we entered into the Amendment and Forbearance Agreement with JGB, pursuant to which we and JGB agreed to apply $31.0 million (the "Account Balances") previously held in a control account in accordance with the Transaction Agreements against the Outstanding Notes on a pro rata basis, and JGB waived any application of the 25% prepayment premium permitted under the Outstanding Notes with respect to the Account Balances through the forbearance period. In addition, JGB agreed to refrain and forebear from exercising or pursuing any rights or remedies under the Transaction Agreements with respect to the Events of Default until the earlier to occur of (i) October 29, 2022, (ii) the occurrence of any event of default under the Transaction Agreements (other than the Events of Default), and (iii) the date upon which a preliminary moratorium has been granted by the courts of competent jurisdiction of the Swiss canton of Geneva. In exchange for the waiver of the prepayment penalty and forbearance on exercising such rights and remedies, $1.5 million was added to the outstanding principal balance under the Outstanding Notes, resulting in an aggregate outstanding balance of approximately $11.0 million under the Outstanding Notes, the conversion price of the Outstanding Notes was adjusted to a conversion price of $0.26 per share (subject to adjustment as provided in the Outstanding Notes) and our right to mandatory conversion of any convertible notes issued pursuant to the Securities Purchase Agreement, including the Outstanding Notes, was terminated. In addition, JGB is no longer obligated to fund any future mandatory or optional tranche closing under the Securities Purchase Agreement.

Following the execution of the amendment, JGB converted $3.8 million of the outstanding principal balance and $0.4 million of accrued and unpaid interest under the Outstanding Notes into 16,346,135 common shares.

On October 26, 2022, we entered into the Extension Amendment with JGB, pursuant to which JGB agreed to refrain and forebear from exercising or pursuing any rights or remedies under the Transaction Agreements with respect to the Events of Default until the earlier to occur of (i) December 1, 2022, (ii) the occurrence of any event of default under the Transaction Agreements (other than the Events of Default), and (iii) the date upon which a preliminary moratorium has been granted by the courts of competent jurisdiction of the Swiss canton of Geneva. In exchange for the forbearance on exercising such rights and remedies, (i) the conversion price for $2.0 million of outstanding principal amount of the Outstanding Notes was adjusted to a conversion price of $0.19 per share (subject to adjustment as provided in the Outstanding Notes), and (ii) an aggregate of $0.5 million of outstanding principal amount (such amount a part of the $2.0 million principal amount with a conversion price of $0.19 per share) and all accrued and unpaid interest on the Outstanding Notes through and including October 31, 2022, was exchanged for 2,631,579 common shares, representing a conversion price of $0.19 per share.

On November 21, 2022, we and JGB entered into the Consent, whereby JGB consented to our transaction with XOMA, and we agreed to maintain in a control account in favor of JGB a minimum cash balance of $6.7 million, representing the aggregate principal balance under the Outstanding Notes as of the date of the Consent, provided such minimum cash balance shall be correspondingly reduced upon any conversion of the outstanding balance or payoff of the outstanding notes. In addition, pursuant to the Consent, the maturity date for each Outstanding Note was amended to December 31, 2023.

On November 22, 2022, JGB converted $0.2 million of the outstanding principal balance under the Outstanding Notes into 1,052,632 common shares.

On February 24, 2023, we announced the early retirement of the $6.5 million of remaining principal of the Outstanding Notes. Under the terms of the early retirement, we and JGB agreed to apply $6.5 million previously held as collateral in a control account against the Outstanding Notes on a pro rata basis, with JGB waiving a $1.1 million prepayment penalty in exchange for approximately $0.6 million in cash and $0.3 million in the form of approximately 1.5 million common shares.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2022 and 2021:

(in thousands, except percentages)	Year Ended December 31, 2022	2021	Increase (Decrease)	
Net cash provided by (used in):				
Operating activities	$ (23,144)	$ (50,423)	$ 27,279	(54)%
Investing activities	3	(14)	17	(121)%
Financing activities	(16,809)	74,270	(91,079)	(123)%
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (39,950)	$ 23,833	$ (63,783)	(298)%

Operating Activities

Net cash used in operating activities was $23.1 million for the year ended December 31, 2022 compared to $50.4 million for the year ended December 31, 2021. The decrease in our cash used in operating activities of $27.3 million is due to a decrease in net loss before taxes of $23.1 million and changes in net working capital of $10.0 million, offset by an increase in non-cash items of $14.2 million.

Investing Activities

Net cash provided by investing activities was $3 thousand for the year ended December 31, 2022 compared to net cash used in investing activities of $14 thousand for the year ended December 31, 2021. The net cash provided by investing activities during 2022 was primarily due to sales of property, plant and equipment.

Financing Activities

Net cash used in financing activities was $16.9 million for the year ended December 31, 2022 compared to net cash provided by financing activities of $74.3 million for the year ended December 31, 2021. The decrease in net cash from financing activities of $91.1 million is primarily due to a decrease in proceeds from the issuance of shares of $46.6 million from our expired ATM programs ($6.6 million in net proceeds received in the year ended December 31, 2022 compared to the $53.2 million in net proceeds received in the year ended December 31, 2021), a decrease in the proceeds from the issuance of convertible debt of $19.5 million, and a decrease in the proceeds from the exercise of warrants of USD 22.1 million, offset by an increase in debt repayments of $4.0 million ($31.0 million prepayment on the JGB debt made in the year ended December 31, 2022 compared to the $27.0 million in repayment of the Oxford Credit facility in the year ended December 31, 2021).

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of our consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses, and the disclosure of contingent liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in Footnote 2, "Summary of Significant Accounting Policies", to our consolidated financial statements appearing elsewhere in this Annual Report, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Fair Value Measurements

We follow the guidance in Financial Accounting Standards Board ("FASB") Accounting Standard Codification 820, *Fair Value Measurements and Disclosures*, which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 — Quoted prices (unadjusted) in active markets for identical assets or liabilities that we can access at the measurement date.

Level 2 — Inputs other than quoted prices included within Level 1 that are either directly or indirectly observable. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term.

Level 3 — Unobservable inputs developed using estimates of assumptions developed by us, which reflect those that a market participant would use.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by us in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. We use prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may change for many instruments. This condition could cause an instrument to be reclassified within levels in the fair value hierarchy. There were no transfers within the fair value hierarchy during the years ended December 31, 2022 and 2021.

Our financial instruments include cash and cash equivalents, restricted cash, other receivables, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities, convertible notes, and warrants. The carrying amounts of cash and cash equivalents, restricted cash, other receivables, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities approximates their fair value due to the short-term nature of these instruments.

The convertible notes issued in conjunction with the Securities Purchase Agreement with JGB Management Inc. ("JGB") is carried at amortized cost, which management believes approximates fair value. The derivative liability related to certain embedded features contained within the convertible notes is carried at fair value. We value the derivative liability using a lattice-binomial option pricing model ("Binomial Model"). The convertible notes are initially fair valued using the Binomial Lattice model and with the straight debt fair value calculated using the discounted cash flow method. The fair value of the derivative liability is the difference between the fair value of the convertible notes and the straight debt fair value. The fair value determined by the Binomial Model is affected by our share price as well as assumptions regarding a number of highly complex and subjective variables. The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) share price as of the valuation date, (2) expected volatility, (3) risk-free rate, and (4) credit spread. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

Additionally, the warrant liability is carried at fair value. The fair values of these warrants have been determined using the Black-Scholes valuation method. These values are subject to a significant degree of our judgment. The estimated fair value of the warrants is determined with Level 3 inputs using the Black-Scholes model. The significant inputs and assumptions in this method are the share price, exercise price, expected volatility, risk-free rate and term or maturity. The underlying share price input is the closing share price as of each valuation date and the exercise price is the price as stated in the warrant agreement. The volatility input was determined using the historical volatility of our common shares, adjusted for transaction specific factors. The Black-Scholes analysis is performed in a risk-neutral framework, which requires a risk-free rate assumption based upon constant-maturity treasury yields, which are interpolated based on the remaining term of the warrants as of each valuation date.

Smaller Reporting Company Status

We are a smaller reporting company as defined in the Exchange Act. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as (i) our voting and non-voting common shares held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company and not required to provide this information.

Item 8. Financial Statements and Supplementary Data

OBSEVA SA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for the years then ended, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 16 to the consolidated financial statements, the Company has incurred recurring losses since inception and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 16. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation of embedded conversion option derivative liability

As described in Note 7 to the consolidated financial statements, the Company determined the fair value of the embedded conversion option derivative liability issued in connection with the Second Tranche Notes was $5,331 thousand and the change in fair value of the conversion option derivative liability for the year ended December 31, 2022 was $6,940 thousand. Management classified the conversion option embedded within the Notes as a derivative liability measured at fair value upon issuance and the change in fair value was reported in the consolidated statement of operations and comprehensive loss as a gain. Management used Level 3 inputs for its valuation methodology for the embedded conversion option derivative liability as the fair values were determined by using a binomial model. The significant assumptions used to determine the fair value of the embedded conversion option derivative liability were price volatility and the implied credit spread.

The principal considerations for our determination that performing procedures relating to the valuation of embedded conversion option derivative liability is a critical audit matter are (i) the significant judgement by management when determining the fair value estimate of the embedded conversion option derivative liability; (ii) a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating management's significant assumptions related to price volatility and the implied credit spread; and (iii) the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, (i) testing management's process for developing the fair value estimate of the embedded conversion option derivative liability; (ii) evaluating the appropriateness of the model, (iii) testing the completeness and accuracy of underlying data used in the model; (iv) reading the convertible loan agreement; and (v) evaluating the reasonableness of significant assumptions used by management in relation to the determination of the embedded conversion option derivative liability. Professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of the binomial model and evaluating the reasonableness of the price volatility and implied credit spread assumptions. The work of management's specialists was used in performing the procedures to evaluate the reasonableness of the embedded conversion option derivative liability. As a basis for using this work, the specialists' qualifications were understood and the Company's relationship with the specialists was assessed. The procedures performed also included evaluation of the methods and assumptions used by the specialists, tests of the data used by the specialists, and an evaluation of the specialists' findings.

/s/ PricewaterhouseCoopers SA
Geneva, Switzerland
March 31, 2023

We have served as the Company's auditor since 2013.

OBSEVA SA

CONSOLIDATED BALANCE SHEETS

(in '000)	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,424	$ 54,734
Restricted cash	6,534	—
Accounts receivable	252	3,459
Prepaid expenses	783	5,223
Total current assets	15,993	63,416
Right of use asset	227	774
Other long-term assets	324	346
Total assets	$ 16,544	$ 64,536
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accrued expenses	$ 2,040	$ 13,783
Accounts payable and other current liabilities	1,674	9,038
Current lease liabilities	237	686
Derivative liability	445	—
Current borrowings	2,790	—
Total current liabilities	7,186	23,507
Non-current lease liabilities	—	240
Non-current borrowings	—	13,692
Post-employment obligations	582	7,167
Derivative liability	—	5,717
Warrant liability	1	715
Other long-term liabilities	292	592
Total liabilities	8,061	51,630
Commitments and contingencies (Note 15)		
Shareholders' equity:		
Common shares, CHF 1/13 par value:	8,755	6,489
Authorized shares - 196,751,165 at December 31, 2022		
Issued and outstanding shares - 107,706,699 and 79,955,268 at December 31, 2022 and 2021, respectively		
Additional paid-in capital	472,257	455,407
Accumulated deficit	(472,819)	(442,940)
Accumulated other comprehensive income (loss)	290	(6,050)
Total shareholders' equity	8,483	12,906
Total liabilities and shareholders' equity	$ 16,544	$ 64,536

The accompanying notes are an integral part of the consolidated financial statements.

OBSEVA SA

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in '000, except per share data)	Year Ended December 31, 2022	2021
Net revenues		
Revenue from licensing arrangements	$ 14,197	$ 22,200
Revenue from collaboration arrangements	5,440	—
Total net revenues	19,637	22,200
Operating income (expense):		
Research and development	(10,710)	(53,894)
General and administrative	(24,725)	(25,021)
Other operating income	121	108
Total operating (expense)	(35,314)	(78,807)
Loss from operations	(15,677)	(56,607)
Other (expense) income		
Interest expense	(9,228)	(3,426)
Loss on debt extinguishment	(14,155)	(1,362)
Change in fair value of warrant liability	1,270	792
Change in fair value of derivative liability	6,940	7,743
Foreign exchange gain, net	982	94
Total other (expense) income	(14,191)	3,841
Net loss before income taxes	(29,868)	(52,766)
Income tax expense	(11)	(213)
Net loss	$ (29,879)	$ (52,979)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.32)	$ (0.70)
Weighted-average common shares outstanding, basic and diluted	92,080,998	75,281,838
Other comprehensive income — unrealized components of post-employment benefit plan, net of tax ($0 and $0, respectively)	6,340	2,139
Comprehensive loss	$ (23,539)	$ (50,840)

The accompanying notes are an integral part of the consolidated financial statements.

OBSEVA SA

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

(in '000)	Registered shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Total Shareholders' Equity
	Shares	Amount				
Balance at December 31, 2020	57,552,578	$ 4,574	$ 375,041	$ (389,961)	$ (8,189)	$ (18,535)
Share-based compensation	—	—	8,443	—	—	8,443
Issuance of common shares in at-the-market offerings, net	15,954,450	1,360	50,361	—	—	51,721
Issuance of common shares upon the exercise of warrants	6,448,240	555	21,562	—	—	22,117
Other comprehensive income - unrealized components of post-employment benefit plan, net of tax	—	—	—	—	2,139	2,139
Net loss	—	—	—	(52,979)	—	(52,979)
Balance at December 31, 2021	79,955,268	6,489	455,407	(442,940)	(6,050)	12,906
Share-based compensation	—	—	5,796	—	—	5,796
Issuance of common shares in at-the-market offerings, net	6,821,086	588	5,774	—	—	6,362
Issuance of common shares upon conversion of convertible debt	20,930,345	1,678	5,280	—	—	6,958
Other comprehensive income - unrealized components of post-employment benefit plan, net of tax	—	—	—	—	6,340	6,340
Net loss	—	—	—	(29,879)	—	(29,879)
Balance at December 31, 2022	107,706,699	$ 8,755	$ 472,257	$ (472,819)	$ 290	$ 8,483

The accompanying notes are an integral part of the consolidated financial statements.

OBSEVA SA

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in '000)	Year Ended December 31, 2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (29,879)	$ (52,979)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	20	87
Impairment loss on right-of-use asset	—	148
Change in fair value of warrant liability	(1,270)	(792)
Change in fair value of derivative liability	(6,940)	(7,743)
Loss on extinguishment of debt	14,155	1,362
Post-employment expense	169	1,034
Share-based compensation expense	5,796	8,443
Amortization of operating right-of-use assets	547	576
Foreign currency gain, net	(982)	(94)
Non-cash interest expense	6,714	1,004
Changes in operating assets and liabilities:		
Accounts receivable	3,207	(2,639)
Prepaid expenses and other long-term assets	4,440	191
Operating lease liabilities	(667)	(683)
Accounts payable and other current liabilities	(7,068)	(1,872)
Accrued expenses	(11,388)	3,534
Net cash used in operating activities	(23,146)	(50,423)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale (purchases) of property, plant and equipment	3	(14)
Net cash provided by (used in) investing activities	3	(14)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of shares in at-the-market offerings	6,596	53,226
Proceeds from issuance of convertible debt	8,971	28,493
Proceeds from issuance of warrants	554	1,507
Proceeds from the exercise of warrants	—	22,117
Prepayment of JGB convertible debt	(31,000)	—
Repayment of Oxford credit facility	—	(26,986)
Payments of issuance costs related to common shares	(234)	(1,959)
Payments of issuance costs related to convertible debt and warrant	(1,696)	(2,128)
Net cash (used in) provided by financing activities	(16,809)	74,270
Net (decrease) increase in cash, cash equivalents and restricted cash	(39,952)	23,833
Cash, cash equivalents and restricted cash — beginning of year	54,734	31,183
Effects of exchange rate changes on cash, cash equivalents and restricted cash	176	(282)
Cash, cash equivalents and restricted cash — end of year	$ 14,958	$ 54,734
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	$ 2,496	$ 2,391
Cash paid for taxes	$ 150	$ 36
SUPPLEMENTAL NON-CASH ACTIVITIES:		
Issuance of common shares (in connection with conversion of convertible debt)	$ 6,958	$ —

The accompanying notes are an integral part of the consolidated financial statements.

OBSEVA SA

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Organization

ObsEva SA (the "Company") was founded on November 14, 2012, and its address is 12 Chemin des Aulx, 1228 Plan-les-Ouates, Geneva, Switzerland. Obseva SA has four wholly-owned subsidiaries, ObsEva Ireland Ltd, which is registered in Cork, Ireland and organized under the laws of Ireland, ObsEva Switzerland SA, which is registered and organized under the laws of Switzerland, ObsEva USA Inc., which is registered and organized under the laws of Delaware, USA, and ObsEva Europe B.V., which is registered in Rotterdam, The Netherlands, and organized under the laws of The Netherlands. The terms "ObsEva" or "the Company" refer to ObsEva SA together with its subsidiaries.

The Company is a biopharmaceutical company focused on the development of novel therapies to improve women's reproductive health. The Company is advancing a development program for nolasiban, an oral oxytocin receptor agonist, focused on improving clinical pregnancy and live birth rates in women undergoing in-vitro fertilization. The Company has no currently marketed products.

2. Summary of Significant Accounting Policies

Basis of preparation and principles of consolidation

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). Previously, the Company prepared its consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). At the end of the second quarter of 2022, the Company determined that it no longer qualified as a Foreign Private Issuer under SEC rules. As a result, beginning January 1, 2022, the Company is required to report with the SEC on domestic forms and comply with domestic company rules in the United States. The transition to US GAAP was made retrospectively for all periods from the Company's inception.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Liquidity and capital resources

As of December 31, 2022, the Company had approximately $8.4 million in cash and cash equivalents. The Company believes that its current cash and cash equivalents are only sufficient to fund its operating expenses into the fourth quarter of 2023 and this raises substantial doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these consolidated financial statements.

The future viability of the Company is dependent upon earning milestone payments under its licensing agreements and/or on its ability to raise additional debt and equity capital to finance its future operations. There can be no assurances that such funding sources will be available at terms acceptable to the Company, or at all. If the Company has insufficient funding to meet its working capital needs, it could be required to delay, limit, reduce, or terminate its drug development programs or limit or cease operations.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to companies in the biotechnology and pharmaceutical industries, including, but not limited to, risks of failure or unsatisfactory results of nonclinical and clinical studies, the need for significant capital to fund the development of its product candidates and the commercialization of any product candidates that may obtain marketing approval, the need to obtain marketing approval for its product candidates, the need to successfully commercialize and gain market acceptance of any of its product candidates that obtain regulatory approval, dependence on strategic relationships with collaboration and commercialization partners and on key personnel,

securing and protecting proprietary technology, compliance with government regulations, development by competitors of technological innovations, ability to transition from pilot-scale manufacturing to large-scale production of products, and dependence on third-party service providers such as contract research organizations ("CROs"), contract manufacturing organizations ("CMOs"), other suppliers, and third-party logistics providers.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosures of asset impairments, revenue recognition, depreciation and amortization, stock-based compensation, income taxes, the fair value of warrant and derivative liabilities, and accounting for project development and certain accruals. These estimates are sometimes complex, sensitive to changes in assumptions and require fair value determinations using Level 3 fair value measurements. Actual results may differ materially from those estimates.

Cash, cash equivalents and restricted cash

Cash and cash equivalents include cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of 90 days or less. Restricted cash represents deposited amounts securing obligations under the Company's convertible note financing arrangement with JGB Management, Inc. Restricted cash consists of $6.5 million held in a restricted depository account.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts in the statement of cash flows.

in'000	As of December 31, 2022	2021
Cash and cash equivalents	$ 8,424	$ 54,734
Restricted cash	6,534	—
Total cash, cash equivalents and restricted cash	$ 14,958	$ 54,734

Fair value measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability, an exit price, in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value includes:

Level 1 — Observable inputs for identical assets or liabilities such as quoted prices in active markets;

Level 2 — Inputs other than quoted prices in active markets that are either directly or indirectly observable; and

Level 3 — Unobservable inputs in which little or no market data exists, which are therefore developed by the Company using estimates and assumptions that reflect those that a market participant would use.

The Company's financial instruments include cash and cash equivalents, restricted cash, other receivables, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities, convertible notes, and warrants. The carrying amounts of cash and cash equivalents, restricted cash, other receivables, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities approximates their fair value due to the short-term nature of these instruments.

The convertible notes issued in conjunction with the Securities Purchase Agreement with JGB Management Inc. ("JGB") is carried at amortized cost, which management believes approximates fair value. Additionally, the derivative

liability related to certain embedded features contained within the convertible notes is carried at fair value. The warrant liability is also carried at fair value.

Concentration of credit risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents, restricted cash, and other receivables. As of December 31, 2022, the Company's cash is held by one institution in the U.S. and two institutions in Switzerland. Periodically, the Company maintains deposits in financial institutions in excess of government insured limits. On March 10, 2023, Silicon Valley Bank ("SVB") was closed by California and federal regulatory agencies. As a result of these actions, the Federal Deposit Insurance Corporation (FDIC) established Silicon Valley Bridge Bank, N.A. (the "Bridge Bank") as successor to SVB. On March 12, 2023, the U.S. Treasury, Federal Reserve and FDIC rolled out emergency measures to fully protect all depositors of SVB and, on March 13, 2023, we had full access to our cash on deposit with SVB. As a result, we do not anticipate any losses with respect to such balances.

As part of our cash management process, we perform periodic evaluations of the relative credit standing of these financial institutions. The Company manages its accounts receivable credit risk through ongoing credit evaluation of its customers' financial conditions.

Leases

In February 2016, the FASB issued ASU 2016-02, Leases (ASC 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2019.

The Company has leases for its corporate offices, which are accounted for as operating leases under ASC 842. The Company has no finance or sales-type leases. The Company determines if an arrangement is a lease at inception. Operating leases are recorded as a current and long-term lease obligation, with a corresponding right of use asset ("ROU asset"). ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

The Company has elected to combine lease and non-lease components as a single component for all leases in which it is a lessee or a lessor. The lease expense is recognized over the expected term on a straight-line basis. Operating leases are recognized on the balance sheet as right-of-use assets, operating lease liabilities current and operating lease liabilities non-current.

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 Company has an unconditional right to defer settlement of the liability until more than 12 months after the reporting period. The Company recognizes debt extinguishment in other income (expense), net as the difference between the extinguishment payment and the carrying value of the loan.

Warrants to purchase common shares

The Company accounts for the issuance of warrants to purchase common shares in accordance with the provisions of ASC 815, *Derivatives and Hedging*. The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). The Company classifies as assets or liabilities any contracts that (i) require net cash

settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). For warrants that are classified as liabilities, the Company records the fair value of the warrants at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the consolidated statements of comprehensive loss. The fair values of these warrants have been determined using the Black-Scholes valuation method. These values are subject to a significant degree of the Company's judgment. The estimated fair value of the warrants is determined with Level 3 inputs using the Black-Scholes model. The significant inputs and assumptions in this method are the share price, exercise price, expected volatility, risk-free rate and term or maturity. The underlying share price input is the closing share price as of each valuation date and the exercise price is the price as stated in the warrant agreement. The volatility input was determined using the historical volatility of Company common shares, adjusted for transaction specific factors. The Black-Scholes analysis is performed in a risk-neutral framework, which requires a risk-free rate assumption based upon constant-maturity treasury yields, which are interpolated based on the remaining term of the warrants as of each valuation date.

Derivative Liability

The Company analyzes the conversion feature of convertible notes for derivative accounting consideration under ASC 815-15, *Derivatives and Hedging*. ASC 815-15 requires that the conversion features are bifurcated and separately accounted for as a derivative instrument on the balance sheet at fair value. Any unrealized change in fair value, as determined at each measurement period, is recorded as a component of the statement of operations and comprehensive loss and the associated carrying amount on the balance sheet is adjusted by the change. The Company values the derivative liability using a lattice-binomial option pricing model ("Binomial Model"). The convertible notes are initially fair valued using the Binomial Lattice model and with the straight debt fair value calculated using the discounted cash flow method. The fair value of the derivative liability is the difference between the fair value of the convertible notes and the straight debt fair value. The fair value determined by the Binomial Model is affected by the Company's share price as well as assumptions regarding a number of highly complex and subjective variables. The fair value measurement of the derivative liability is classified as Level 3 under the fair value hierarchy as it has been valued using certain unobservable inputs. These inputs include: (1) share price as of the valuation date, (2) expected volatility, (3) risk-free rate, and (4) credit spread. Significant increases or decreases in any of those inputs in isolation could result in a significantly lower or higher fair value measurement.

Upon conversion of a convertible note where the embedded conversion option has been bifurcated and accounted for as a derivative liability, the Company records the shares at fair value, relieves all related notes, derivatives and debt discounts and recognizes a net gain or loss on debt extinguishment.

Post-employment benefits

The Company sponsors a defined benefit pension plan in Switzerland, covering all local Obseva SA employees. The Company recognizes the overfunded or underfunded status of its defined benefit pension plan as an asset or a liability, measured as the difference between the fair value of plan assets and the benefit obligation, in the consolidated balance sheets, with changes in the funded status recorded through other comprehensive income (loss) in the year in which those changes occur.

The Company uses the corridor approach in the valuation of the defined benefit pension plan. The corridor approach defers all actuarial gains and losses resulting from variances between actual results and actuarial assumptions. Those unrecognized gains and losses are amortized when the net gains and losses exceed 10% of the greater of the market-related value of plan assets or the projected benefit obligation at the beginning of the year. The amount in excess of the corridor is amortized over the average remaining service period of plan participants. Prior service costs, credits and transition costs are charged or credited to accumulated other comprehensive income and subsequently amortized over the average remaining service period of employees expected to receive benefits under the plan.

The Company also sponsors a 401K defined contribution plan in the U.S. All U.S. employees are immediately eligible to participate in the plan. Participants are eligible for 401K matching contributions based upon the employee's contribution to the plan. The plan assets are held by a third-party custodian. ObsEva USA, Inc. contributions to the defined

contribution plan are charged to the consolidated statement of comprehensive loss as incurred. The Company has no further obligation once the contributions have been paid.

Collaborative Arrangements

The Company may enter into collaboration arrangements with biotechnology partners. The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements, to determine whether such arrangements involve joint operating activities performed by the parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple units of account, the Company first determines which units of account of the collaboration are deemed to be within the scope of ASC 808 and those that are reflective of a vendor-customer relationship and, therefore, within the scope of ASC 606, Revenue from Contracts with Customers. While ASC 808 defines collaboration arrangements and provides guidance on income statement presentation, classification, and disclosures related to such arrangements, it does not address recognition and measurement matters, such as (1) determining the appropriate unit of account or (2) when the recognition criteria are met. Therefore, the accounting for these arrangements is either based on an analogy to other accounting literature, such as ASC 606, or an accounting policy election by management. For units of account within collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate revenue recognition method is determined and applied consistently.

The Company evaluates the presentation of amounts due from its collaborative partners associated with activities in the collaborative arrangements based on the nature of each activity. Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in the Company's consolidated balance sheets. If the related efforts underlying the deferred revenue are expected to be satisfied within the next twelve months, the deferred revenue is classified in current liabilities, otherwise it is classified as a non-current liability.

Revenue Recognition

For units of account under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the Company will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

License, milestone, and other revenue

For units of account under ASC 606, the Company applies significant judgment when evaluating whether contractual obligations represent distinct performance obligations, allocating transaction price to performance obligations within a contract, determining when performance obligations have been met, assessing the recognition and future reversal of variable consideration, and determining and applying appropriate methods of measuring progress for performance obligations satisfied over time. These judgments are discussed in more detail below.

- *Licenses of intellectual property rights:* If the licenses to intellectual property are determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is

able to use and benefit from the license. For licenses that are not distinct from other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition accordingly.

- *Milestone payments:* At the inception of each arrangement that includes research, development or regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price on a cumulative catch-up basis in earnings in the period of the adjustment.

- *Royalties and sales-based milestone payments:* For arrangements that include sales-based royalties, including sales-based milestone payments based on pre-specified level of sales, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Research and development

Research expenses are charged to the consolidated statement of comprehensive loss as incurred. Research and development costs consist of salaries, share-based compensation and benefits of employees, costs related to the Company's R&D activities, including contracts with clinical research organizations ("CROs") and contract manufacturing organizations ("CMOs"), and allocated overhead expenditures, including depreciation and amortization, rent and utilities. As part of the process of preparing financial statements the Company is required to estimate its expenses resulting from its obligation under contracts with vendors and consultants and clinical site agreements in connection with its R&D efforts. The Company's objective is to reflect the appropriate clinical trial expenses in its financial statements by matching those expenses with the period in which services and efforts are expended. The Company determines prepaid and accrual estimates through discussions with applicable personnel and outside service providers as to the progress of clinical trials, or other services completed. Although the Company does not expect its estimates to be materially different from amounts actually incurred, its understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in the Company reporting amounts that are too high or too low for any particular period.

Share-based compensation

The Company accounts for share-based compensation plans using the fair value recognition and measurement provisions under U.S. GAAP. Share-based compensation awarded to employees is measured at the grant date fair value of stock option grants and is recognized over the requisite service period of the awards, usually the vesting period, on a straight-line basis. The Company recognizes forfeitures as they occur.

The Company estimates the grant date fair value of stock options, and the resulting share-based compensation, using the Black-Scholes option-pricing model, which requires the use of subjective assumptions. These assumptions include:

- *Share price.* The share price represents the underlying price of the Company's common shares which is based on the public share price quote on the grant date.

- *Expected term.* The expected term represents the period that the Company's share-based awards are expected to be outstanding and is determined based on historical exercise data.

- *Expected volatility.* The expected volatility considers the Company's historical volatility and weighted average measures of volatility of a peer group of companies for a period equal to the expected term of the stock options. The Company's peer group of publicly traded biopharmaceutical companies was chosen based on their similar size, stage in the life cycle or area of specialty.

- *Risk-Free Interest Rate.* The risk-free interest rate is based on the U.S. treasury yield curve in effect at the time of grant for the expected term of the stock option.

- *Expected dividend.* The Company has never paid, and does not anticipate paying, cash dividends on its common shares. Therefore, the expected dividend yield was assumed to be zero.

The fair value of stock options on the grant date is estimated using the Black-Scholes option-pricing model using the single-option approach. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions, including the option's expected term and the price volatility of the underlying stock, to determine the fair value of the award. The Company recognizes the expense associated with options using a single award approach over the requisite service period.

Income taxes

The Company is subject to income taxes in the United States and other foreign jurisdictions. Judgment is required in determining the Company's expense (benefit) for income taxes and income tax assets and liabilities, including evaluating uncertainties in the application of accounting principles and complex tax laws.

The Company records an expense (benefit) for income taxes for the anticipated tax consequences of the reported results of operations using the asset and liability method. Under this method, the Company recognizes deferred income tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities, as well as for loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using the tax rates that are expected to apply to taxable income for the years in which those tax assets and liabilities are expected to be realized or settled. The Company recognizes the deferred income tax effects of a change in tax rates in the period of enactment.

The Company records a valuation allowance to reduce the Company's deferred tax assets to the net amount that the Company believes is more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax planning strategies, and results of operations. If the Company determines that it would be able to realize its deferred tax assets in the future in excess of its net recorded amount, the Company would make an adjustment to the deferred tax asset valuation allowance, which would reduce the provision for income taxes.

The Company recognizes tax benefits from uncertain tax positions if the Company believes that it is more likely than not that the tax position will be sustained upon examination by the taxing authorities based on the technical merits of the position as well as consideration of the available facts and circumstances. Interest and/or penalties related to income tax matters are recognized as a component of income tax expense as incurred.

Net loss per share

Basic net loss per common share is computed by dividing net loss available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted-average number of common shares and potentially dilutive shares of common shares outstanding during the period. Potential dilutive securities outstanding include common shares issuable upon conversion of debt, warrants to purchase common shares, and stock options. During all periods presented, the Company incurred net

losses. Accordingly, the effect of any common share equivalents would have been anti-dilutive during those periods and are not included in the calculation of diluted weighted-average number of common shares outstanding.

Foreign currencies

The functional currency of the Company's operations is primarily the U.S. Dollar. The financial statements of the Company's subsidiaries whose functional currency is other than the U.S. Dollar are translated to U.S. Dollars using period-end rates of exchange for assets and liabilities and monthly average rates for sales, income and expenses. Cumulative translation gains and losses are included as a component of shareholders' equity in accumulated other comprehensive income (loss). Gains and losses arising from transactions denominated in currencies other than a subsidiary's functional currency are reported in other income (expense), net in the consolidated statements of comprehensive loss.

Segment information

The Company operates in one segment, which is the research and development of innovative women's reproductive, health and pregnancy therapeutics. The Chief Executive Officer of the Company (Chief Operating Decision Maker) reviews the consolidated statement of operations of the Company on an aggregated basis and manages the operations of the Company as a single operating segment.

The Company currently generates no revenue from the sales of therapeutics products. The Company's activities are not affected by any significant seasonal effect.

The geographical analysis of total assets is as follows (in thousands):

	As of December 31,	
	2022	2021
Switzerland	$ 1,507	$ 9,564
USA	79	238
Total assets	$ 1,586	$ 9,802

The geographical analysis of total net revenues is as follows (in thousands):

	Year ended December 31,	
	2022	2021
Switzerland	$ 19,637	$ 22,200
USA	—	—
Total net revenues	$ 19,637	$ 22,200

Recently issued accounting pronouncements

Issued but not yet adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which institutes a new model for recognizing credit losses on financial instruments that are not measured at fair value. The new standard is effective for the first quarter of the year ending December 31, 2023. The Company is currently evaluating the impact that the new guidance will have on the consolidated financial statements.

3. Revenue Components

The Company currently derives no revenue from sales of its biopharmaceutical product candidate.

Collaboration Revenue

Collaboration revenue for the years ended December 31, 2022 and 2021 was $5.4 million and $0, respectively.

Collaboration revenue is derived from the collaboration arrangement entered into with Theramex HQ UK Limited ("Theramex") for the commercialization and further development of linzagolix across global markets outside of the U.S., Canada and Asia (the "Theramex License Agreement") in February 2022. For the year ended December 31, 2022, collaboration revenue represents the recognition of the upfront payment, net of transactions costs, the Company received from Theramex upon entering into the Theramex License Agreement. The upfront payment was fully recognized upon the Company's receipt of marketing authorization for the uterine fibroid indication in the European Union and the UK. As a result of termination of the Kissei License Agreement, the Theramex License Agreement was automatically assigned to Kissei and the Company has no further rights or obligations under the agreement.

License Revenue

License revenue for the years ended December 31, 2022, and 2021 was $14.2 million and $22.2 million, respectively.

In November 2022, the Company entered into an IP Acquisition Agreement (the "IP Acquisition Agreement") with XOMA Corporation ("XOMA") for the sale of all of its rights to ebopiprant for an upfront payment of $15 million and future milestone payments of up to approximately $98 million upon the achievement of certain development and regulatory milestones and sales milestones under the July 2021 Organon License Agreement (the "Organon License Agreement") with Organon & Co. ("Organon"). Under the terms of the IP Acquisition Agreement, the Company sold to XOMA all of its rights, including the assignment of its license agreements with Organon and Merck Serono, and the intellectual property estate of ebopiprant. The Company does not have material remaining performance obligations related to Organon or XOMA for ebopiprant. In consideration for entering into this agreement, the Company recognized the upfront payment, net of fees, of $14.2 million in accordance with ASC 606, *Contracts with Customers* as license revenue on the Company's consolidated statements of operations and comprehensive loss.

In July 2021, the Company entered into the Organon License Agreement with Organon to develop and commercialize ebopiprant. Under the terms of the the Organon License Agreement, Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. In consideration for entering into this agreement, the Company received an upfront payment of $25 million. The Company recognized the upfront payment, net of fees, of $22.2 million in accordance with ASC 606, *Contracts with Customers* as license revenue on the Company's consolidated statements of operations and comprehensive loss.

4. Fair value measurements

The table below presents information about our assets and liabilities that are regularly measured and carried at fair value and indicate the level within the fair value hierarchy of the valuation techniques we utilized to determine fair value:

	Fair value measurement at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 1	$ —	$ —	$ 1
Derivative liability	445	—	—	445
Total	$ 446	$ —	$ —	$ 446

	Fair value measurement at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 715	$ —	$ —	$ 715
Derivative liability	5,717	—	—	5,717
Total	$ 6,432	$ —	$ —	$ 6,432

The warrant liability was valued using the Black Scholes pricing model using level 3 inputs (refer to footnote 6 for significant assumptions). The derivative liability was valued using a binomial model using level 3 inputs (refer to footnote 7 for significant assumptions).

Separate disclosure is required for assets and liabilities measured at fair value on a recurring basis from those measured at fair value on a non-recurring basis. During the years ended December 31, 2022 and 2021, the Company had no significant assets or liabilities that were measured at fair value on a non-recurring basis.

5. Borrowings

The following is the activity of the Company's borrowings in the years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Borrowings as of January 1,	$ 13,692	$ 25,487
Issuance of JGB convertible note, net of transaction costs	2,042	13,012
Repayment of Oxford Credit Facility	—	(26,985)
Prepayment of convertible notes	(31,000)	—
Loss on debt extinguishment	17,304	1,362
Conversion of convertible note	(5,961)	—
Interest expense	9,209	3,300
Interest paid	(2,496)	(2,484)
Borrowings as of December 31,	$ 2,790	$ 13,692
Of which are:		
Current	$ 2,790	—
Non-current	—	$ 13,692

Oxford Credit Facility

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 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 amended the Credit Facility Agreement pursuant to which the third tranche of $25.0 million was available to be drawn at any time between April 7, 2020 and August 1, 2024 upon our request and at Oxford's discretion. The credit facility was secured by substantially all of our assets, including our intellectual property. The loan bore a floating interest rate (partially based on thirty-day U.S. LIBOR rate) at 8.68% per year in total and was set mature to on August 1, 2024.

Securities Purchase Agreement with JGB

In October 2021, the Company entered into a convertible note financing agreement (the "Securities Purchase Agreement") with certain funds and accounts managed by JGB, pursuant to which the Company could borrow up to $135 million in nine tranches through the issuance of convertible notes to JGB, together with warrants to purchase common shares in an amount equal to approximately 5% of the funded amount for such tranche. In connection with the first tranche, the Company issued $31.5 million (offer issue discount of $1.5 million) of convertible notes (the "First Tranche Note") and warrants to purchase 1,634,877 common shares of the Company at an exercise price of $3.67 per share (the "First Tranche Warrants"). The Company received gross proceeds of $30.0 million at closing and used the proceeds to repay all amounts outstanding under the Company's existing Oxford Credit Facility. Upon payoff, the Oxford Credit Facility was terminated and the security interests in the Company's assets that secured the Oxford Credit Facility were released. At the time of the payoff, the carrying amount of the Oxford Credit Facility was $25.6 million and the actual payoff amount was $27.0 million. The difference between the carrying amount and the payoff amount was

$1.4 million and was recorded in other income (expense) on the Company's consolidated statement of operations and comprehensive loss for the year ended December 31, 2021.

On January 28, 2022, the Company entered into an amendment agreement (the "Amendment Agreement") with JGB regarding the second tranche of the Securities Purchase Agreement. The Amendment Agreement adjusted the principal balance payable at maturity for the notes to be issued in the second tranche to $10.5 million ($975 thousand of original issue discount) and the conversion price for the notes to be issued in the second tranche to a price of $1.66 per common share and accelerated the issuance of the second tranche to January 28, 2022 (the "Second Tranche Note", and together with the First Tranche Note, the "Notes"). In addition, as adjusted pursuant to the Amendment Agreement, the Company issued warrants to purchase 1,018,716 common shares of the Company at an exercise price of $1.87 per share (the "Second Tranche Warrants", and together with the First Tranche Warrants, the "Warrants"). Additionally, JGB waived certain conditions required to be met to fund the second tranche, including that the Company's volume-weighted average price could not be below $3.00 per share for five or more trading days during the 30 days prior to the funding date for the second tranche, in exchange for a payment of $1.25 million and the amended terms for the notes and warrants issued in the second tranche. In connection with the Amendment Agreement, the Company received $8.25 million from the second tranche, after accounting for expenses and the $1.25 million waiver payment to JGB.

The Company evaluated the Notes in accordance with Accounting Standards Update ("ASU") 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contract in Entity's Own Equity (Subtopic 815-40), Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which was adopted by the Company effective January 1, 2021. Upon issuance of the Notes, the Company determined that the Notes and the Warrants represent freestanding financial instruments to be accounted for separately. Under ASC 815, Derivatives and Hedging, ("ASC 815"), the Company concluded that the Warrants do not meet the criteria for classification in shareholder's equity and should be initially classified as a liability at their estimated fair values (refer to footnote 6). The Convertible Notes were subsequently recognized on an amortized cost basis using the effective interest method until extinguished upon conversion or maturity of the Notes. Accordingly, the Company allocated proceeds first to the Warrants equal to the full fair value of the Warrants, with the residual amount allocated to the outstanding Convertible Notes. The Company further evaluated the Notes to determine whether embedded features require bifurcation. The Company concluded that the conversion features require bifurcation and should be accounted for separately as a derivative liability instrument with changes in fair value recorded in earnings (refer to footnote 7). The residual amount allocated to the Notes was further adjusted downward for the fair value of the derivative liability of the conversion features. The allocated amounts upon issuance of the Notes were as follows:

	Allocated proceeds	
	First Tranche Note	Second Tranche Note
Instruments:		
Warrant liability	$ 1,507	$ 556
Convertible note	15,033	3,638
Derivative liability	13,460	5,331
Total	$ 30,000	$ 9,525

The Company allocated the transaction fees associated with the Securities Purchase Agreement based on the debt balance and the fair value of the Warrants upon issuance. The allocation of the transaction fees associated with the convertible note was $1.6 million for the Second Tranche Note and $2.0 million for the First Tranche Note and was recorded against the outstanding note balance upon issuance. The convertible note balance was presented on a net-basis on the consolidated balance sheets as of December 31, 2022 and 2021. The allocation of the transaction fees associated with the warrant liability was $0.1 million for the Second Tranche Note and $0.1 million for the First Tranche Note for the years ended December 31, 2022 and 2021, respectively, and was recorded as a period cost and included in general and administrative expenses on the consolidated statements of operations and comprehensive loss.

The availability of each of the seven remaining tranches was subject to the Company meeting certain conditions, including, among others, that the Company's volume-weighted average price is not below $3.00 per share for five or

more trading days during the 30 days prior to a tranche funding date (the "Minimum Stock Price Condition"). At May 25, 2022, the original planned funding date of the third tranche, the Company had not met the Minimum Stock Price Condition for such tranche. On May 27, 2022, the Company entered into a waiver and amendment agreement with JGB, whereby JGB agreed to waive its right to terminate its obligation to fund future tranches under the Securities Purchase Agreement, which JGB would be entitled to as a result of the Company's failure to meet the Minimum Stock Price Condition. In exchange, the Company agreed to establish a "blocked" account control agreement with respect to the existing account control agreement in favor of JGB, which previously held $31.0 million in such controlled deposit account (the "Account Balances"). The Account Balances were classified as restricted cash on the Company's consolidated balance sheet.

On July 27, 2022, the Company applied for a court-sanctioned moratorium to the courts of competent jurisdiction of the Swiss canton of Geneva, which resulted in certain events of default (the "Events of Default") under the Notes. On July 31, 2022, the Company entered into an amendment and forbearance agreement (the "July 2022 JGB Amendment") with JGB in relation to the Securities Purchase Agreement, the First Tranche Note, and the Second Tranche Note. Pursuant to the July 2022 JGB Amendment, the Company and JGB agreed to apply the Account Balances against the Notes on a pro rata basis, and JGB waived any application of the 25% prepayment premium permitted under the Notes with respect to the Account Balances. In addition, JGB agreed to refrain and forebear from exercising or pursuing any rights or remedies under the Transaction Agreements with respect to the Events of Default until October 29, 2022. In exchange for the waiver of the prepayment penalty and forbearance on exercising such rights and remedies, $1.5 million was added to the outstanding principal balance under the Notes, resulting in an aggregate outstanding balance of approximately $11.0 million under the Notes (the "New Notes"), the conversion price of the New Notes was adjusted to a conversion price of $0.26 per share (subject to adjustment as provided in the New Notes) and the Company's right to mandatory conversion of any convertible notes issued pursuant to the Securities Purchase Agreement, including the New Notes, was terminated. In addition, JGB is no longer obligated to fund any future mandatory or optional tranche closing under the Securities Purchase Agreement.

The amendment of the Notes pursuant to the July 2022 JGB Amendment was evaluated under ASC 470-50, *Modifications and Extinguishments* ("ASC 470-50"). The debt instruments were determined to be substantially different as the present value of the remaining cash flows under the Notes and the present value of the remaining cash flows under the New Notes differed by greater than 10%. The Company treated the transaction as a debt extinguishment and a reissuance of new debt instruments pursuant to the guidance of ASC 470-50. As a result, the Company recorded a loss on debt extinguishment of $17.3 million during the year ended December 31, 2022, which was calculated as follows:

	Amount
Loss on extinguishment of debt	
Carrying value of the Notes	$ 40,502
Unamortized debt discount	(22,691)
Cash paid	(31,000)
Carrying value of New Notes	(4,115)
Total	$ (17,304)

In October 2022, the Company entered into an Amendment and Forbearance Extension Agreement (the "Extension Amendment") with JGB in relation to the Securities Purchase Agreement and the New Notes. Pursuant to the Extension Amendment, JGB agreed to extend its forbearance from exercising or pursuing any rights or remedies under the Transaction Agreements with respect to the Events of Default until December 1, 2022. In exchange, the Company agreed to adjust the conversion price for $2.0 million of the New Notes to $0.19 per share, subject to adjustments as provided in the New Notes, and to exchange $0.5 million of such $2.0 million of the New Notes and the interest accrued and unpaid thereon through October 31, 2022 for an aggregate of 2,631,579 common shares based on a conversion price of $0.19 per share.

In November 2022, in connection with its entry into an IP Acquisition Agreement with XOMA, the Company entered into a Consent and Amendment Agreement (the "Consent Agreement") with JGB related to the Securities Purchase

Agreement and the New Notes. Pursuant to the Consent, JGB consented to the Company's entry into the IP Acquisition Agreement, and also agreed (i) to amend the maturity date of each of the New Notes to December 31, 2023 and (ii) that the Company shall maintain in a control account pursuant to the Transaction Agreements a minimum cash balance representing the aggregate outstanding principal balance under the New Notes as of the date of the Consent, provided such minimum cash balance shall be correspondingly reduced upon any conversion of the outstanding balance or payoff of the New Notes. As of December 31, 2022, the aggregate outstanding principal balance under the New Notes was approximately $6.5 million. The Consent Agreement was treated as a modification pursuant to ASC 470-50. The transaction costs incurred were not material.

During the year ended December 31, 2022, JGB converted $6.0 million of the outstanding principal balance and $0.5 million of accrued and unpaid interest under the Notes into 20,930,345 common shares. In connection with the conversions, the Company recognized a gain on debt extinguishment upon conversion, net of $3.2 million, representing the excess of the fair value of the shares issued at conversion over the carrying value of the Notes and the fair value of the bifurcated conversion option at the time of conversion. The gain on extinguishment of debt upon conversion, net is included in the statements of operations and comprehensive loss within loss on extinguishment of debt for the year ended December 31, 2022. A reconciliation of the loss on debt extinguishment is as follows:

	Amount
Loss on extinguishment of debt	$ (17,304)
Gain on extinguishment of debt upon conversion, net	3,149
Total	$ (14,155)

The Securities Purchase Agreement includes affirmative and negative covenants applicable to the Company and its subsidiaries. The affirmative covenants include, among other things, requirements to file certain financial reports with the Securities and Exchange Commission, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. Further, subject to certain exceptions, the Securities Purchase Agreement contains customary negative covenants limiting its ability to, among other things, transfer or sell certain assets, consummate mergers or acquisitions, allow changes in business, incur additional indebtedness, create liens, pay dividends or make other distributions and make investments. As of December 31, 2022, the Company was in compliance with its covenants.

Subsequent to the balance sheet date, the Company retired the $6.5 million of remaining principal of the New Notes on February 24, 2023. Under the terms of the early retirement, we and JGB agreed to apply $6.5 million previously held as collateral in a control account against the New Notes on a pro rata basis, with JGB waiving a $1.1 million prepayment penalty in exchange for approximately $0.6 million in cash and $0.3 million in the form of approximately 1.5 million common shares.

6. Warrants

On October 12, 2021, in connection with the first tranche from the Securities Purchase Agreement, the Company issued 1,634,877 warrants to purchase common shares at an exercise price of $3.67 per share. Upon the funding of the second tranche on January 28, 2022, the Company issued 1,018,716 warrants to purchase common shares at an exercise price of $1.87 per share. The terms of the Warrants provide that in the event of certain specified fundamental transactions accepted by holders of 50.0% or more of the outstanding shares of the Company's outstanding common shares as defined in the Securities Purchase Agreement (which may be outside the Company's control), the Company may be obligated to cash-settle the outstanding Warrants (the "Fundamental Transaction Provision"). The Fundamental Transaction Provision precludes the Company from classifying the Warrants in shareholder's equity regardless of the likelihood that such instruments may be cash settled. Accordingly, the Warrants are initially classified as a liability at their estimated fair values. In periods subsequent to issuance, changes in the estimated fair value of the liabilities are reported through earnings. The fair values of the Warrants have been determined using the Black-Scholes valuation model. The key assumptions used to value the Warrants upon the respective issuance dates were as follows:

	January 28, 2022	October 12, 2021
Expected price volatility	50.0 %	50.0 %
Expected term (in years)	4.00	4.00
Risk-free interest rate	1.38 %	0.86 %
Dividend yield	0 %	0 %

The key assumptions used to value the Warrants as of December 31, 2022 and 2021 were as follows:

	December 31, 2022	December 31, 2021
Expected price volatility	50.0 %	50.0 %
Expected term (in years)	3.25	4.00
Risk-free interest rate	4.41 %	0.97 %
Dividend yield	0 %	0 %

The change in fair value of the warrant liability is as follows (in thousands):

	Amount
Balance as of January 1, 2021	$ —
Fair value of warrants issued	1,507
Change in fair value of liability to issue warrants	(792)
Balance as of December 31, 2021	715
Fair value of warrants issued	556
Change in fair value of liability to issue warrants	(1,270)
Balance as of December 31, 2022	$ 1

7. Derivative Liability

In connection with the issuance of the Notes, the Company evaluated the conversion option for derivative treatment under ASC 815-15, *Derivatives and Hedging*, and determined conversion feature qualified as a derivative. ASC 815 requires that embedded derivative instruments be bifurcated and measured at their fair value for accounting purposes. The Company classified the conversion features embedded within the Notes as a derivative liability and measured at fair value upon issuance. The fair value of this liability is re-measured at the end of every reporting period and the change in fair value will be reported in the consolidated statements of operations and comprehensive loss as a gain or loss on change in fair value of derivative liabilities. Upon conversion of a note where the embedded conversion option has been bifurcated and accounted for as a derivative liability, the Company records the shares at fair value, relieves all related notes, derivatives and debt discounts and recognizes a net gain or loss on debt extinguishment. The table below sets forth a summary of changes in the fair value of the embedded conversion option derivative liability:

	Amount
Balance as of January 1, 2021	$ —
Fair value of embedded conversion option issued with First Tranche Notes	13,460
Change in fair value of embedded conversion option derivative liability	(7,743)
Balance as of December 31, 2021	5,717
Fair value of embedded conversion option issued with Second Tranche Notes	5,331
Extinguishment of derivative liability upon conversion of debt	(3,663)
Change in fair value of embedded conversion option derivative liability	(6,940)
Balance as of December 31, 2022	$ 445

The Company uses Level 3 inputs for its valuation methodology for the embedded conversion option liability as the fair values were determined by using a binomial model based on various assumptions. Significant changes in any of these inputs in isolation would result in a significant change in the fair value measurement. As required, these are classified based on the lowest level of input that is significant to the fair value measurement. The key assumptions used to value the derivative liability upon the respective issuance dates were as follows:

	January 28, 2022	October 12, 2021
Price volatility	50.0 %	50.0 %
Share price	1.57	2.88
Time to expiration (in years)	3.0	3.0
Risk-free interest rate	1.38 %	0.64 %
Implied credit spread	41.4 %	38.9 %

The key assumptions used to value the derivative liability for multiple valuation dates in the year ended December 31, 2022 were as follows (values presented as ranges):

	Year ended December 31, 2022
Price volatility	50.0 %
Share price	0.15 - 1.81
Time to expiration (in years)	1.0 - 3.0
Risk-free interest rate	0.92 - 4.70 %
Implied credit spread	39.8 - 58.1 %

The key assumptions used to value the derivative liability as of December 31, 2021 were as follows:

	December 31, 2021
Price volatility	50.0 %
Share price	1.99
Time to expiration (in years)	2.8
Risk-free interest rate	0.92 %
Implied credit spread	40.8 %

8. Leases

The Company leases office space in Switzerland, which is classified as an operating lease through June 2023. The Company also leased office space in the United States, which was classified as an operating lease through August 2022.

The office space lease arrangements provide for increases in future minimum annual rental payments as defined in the agreements. The office space lease also includes an option to renew the lease as of the end of the term. The Company has determined that the lease renewal option is not reasonably certain of being exercised. The lease agreements do not include residual value guarantees.

Operating lease expense for the years ended December 31, 2022 and 2021 under the Company's operating leases was $0.6 million and $0.7 million, respectively. The cash paid for operating lease liabilities for the year ended December 31, 2022 and 2021 was $0.7 million and $0.7 million, respectively.

On June 1, 2021, ObsEva USA Inc. signed a sublease agreement to sublease office spaces located in the United States. This sublease covered a period from June 1, 2021 until September 30, 2022. The Company identified an impairment of the right-of-use asset upon execution of the sublease and recorded a charge of $0.2 million in the year ended December 31, 2021. The Company recognized $0.1 million and $0.1 million in sublease income in the years ended December 31, 2022 and 2021, respectively and included in other operating income on the consolidated statements of operations and comprehensive loss.

Supplemental balance sheet information related to the operating leases is as follows:

	As of December 31,	
	2022	2021
Operating lease obligations	$ 237	$ 926
Operating lease right-of-use assets	$ 227	$ 774
Weighted-average remaining lease term (years)	0.5	1.29
Weighted-average discount rate	3.50 %	4.64 %

The maturity of operating lease liabilities for the year ended December 31, 2023 is $0.2 million, net of imputed interest.

9. Post-employment benefits

Defined benefit plan

In accordance with the mandatory Swiss pension fund law, all local employees of the Company participate in a defined benefit retirement 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.

The Company recognizes the overfunded or underfunded status of the defined benefit pension plan as an asset or liability in its consolidated balance sheets and recognizes changes in the funded status of the defined benefit pension plan in the year in which the changes occur through accumulated other comprehensive income (loss), which is a component of shareholder's equity. The plan's assets and benefit obligations are remeasured as of December 31 each year.

On September 12, 2022, following a consultation process with the Company's employees, the Board of Directors authorized the termination of approximately 70% of employees. This resulted in a curtailment gain of $1.3 million, which is included in net actuarial gains/losses and is presented as a component of Other Comprehensive Income in the Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2022.

The defined benefit cost is included in general and administrative expenses in the consolidated statements of operations and comprehensive loss. The defined benefit cost for the years ended December 31, 2022 and 2021 was as follows (in thousands):

	Year ended December 31,	
	2022	2021
Components of defined benefit cost		
Service cost	$ 1,387	$ 1,703
Interest cost	56	22
Expected return on plan assets	(108)	(147)
Employee contributions	(643)	(700)
Amortization of actuarial gains	611	1,023
Amortization of net prior service cost	(232)	(173)
Amortization of gains/(losses) due to settlement and benefit payments	648	—
Amortization of net prior service cost due to reduction in service years	(914)	—
Defined benefit cost	$ 805	$ 1,728

The changes in projected benefit obligations for the years ended December 31, 2022 and 2021 were as follows (in thousands):

	2022	2021
Change in projected benefit obligation		
Projected benefit obligation at January 1,	$ (22,230)	$ (23,602)
Service cost	(1,387)	(1,703)
Interest cost	(56)	(22)
Change in assumptions	3,570	1,009
Other actuarial gains (losses)	1,361	(507)
Benefit payments	248	915
Foreign currency exchange	855	815
Settlement	12,778	—
Curtailment	1,263	—
Plan amendment	32	865
Projected benefit obligation at December 31,	$ (3,566)	$ (22,230)

The accumulated benefit obligation is the present value of pension benefits attributed to employee service rendered before the measurement date and based on employee service and compensation prior to that date. The accumulated benefit obligation was $3.4 million and $21.4 million as of December 31, 2022 and 2021, respectively.

Actuarial gains related to the change in the projected benefit obligation for the Company's pension plan for the year ended December 31, 2022 was primarily due to an increase in discount rate. Actuarial losses related to the change in projected benefit obligation for the year ended December 31, 2021 was primarily due to the decrease in the discount rate.

The following table presents the changes in the fair value of defined benefit pension plan assets for years ended December 31, 2022 and 2021 (in thousands):

	2022	2021
Change in plan assets		
Fair value of plan assets at January 1,	$ 15,063	$ 15,030
Expected return on plan assets	108	147
Employee contributions	643	700
Company contribution	643	700
Plan assets gains (losses)	116	(81)
Benefit payments	(248)	(915)
Foreign currency exchange	(563)	(518)
Settlement	(12,778)	—
Fair value of plan assets at December 31,	$ 2,984	$ 15,063

The Company's investment objectives are to ensure that the assets of its defined benefit plans are invested to provide an optimal rate of investment return on the total investment portfolio, consistent with the assumption of a reasonable risk level, and to ensure that pension funds are available to meet the plan’s benefit obligations as they become due. The Company believes that a well-diversified investment portfolio will result in the highest attainable investment return with an acceptable level of overall risk.

The assets are invested by the pension plan, to which many companies contribute, in a diversified portfolio that respects the requirements of the Swiss BVG. Therefore, disaggregation of the pension assets and presentation of plan assets in classes that distinguish the nature and risks of those assets is not possible.

The funded status of the plan is as follows (in thousands):

	As of December 31,	
	2022	2021
Funded status		
Defined benefit obligation	$ (3,566)	$ (22,230)
Fair value of plan assets	2,984	15,063
Net defined benefit obligation	$ (582)	$ (7,167)

Amounts recognized in accumulated other comprehensive loss related to the defined benefit pension plan is as follows (in thousands):

	Year ended December 31,	
	2022	2021
Net prior service credits	$ 444	$ 1,816
Net actuarial loss	(154)	(7,866)
Accumulated other comprehensive income (loss)	$ 290	$ (6,050)

The significant assumptions used to determine the benefit obligations and pension expense for years ended December 31, 2022 and 2021 are as follows:

	2022	2021
Discount rate	0.35%	0.35%
Salary increase (including inflation)	1.00%	1.00%
Rate of pension increases	0.25%	0.25%
Post-employment mortality table	LPP 2020 G	LPP 2020 G

The discount rate is estimated based on corporate bond yields or securities of similar quality in the respective country, with a duration approximating the period over which the benefit obligations are expected to be paid. The Company bases the compensation increase assumptions on historical experience and future expectations. The expected average rate of return for the Company's defined benefit pension plans represents the average rate of return expected to be earned on plan assets over the period that the benefit obligations are expected to be paid, based on government bond notes in the respective country, adjusted for corporate risk premiums as appropriate.

Pension benefit payments are made from assets of the pension plan. It is anticipated that future benefit payments for the next 10 years will be as follows (in thousands):

	Amount
Years ending December 31,	
2023	$ 305
2024	246
2025	191
2026	137
2027	111
2028-2032	1,841
Total expected benefit payments	$ 2,831

The Company expects to contribute $0.2 million to its defined benefit pension plan for the year ended December 31, 2023.

Defined contribution plan

The Company also sponsors a 401K defined contribution plan in the U.S. Participants are eligible for 401K matching contributions based upon the employee's contribution to the plan. The Company's contributions to the defined contribution plan charged to expense were $60 thousand and $33 thousand in the years ended December 31, 2022 and 2021, respectively.

10. Accrued expenses

As a result of termination of the Kissei License Agreement, the Company terminated and assigned to Kissei a number of clinical, manufacturing, and scientific contracts related to the development of linzagolix. The terminations resulted in a significant decrease in the Company's accrued research and development expenses. Furthermore, the assignments resulted in the transfer of $4.9 million in contractual obligations to Kissei, $1.2 million of which was recognized as an offset to accrued research and development expenses as of December 31, 2022.

As part of the current year restructuring plans, the Company terminated approximately 70% of its employees in the fourth quarter of 2022, which resulted in a significant decrease in accrued compensation-related expenses as of December 31, 2022.

As of December 31, 2022 and 2021, accrued expenses and other current liabilities consisted of the following (in thousands):

	As of December 31,	
	2022	2021
Accrued research and development expenses	$ 1,560	$ 10,123
Assigned contractual obligations	(1,224)	—
Accrued compensation-related expenses	1,504	3,125
Accrued other expenses	200	535
Total accrued expenses	$ 2,040	$ 13,783

11. Shareholders' equity

As of December 31, 2022, the total outstanding share capital of $8.8 million, fully paid, consisted of 107,706,699 common shares, excluding 39,212,538 treasury shares. As of December 31, 2022, the Company has additional shares that may be issued out of conditional capital of 17,545,987 and authorized capital of 34,310,230. As of December 31, 2021, the total outstanding share capital of $6.5 million, fully paid, consists of 79,955,268 common shares, excluding 5,265,203 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.

During the year ended December 31, 2022, JGB converted $5.5 million of the outstanding principal and $0.5 million of the accrued and unpaid interest under the Outstanding Notes into 20,930,345 common shares. As the conversions were completed within the terms of the Securities Purchase Agreement, no gain or loss was recognized as a result of these conversions.

In February 2022, the Company announced the issuance of 23,400,000 common shares at par value of 1/13 of a Swiss franc per share. In December 2022, the Company announced the issuance of 20,000,000 common shares 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 were initially held as treasury shares.

During the year ended December 31, 2022, the Company sold a total of 6,821,086 treasury shares at an average price of USD 0.97 per share, as part of its ATM program with SVB Leerink LLC. These multiple daily transactions generated total gross proceeds of $6.6 million. Directly related share issuance costs of $0.2 million were recorded as a deduction in

equity. The Company's ATM program with SVB Leerink LLC expired during the three-months ended September 30, 2022.

During the year ended December 31, 2021, the Company sold a total of 15,933,420 treasury shares at an average price of USD 3.28 per share, as part of its ATM program. These multiple daily transactions generated total gross proceeds of USD 53.7 million. Directly related share issuance costs of USD 2.0 million were recorded as a deduction in equity. In January 2021, 6,448,240 warrants were exercised at an average price of USD 3.43 per share, resulting in proceeds of USD 22.1 million.

12. Share-based compensation

Stock-based compensation expense is classified in the accompanying consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021 as follows (in thousands):

	Year ended December 31,	
	2022	2021
Research and development	$ 2,307	$ 3,915
General and administrative	3,489	4,528
Total share-based compensation	$ 5,796	$ 8,443

2013 Equity Incentive Plan

The Company established the 2013 Equity Incentive Plan (the "2013 EIP") for employees, executives, directors and consultants (the "Beneficiaries") of the Company. 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 elapsed. 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 Company has no present obligation to repurchase or settle the shares in cash. The Company stopped granting stock options under the 2013 EIP in 2016, resulting in the 2013 EIP being fully vested as of December 31, 2020. There was no share based compensation expense for the 2013 EIP in the years ended December 31, 2022 and 2021. There are 469,139 stock options outstanding as of December 31, 2022.

2017 Equity Incentive Plan

The Company established the 2017 Equity Incentive Plan (the "2017 EIP") for Beneficiaries of the Company, under which 4,949,265 and 3,050,340 stock options were granted during the year ended December 31, 2022 and 2021, 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. During the year ended December 31, 2022, performance-based stock options of 1,126,375 were granted to certain employees. Following the termination of the Kissei License Agreement, the performance-based stock options were cancelled as the vesting conditions could no longer be met.

Movements in the number of stock options outstanding under the 2017 EIP were as follows:

	2022		2021	
	Weighted- average exercise price (USD)	Number of options	Weighted- average exercise price (USD)	Number of options
Outstanding, at January 1,	$ 5.15	8,937,473	$ 6.49	7,035,388
Granted	1.51	4,949,265	3.29	3,050,340
Forfeited	2.40	(3,728,260)	6.08	(519,979)
Expired	7.34	(1,311,775)	10.35	(628,276)
Exercised	—	—	—	—
Outstanding, at December 31,	$ 3.95	8,846,703	$ 5.15	8,937,473

No exercise of options occurred during the years ended December 31, 2022 and 2021. As of December 31, 2022, 4,298,905 stock options were vested and exercisable with a weighted average exercise price of $6.00 per share and a weighted average remaining contractual term of 6.89 years. The aggregate intrinsic value of the vested and exercisable options was zero.

The weighted average fair value of the stock-options granted during the years ended December 31, 2022 and 2021, determined using a Black-Scholes model was $1.22 and $2.57, respectively. The significant inputs to the model were:

	2022	2021
Weighted average share price at grant date	$ 1.51	$ 3.29
Weighted average exercise price	$ 1.51	$ 3.29
Weighted average 10-year volatility	80 %	80 %
Dividend yield	— %	— %
Weighted average 10-year risk free rate	1.88 %	1.45 %

The total fair value of awards vested during the years ended December 31, 2022 and 2021 was $5.2 million and $6.4 million, respectively. At December 31, 2022, there was $6.1 million of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted-average period of 1.7 years.

13. Income taxes

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

The Company is subject in Switzerland to a municipal and cantonal income tax rate of 14% and to a federal tax rate of 8.5% on its profits after tax. It is entitled to carry forward any loss incurred for a period of seven years and can offset such losses carried forward against future taxes. In 2015, the Company was granted by the State Council of the Canton of Geneva an exemption of income and capital tax at municipal and cantonal levels for the period from 2013 until 2022. Because of this exemption, and the fact that the Company has incurred net losses since its inception, no income tax expense at the municipal, cantonal or federal levels was recorded in the Company for the years ended December 31, 2022 and 2021. Additionally, the Company recorded a full valuation allowance against its net deferred tax assets as of December 31, 2022 and 2021 as they are not more likely than not realizable. The change in the valuation allowance in the year ended December 31, 2022 was not material.

The Company’s net operating loss carryforwards and the respective expiration dates are as follows (in thousands):

	As of December 31,	
	2022	2021
2022	$ —	$ 17,372
2023	30,213	30,603
2024	61,832	62,631
2025	71,835	72,763
2026	104,529	105,879
2027	76,354	77,340
2028	54,945	55,480
2029	37,733	—
Total net operating loss carry forwards	$ 437,441	$ 422,068

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, 2022 and 2021.

ObsEva USA Inc., the U.S. subsidiary, is a service organization for the Company and is therefore subject to taxes on the revenues generated from its services to the Company that are charged based upon the U.S. subsidiary's cost plus arrangement. The profits of the U.S. subsidiary for the year ended December 31, 2022 and 2021 were subject to a total U.S. income tax rate of 27.3% based on both the U.S. Federal and state tax rates. The income tax for the year ended December 31, 2022 and 2021 was $0.0 million and $0.2 million, respectively. Additionally, since ObsEva USA Inc. is totally dependent on ObsEva SA for revenue, the Company recorded a full valuation allowance against its net deferred tax assets as they are not more likely than not realizable as of December 31, 2022 and 2021.

The components of the income tax expense for Obseva USA, Inc. are as follows (in thousands):

	Year ended December 31,	
	2022	2021
Federal statutory rate		
Current	$ (3)	$ 164
Deferred	—	—
State and local		
Current	14	49
Deferred	—	—
Foreign		
Current	—	—
Deferred	—	—
Income tax expense	$ 11	$ 213

Reconciliation between the effect of applying the federal statutory rate and the effective income tax rate used to calculate the Company's income tax expense for Obseva USA, Inc. is as follows:

	Year ended December 31,	
	2022	2021
Federal statutory rate	21.0 %	21.0 %
State income tax, net of federal benefit	1.1	6.3
Share-based compensation	10.6	(4.4)
Other	(31.5)	(33.4)
Effective income tax rate	1.2 %	(10.5)%

As of December 31, 2022 and 2021, the Company does not have any material unrecognized tax benefits. The Company files income tax returns in the United States, various U.S. states, Switzerland, and Ireland. The Company is still open to examination by the applicable taxing authorities from 2019 forward.

14. Loss per share

Because the Company has reported net loss attributable to common shareholders for the years ended December 31, 2022 and 2021, diluted net loss per share attributable to common shareholders are the same for both years. The basic loss per share is computed by dividing the loss of the period attributable to common shareholders by the weighted average number of common shares outstanding for the period as follows:

	Year ended December 31,	
	2022	2021
Net loss attributable to shareholders (in '000)	$ (29,879)	$ (52,979)
Weighted average number of shares outstanding	92,080,998	75,281,838
Basic and diluted loss per share	$ (0.32)	$ (0.70)

Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. As such, all convertible debt, warrants to purchase common shares, and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an anti-dilutive impact for all periods presented.

Potential common shares issuable upon conversion of debt, warrants to purchase common shares, and stock options that are excluded from the computation of diluted weighted-average shares outstanding, as they are anti-dilutive, are as follows:

	As of December 31,	
	2022	2021
Common shares issuable upon conversion of debt	26,974,359	9,842,520
Common shares issuable upon exercise of warrants	2,653,593	1,634,877
Common shares issuable upon exercise of stock options	8,846,703	8,937,473
Total	38,474,655	20,414,870

15. Commitments and contingencies

License Obligations

Under the terms of the two license agreements with Merck Serono for nolasiban, the Company would be obligated to pay Merck Serono a high-single digit and a mid-single digit royalty, respectively, of net sales generated by the Company, its affiliates or sub-licensees of any product containing the in-licensed compounds.

Disputes and potential claims

The Company is a party in various contracts and subject to disputes, litigation, and potential claims arising in the ordinary course of business none of which are currently reasonably possible or probable of material loss.

On February 13, 2023, the Company received a letter from CMS von Erlack Partners SA on behalf of Wincasa SA ("Wincasa") regarding the lease of office and parking space between the Company and Wincasa entered into on May 10, 2022 (the "Lease Agreement") and subsequently terminated by Wincasa on September 30, 2022. The letter claimed a breach of contractual obligation pursuant to the Lease Agreement that led to the termination and requested payment for damages of approximately $0.4 million. The Company believes the allegations in the letter are without merit and intends to defend the claim. The Company believes the range of loss is between $0 and $0.4 million; however, the outcome of this dispute is uncertain and not probable at this time. Accordingly, the Company has not accrued any liability.

16. Going concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced recurring losses since its inception. The Company incurred a net loss of $29.9 million and used $23.1 million in cash to fund operations during the year ended December 31, 2022 and had an accumulated deficit of $472.8 million as of December 31, 2022. The Company expects to continue to generate operating losses for the foreseeable future. As of December 31, 2022, the Company had cash and cash equivalents of $8.4 million. The Company believes that its current cash and cash equivalents are only sufficient to fund its operating expenses into the fourth quarter of 2023 and this raises substantial doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these consolidated financial statements.

The future viability of the Company is dependent on its ability to raise additional debt and equity capital to finance its future operations. There can be no assurance that such capital will be available in sufficient amounts or on terms acceptable to the Company. 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 Company may receive future milestone payments from licensors or pursuant to the IP Acquisition Agreement, but that is dependent on achieving certain regulatory or commercial milestones that may never happen. The Company may seek additional funding through public or private financings, debt financing or collaboration agreements. On March 14, 2023, we received a delisting notice from The Nasdaq Stock Market LLC notifying us that our common shares were scheduled for delisting from the Nasdaq Capital Market on March 23, 2023 due to our failure to regain compliance with Nasdaq Listing Rule 5450(a)(1) because the bid price of our common shares has not closed at or above $1.00 per share for a minimum of ten consecutive business days. As a result, our common shares were delisted from The Nasdaq Capital Market and began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF." The Company expects that its delisting will also impact its ability to obtain funding. 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 candidate, 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 continues to explore options to obtain additional funding, including through collaborations with third parties related to the future potential development and/or commercialization of its product candidate. 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 Company's business, results of operations and financial conditions.

17. Subsequent events

On February 23, 2023, the Board of Directors of the Company approved a reorganization plan, to, among other things, consolidate its operations in Switzerland, where its headquarters are located. The reorganization plan is intended to preserve cash, focus resources towards the development of Nolasiban and manage out-licensed programs. As part of the reorganization, the Company reduced its overall workforce by approximately 57%, including downsizing its US-based executive management team. The Company is beginning the activities with respect to the reorganization plan effective immediately. As a result, the Company expects to incur restructuring charges approximately $1.2 million attributable to cash payments primarily for notice period payments, including healthcare coverage to employees with respect to eliminated positions. Such restructuring charges are expected to be incurred and recorded in the first quarter of 2023.

On February 23, 2023, the Company entered into a Payoff and Termination Agreement (the "Payoff Agreement") with JGB, pursuant to which JGB agreed to accept a reduced prepayment premium of (i) $0.6 million in cash and (ii) $0.3 million in the form of approximately 1.5 million common shares of the Company (the "Payoff Shares") as prepayment for the New Notes issued by the Company to JGB due December 31, 2023. As of February 23, 2023, $4.7 million aggregate principal amount of the First Tranche Note and $1.9 million aggregate principal amount of the Second

Tranche Note remained outstanding. The Company completed the transactions contemplated by the Payoff Agreement on February 24, 2023, in full satisfaction of its obligations under the New Notes and that certain Amended and Restated Securities Purchase Agreement, deemed dated as of October 12, 2021, among the Company and certain funds and accounts managed by JGB Management, Inc. (including JGB).

On February 28, 2023, the Company entered into a share purchase agreement with Ernest Loumaye, Founder and Board Member of the Company, pursuant to which the Company sold 4,000,000 common shares, at a price of approximately $0.11 per share, for an aggregate amount of approximately $0.4 million. The shares were issued from the Company's pool of treasury shares.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by California and federal regulatory agencies. As a result of these actions, the Federal Deposit Insurance Corporation (FDIC) established Silicon Valley Bridge Bank, N.A. (the "Bridge Bank") as successor to SVB. We maintained a portion of our cash with SVB. On March 12, 2023, the U.S. Treasury, Federal Reserve and FDIC rolled out emergency measures to fully protect all depositors of SVB and, on March 13, 2023, we had full access to our cash on deposit with SVB. As a result, we do not anticipate any losses with respect to such balances.

On March 14, 2023, the Company received a delisting notice from The Nasdaq Stock Market LLC notifying us that our common shares were scheduled for delisting from the Nasdaq Capital Market on March 23, 2023 due to our failure to regain compliance with Nasdaq Listing Rule 5450(a)(1) because the bid price of the Company's common shares has not closed at or above $1.00 per share for a minimum of ten consecutive business days. As a result, the Company's common shares were delisted from The Nasdaq Capital Market and began trading on the over-the-counter market on March 23, 2023 under the symbol "OBSVF". On March 28, 2023, the Company filed a post-effective amendment to various outstanding registration statements on Form F-3, which amendment was declared effective by the United States Securities and Exchange Commission on March 29, 2023, and a post-effective amendment to various outstanding registration statements on Form S-8, which amendment became effective immediately upon filing, each to remove and withdraw from registration the shares that were registered but remained unsold thereunder.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Securities Exchange Act of 1934, as of December 31, 2022. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining disclosure controls and procedures, as defined by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, and internal control over financial reporting, as defined by Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our management conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management has concluded that our internal control over financial reporting was effective as of December 31, 2022.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

We are a non-accelerated filer and smaller reporting company, and therefore our independent registered public accounting firm has not issued a report on the effectiveness of internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

Our directors are appointed, individually, for one-year terms, which expire on the occasion of each annual general meeting and can be re-elected indefinitely. As of the date hereof, all members of the Board are non-executive members. Dr. Ernest Loumaye, Co-Founder, was our Chief Executive Officer until December 2020, and Brian O'Callaghan served as Chief Executive Officer from that date until February 2023. None of the other non-executive members have held management roles in the Company in the three financial years preceding the period under review, nor have had significant business connections with any related party of the Company. The Board of Directors is composed of not more than eight members.

The names, nationality, year joined the Board, position, committee memberships and ages of our directors as of March 24, 2023, are set forth below, followed by a short description of each director's business experience, education and activities:

Name	Nationality	Appointment	Age	Position	AC [1]	CNCGC [2]
Ernest Loumaye	Belgian	2012	70	Interim Chair[3]	—	Chair
Anne VanLent	American	2021	74	Member[4]	Chair	—
Catarina Edfjäll	Swiss	2021	57	Member[5]	—	Member
Stephanie Brown	Canadian	2022	62	Member[6]	Member	—
Ed Mathers	American	2016	62	Member[7]	Member	Member
Brian O'Callaghan	American	2021	53	Member[8]	—	—
Annette Clancy	British	2013	68	Former Chair[9]	—	—

(1) Audit Committee
(2) Compensation, Nominating and Corporate Governance Committee
(3) Dr. Loumaye served as our Chief Executive Officer until December 1, 2020, and was appointed as Interim Chair of the Board of Directors, effective March 13, 2023, to serve until our 2023 Annual General Meeting of Shareholders ("AGM"), at which time he is expected to be nominated for this position for the upcoming year.
(4) BOD member since May 28, 2021. On February 23, 2023, we were notified that the director will not stand for re-election as director nominee at the AGM and, therefore, will cease to be a director effective as of the AGM.
(5) BOD member since May 28, 2021.
(6) BOD member since May 18, 2022. On February 23, 2023, we were notified that the director will not stand for re-election as director nominee at the AGM and, therefore, will cease to be a director effective as of the AGM.
(7) On February 23, 2023, we were notified that the director will not stand for re-election as director nominee at the AGM and, therefore, will cease to be a director effective as of the AGM.
(8) BOD member since May 28, 2021. Mr. O'Callaghan served as our Chief Executive Officer from December 1, 2020 until February 23, 2023. On February 23, 2023, we were notified that the director will not stand for re-election as director nominee at the AGM and, therefore, will cease to be a director effective as of the AGM.
(9) Ms. Clancy resigned from our Board of Directors on March 10, 2023.

Ernest Loumaye is a co-founder and has served as a member of our board of directors since its inception in November 2012, and was appointed Chairman of the Board in March 2023. He served as our Chief Executive Officer since our inception until December 2020. From 2019 to January 2021, he was a member of the board of directors at AVA, a Zurich-based medtech company active in 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 Gynecology. Dr Loumaye was research fellow at the National Institute of Health (NIH, Bethesda, MD, USA).

Anne VanLent has served as a member of our board of directors and chair of the audit committee since May 2021. Since May 2018, Ms. VanLent has been President of AMV Advisors, providing corporate strategy and financial consulting services to emerging growth life sciences companies. Ms. VanLent had been Executive Vice President and Chief Financial Officer of Barrier Therapeutics, Inc., a publicly traded pharmaceutical company, from May 2002 through April 2008. Ms. VanLent also worked for eight years, from March 1985 to February 1993, as Senior Vice President and Chief Financial Officer of The Liposome Company, Inc., a publicly traded biopharmaceutical company. Ms. VanLent has served as a director, chair of the Audit Committee of Trevi Therapeutics, Inc since October 2018 and is currently also a member of the Nominating and Governance Committee. She has also served as a director and chair of the Audit Committee of Applied Genetics Technologies Corporation since August 2016. Until June 2020, she also served as a director, chair of the Audit Committee and member of the Compensation Committee of Vaxart, Inc. as a result of its merger in February 2018 with Aviragen Therapeutics, Inc., where she served as lead director, chair of the Audit Committee and member of the Nominating and Governance Committee. From April 2011 to December 2017, she served as a director, chair of the Audit Committee, and chair of the Nominating and Governance Committee of Ocera Therapeutics, Inc. From April 2013 through June 2017 she served as a director, member of the Audit Committee, and member of the Compliance Committee of Novelion Pharmaceuticals, Inc. From July 2013 to May 2016, Ms. VanLent served as a director, chair of the Audit Committee, and member of the Compensation Committee of Onconova Therapeutics, Inc. From 1997 to May 2013, she served as a director of Integra Life Sciences Holdings, Inc. and chaired its audit committee from 2006 until 2012. Ms. VanLent received a B.A. degree in Physics from Mount Holyoke College.

Catarina Edfjäll is a Global Regulatory Affairs Expert with more than 25 years of experience in the biotech and pharma sector, now working as an independent consultant and mentor. She has profound drug development experience across the entire product lifecycle, from development to launch, and across many therapeutic areas, including rare diseases. She was responsible for the successful regulatory approval of 20 innovative medicinal products and new indications in more than 50 countries. In her most recent senior management role, Ms. Edfjäll was the global head of regulatory affairs at CSL Behring (from 2013 to 2019). Prior to that, she held leadership positions in regulatory affairs at companies formerly known as Shire (from 2011 to 2013), Celgene (from 2006 to 2011) and Actelion (from 2001 to 2006). She started her career at F. Hoffmann-La Roche (from 1993 to 2000). Since 2020, Ms. Edfjäll has served as a Board Member at the Cancer Drug Development Forum (CDDF). She was also a board member at the International Collaboration on Rare Diseases & Orphan Drugs (ICORD) from 2008 to 2012 and from 2014 to 2021. She has been actively involved in several multi-stakeholder organizations, including the European Medicines Agency´s Committee for Orphan Medicinal Products´ Working Group with Interested Parties. Catarina holds a Master in biotechnology engineering from the Ecole Supérieure de Biotechnologie in Strasbourg, a Ph.D. in biochemistry from the University in Basel and a Corporate Governance Certification from the Swiss Board School and the University of St Gallen.

Stephanie Brown has served as a member of our Board of Directors since May 2022. Ms. Brown is an accomplished executive leader with over 30 years of broad commercial experience in the bio-pharma industry. She currently serves as President North America for Santhera Pharmaceuticals, a global specialty pharmaceutical company focused on commercializing medicines for rare diseases. Over the course of her career, Ms. Brown has built and transformed businesses at organizations including Merck (MSD), Genentech, Biogen, and Novartis, where she held a variety of leadership roles in the USA, Canada and globally. She has deep experience in product launches and has successfully brought highly specialized, breakthrough biologics and small molecules from clinic to commercialization across a broad range of therapeutic areas. Ms. Brown has chaired and governed inter-company collaborations, and has chaired, co-chaired and served on multiple executive US and global governance committees. She is a past member of the Board of Directors of the Biotechnology Innovation Organization, the biotechnology industry association in the USA. Ms. Brown has also served on the Operating Board of the West Island Palliative Care Residence, a non-profit organization located in Canada. Stephanie has a BSc in Chemistry with Biology from Mount Allison University, Canada, and her MBA from Edinburgh Business School, University of Edinburgh, Scotland.

Ed Mathers has served as a member of our board of directors since February 2016. Mr. Mathers is a General Partner of New Enterprise Associates (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), Senti Biosciences, Inozyme (Nasdaq: INZY), Reneo Pharma (Nasdaq: RPHM), Akouos (Nasdaq: AKUS), Trevi Therapeutics (Nasdaq:TRVI), Mirum Pharmaceuticals (Nasdaq: MIRM), Shape Therapeutics, MBX Biosciences, Code Biotherapeutics, 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), Amplyx Pharmaceuticals (sold to Pfizer) 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.

Brian O'Callaghan served as our Chief Executive Officer from December 2020 to February 2022. 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 Indaptus Therapeutics, Bolt Biotherapeutics and The Biocom Purchasing Group, all of which are based in California.

Executive Officers

The name and age of our executive officer as of March 24, 2023 are set forth below:

Name	Age	Position
Will Brown	41	Interim Chief Executive Officer and Chief Financial Officer

Will Brown joined ObsEva in January 2022 as Chief Financial Officer with extensive experience in capital markets, finance and accounting. Mr. Brown was appointed interim Chief Executive Officer in February 2022, while also retaining the title of Chief Financial Officer. From May 2018 to December 2021, Mr. Brown served as Chief Financial Officer of Altimmune, Inc. (NASDAQ: ALT) where he was critical in the company's transformation and growth through more than $300 million of new equity issuances and a strategic acquisition. Mr. Brown has been a consultant to several private and public companies in a variety of accounting and tax matters both independently and as the managing partner of Redmont CPAs. Prior to his consulting role, he was an audit manager at PricewaterhouseCoopers and a Division Controller at Rheem, a multinational manufacturing company. Mr. Brown is a Certified Public Accountant (inactive) and earned both his MBA and B.S. from Auburn University at Montgomery.

On March 13, 2023, we announced that Fabien de Ladonchamps, currently Vice President, Corporate Affairs and Finance of our company, will be appointed as our Chief Executive Officer with an anticipated effective date of May 1, 2023. Additionally, Clive Bertram, former Chief Commercial Officer, Brandi Howard, former Chief Clinical Officer, and Luigi Marro, former Chief Transformation Officer also departed the Company effective February 23, 2023.

How nominees to our Board are selected

Candidates for election to our Board of Directors are nominated by our Compensation, Nominating and Corporate Governance Committee (the "CNCG committee") and ratified by our full Board of Directors for nomination to the shareholders at the annual general meeting.

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

Board leadership structure

Currently, Dr. Loumaye serves as the Interim Chairman of the Board. The Board believes that having different individuals serving in the separate roles of Chairman of the Board and CEO is in the best interest of shareholders in the Company's current circumstances because it reflects the CEO's responsibility over management of the Company's operations and the Chairman's oversight of board functions and strategic development.

Board committees

The Board has two established committees: an audit committee and a CNCG committee. Both committees presently reports to the Board on their activities at every regular session of the Board.

Audit Committee
The audit committee, which consists of Anne VanLent, Ed Mathers and Stephanie Brown, assists the Board in overseeing the accounting and financial reporting processes and the audits of the Company's financial statements. In addition, the audit committee is directly responsible for the compensation, retention and oversight of the work of the auditors who are appointed by the shareholders pursuant to Swiss law. Ms. VanLent serves as chair of the audit committee. The audit committee consists exclusively of members of the Board who are independent in accordance with the Nasdaq and SEC requirements for independence, and financially literate, and Ms. VanLent is considered an "audit committee financial expert" as defined by the SEC.

Compensation, Nominating and Corporate Governance Committee
The CNCG committee consists of three members: Ernest Loumaye, Catarina Edfjäll and Ed Mathers. The chair of the CNCG committee is Dr. Loumaye. The primary purpose of the CNCG committee is to oversee the Company's compensation policies, plans and programs and to review and determine the compensation to be paid to the executive officers, directors and other senior management, as appropriate. The Company is 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 CNCG committee must be elected by the shareholders.

In addition, the CNCG committee is also responsible for director nominations as well as reviewing and making recommendations to the Board, if required, on the Company's corporate governance framework and guidelines.

Meetings and attendance

During the fiscal year ended December 31, 2022, the Board held 22 meetings and the Board Committees held a total of 6 meetings. Each director attended 75% or more of the total number of meetings of the Board and the Board Committees of which he was a member during the period he served as a director in fiscal year 2022. The Company has no specific policy regarding director attendance at our general annual meeting of shareholders. Generally, however, a Board meeting is held on the same date as the annual meeting, with directors attending the annual meeting. Our 2022 AGM was attended by all of the directors recommended for election.

Board involvement in risk oversight

The Company's management is responsible for defining the various risks facing the Company, formulating risk management policies and procedures, and managing the Company's risk exposures on a day-to-day basis. The Board's responsibility is to monitor the Company's risk management processes by informing itself of the Company's material risks and evaluating whether management has reasonable controls in place to address the material risks. The Board is not responsible, however, for defining or managing the Company's various risks.

The Board of Directors monitors management's responsibility for risk oversight through regular reports from management to the Audit Committee and the full Board. Furthermore, the Audit Committee reports on the matters discussed at the committee level to the full Board. The Audit Committee and the full Board focus on the material risks facing the Company, including strategic, operational, legal and regulatory risks, to assess whether management has reasonable controls in place to address these risks. In addition, the CNCG Committee is charged with reviewing and

discussing with management whether the Company's compensation arrangements are consistent with effective controls and sound risk management. Finally, risk management is a factor that the Board and the CNCG Committee consider when determining who to nominate for election as a director of the Company and which directors serve on the Audit Committee. The Board believes this division of responsibilities provides an effective and efficient approach for addressing risk management.

Code of Business Conduct and Ethics and other governance documents

We have adopted a written Code of Ethics that applies to our Board of Directors and all of our employees, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions. A copy of our code of conduct can be found on our website, www.obseva.com/corporate-governance.

Copies of the charters of our Board's Audit Committee and CNCG Committee, as well as other governance documents, can be accessed in the Investors — Corporate Governance section of our website. The information on, or that can be accessed through our website is not part of this Annual Report and is not incorporated by reference herein.

Communicating with our Board members

Although our Board of Directors has not adopted a formal process for shareholder communications with the Board, we make every effort to ensure that the views of shareholders are heard by the Board or by individual directors, as applicable, and we believe that this has been an effective process to date. Shareholders may communicate with the Board by sending a letter to the Obseva SA, Chemin des Aulx, 12, 1228, Plan-Les-Ouates, Geneva, Swizerland. The Corporate Secretary will receive the correspondence and forward it to the Chairman of the Board, or to any individual director or directors to whom the communication is directed, as appropriate. Notwithstanding the above, the Chief Executive Officer and Corporate Secretary each has the authority to discard or disregard any communication that is unduly hostile, threatening, illegal or otherwise inappropriate or to take any other appropriate actions with respect to such communications.

In addition, any person, whether or not an employee, who has a concern regarding the conduct of the Company or our employees, including with respect to our accounting, internal accounting controls or auditing issues, may, in a confidential or anonymous manner, communicate that concern in writing by addressing a letter to the Chairman of the Audit Committee, c/o Corporate Secretary, at our corporate headquarters address, which is Chemin des Aulx, 12, 1228, Plan-Les-Ouates, Geneva, Swizerland.

Section 16(a) beneficial ownership reporting compliance and Delinquent Section 16(a) Reports

We did not file Section 16 reports during 2022 as we were a foreign private issuer.

Item 11. Executive Compensation

Our named executive officers ("Named Executive Officers") for the year ended December 31, 2022 are:

- Brian O'Callaghan, our former Chief Executive Officer; and
- William M. Brown, our current Interim Chief Executive Officer and Chief Financial Officer.

Elements of Compensation

The compensation arrangement for each Named Executive Officer is intended to encourage performance and to align the Named Executive Officers' interests with those of our shareholders. In setting compensation for our Named Executive Officers, the CNCG Committee and the Board takes into account the relative amount of compensation that is delivered on a current and long-term basis and in the form of cash and equity. The combination of performance measures for annual bonuses and the equity compensation programs for executive officers, as well as the multi-year vesting schedules

for equity awards encourage employees to maintain both a short-term and a long-term view with respect to Company performance.

The Company's executive compensation program consists of the following elements:

- base salary;
- annual cash bonuses;
- equity awards;
- health and retirement benefits and perquisites; and
- 401(k) plan

Base Salary

The Named Executive Officers receive a base salary to compensate them for services rendered to our Company. The base salary payable to each Named Executive Officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, roles and responsibilities.

Annual Performance-Based Bonus

The Named Executive Officers are entitled to receive annual performance-based cash bonuses, the amount of which is based on satisfaction of corporate and personal objectives that are established by the Board of Directors or the CNCG Committee. The annual bonuses are intended to encourage the Named Executive Officers to promote the growth of the Company's business.

Equity Awards

The Named Executive Officers are eligible to receive equity awards under the Obseva SA 2017 Equity Incentive Plan (the "2017 EIP Plan"). Awards under the 2017 EIP Plan are intended to align the interests of the Named Executive Officers with those of our shareholders and to create a link between executive pay and the long-term performance of our Common Shares.

Employee Benefits

The Named Executive Officers, like our other employees, participate in health and welfare benefit plans, subject to satisfying eligibility requirements.

401(k) Plan

Obseva USA Inc. maintains a tax-qualified retirement plan (the "401(k) Plan") that provides eligible US employees (including the Named Executive Officers) with an opportunity to save for retirement on a tax-advantaged basis. Eligible employees are able to participate in the 401(k) Plan as of the first day of the month following the date they meet the 401(k) Plan's eligibility requirements, and participants are able to defer up to 100% of their eligible compensation subject to applicable annual limits under the Internal Revenue Code of 1986, as amended (the "Code"). All participants' interests in their deferrals are 100% vested when contributed. The 401(k) Plan permits Obseva to make matching contributions and profit sharing contributions to eligible participants. Obseva matches contributions 100% on the first 3% of contributions made by participants.

We believe the benefits described above are necessary and appropriate to provide a competitive compensation package to our Named Executive Officers.

Summary Compensation Table

The following table sets forth the total compensation that was paid to or earned by the Named Executive Officers for the 2022 and 2021 fiscal years.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(4)	All Other Compensation ($)(5)	Total ($)
Brian O'Callaghan	2022	594,104	—	829,400	245,100	71,971	1,740,575
Former Chief Executive Officer	2021	576,800	—	730,000	346,800	81,109	1,734,709
Will Brown(2)(3)	2022	425,000	100,000	729,000	170,000	13,500	1,437,500
Interim Chief Executive Officer and Chief Financial Officer							

(1) Amounts in this column reflect the aggregate grant date fair value of stock options granted during the covered year computed in accordance with the provisions of FASB ASC Topic 718. The assumptions used to calculate the amounts for fiscal years 2022 and 2021 are discussed in Item 8, Financial Statements and Supplementary Data.
(2) Mr. Brown commenced employment with ObsEva on January 1, 2022.
(3) Mr. Brown received a one-time sign on bonus upon joining ObsEva on January 1, 2022.
(4) Amounts in this column reflect performance-based bonus payments earned in the respective years.
(5) All other compensations consist of the following:

Name and Principal Position	Year	Company contributions to benefit plans ($)	Group Term Life Insurance ($)	Housing expense ($)	Other Reimbursements ($)	All Other Compensation ($)
Brian O'Callaghan	2022	11,833	138	60,000	—	71,971
Former Chief Executive Officer	2021	12,221	138	68,750	—	81,109
Will Brown	2022	12,504	60	—	936	13,500
Interim Chief Executive Officer and Chief Financial Officer						

Narrative to Summary Compensation Table

Agreements with Named Executive Officers

We have entered into employment agreements with each of Mr. O'Callaghan and Mr. Brown. The material terms of such agreements are summarized below.

Employment Agreement with Brian O'Callaghan

On November 9, 2020, the Company entered into an employment agreement with Mr. O'Callaghan in connection with his employment as the President and Chief Executive Officer of the Company (the "*Employment Agreement*"). Pursuant to the Employment Agreement, Mr. O'Callaghan commenced employment with the Company on November 9, 2020.

Under the Employment Agreement, Mr. O'Callaghan receives a base salary of $560,000 and, from January 1, 2021, will be eligible to receive an annual discretionary incentive bonus of up to 50% of his base salary based on achievement of performance goals established by the CNCG Committee.

Mr. O'Callaghan is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives. In addition, the Company pays the premium costs for a group term life insurance policy for Mr. O'Callaghan. During the term of Mr. O'Callaghan's employment, and subject to applicable securities laws or listing

standards, the Company will use its best efforts to cause Mr. O'Callaghan to be nominated for election as a member of the Company's board of directors at each annual meeting of stockholders at which Mr. O'Callaghan is up for election.

Pursuant to the Employment Agreement, Mr. O'Callaghan was granted an option to purchase 1,926,962 common shares pursuant to the 2017 EIP Plan at an exercise price of $1.96 per share (the "Stock Option"). The agreement relating to the stock option shall include the following terms:

- For 1,482,278 shares underlying the Stock Option, 25% of the shares underlying the Stock Option will vest on the first anniversary of the Effective Date hereof and the remaining 75% shall vest in equal amounts at the end of each calendar month for the 36-month period following the first anniversary of the Effective Date, subject to Mr. O'Callaghan's continued employment and all other terms and conditions of the 2017 EIP Plan and subject to double-trigger acceleration.

- For the remaining 444,684 shares underlying the Stock Option, 100% of the shares underlying the Stock Option will vest on the third anniversary of the Effective Date, subject to Mr. O'Callaghan's continued employment and all other terms and conditions of the 2017 EIP Plan and subject to doubletrigger acceleration.

In the event of an employment termination, the Company will pay Mr. O'Callaghan his earned but unpaid base salary through the date of termination, accrued but unused vacation pay, unreimbursed business expenses and such employee benefits as may be due to Mr. O'Callaghan under the terms of the any qualified retirement plan or health and welfare benefit plan (the "Accrued Obligations"). In addition, if the Company terminates Mr. O'Callaghan's employment for "cause" (as defined below), Mr. O'Callaghan will be entitled to payment of any unpaid prior year's annual bonus.

If the Company terminates Mr. O'Callaghan's employment without cause or Mr. O'Callaghan resigns his employment for "good reason" (as defined below) within twelve months immediately following a change in control, in addition to the Accrued Obligations, the vesting and exercisability of all outstanding and unvested stock options and other stock awards held by Mr. O'Callaghan shall be accelerated and vest on the date of termination. Additionally, Mr. O'Callaghan will be entitled to receive 9 months of base salary continuation payments, 9 months of continued coverage under the health insurance plans in which Mr. O'Callaghan participates at the time of the termination and payment of any unpaid prior year's annual bonus.

Under the Employment Agreement, "cause" generally means Mr. O'Callaghan's (i) a material breach of any covenant or condition under the Employment Agreement; (ii) any act involving moral turpitude, deceit, dishonesty or fraud, (iii) conviction of, or a plea of nolo contendre or guilty to a felony crime; (iv) any act of gross misconduct or gross negligence; (v) refusal to follow or implement a clear, lawful, and reasonable directive of Company or material violation of any Company policy; (vi) material breach of fiduciary duties; or (vii) material damage to the Company's property. Under the Employment Agreement, "good reason" generally means (i) a material diminution in Mr. O'Callaghan's base salary or target annual bonus opportunity, (ii) a material diminution in Mr. O'Callaghan's title, reporting relationship, authorities, duties or responsibilities, or (iii) any other action or inaction that constitutes a material breach by the Company.

Employment Agreement with Will Brown

Effective January 1, 2022, the Company entered into an employment agreement with Will Brown, the Chief Financial Officer. The agreement provided that Mr. Brown would be employed so long as mutually agreeable to Mr. Brown and the Company.

The agreement provided Mr. Brown with an initial base salary of $425,000. In addition, Mr. Brown was paid a signing bonus of $100,000. In addition, Mr. Brown is eligible to receive an annual discretionary incentive bonus of up to 40% of base salary based as determined by the CNCG Committee. In addition, Mr. Brown would be granted incentive stock options to purchase 450,000 shares of the Company's common shares, Mr. Brown is eligible to participate in the Company's employee benefit plans made available to its similarly situated senior executives.

If the Company terminates Mr. Brown's employment without cause or Mr. Brown resigns his employment for "good reason" (as defined below) within twelve months immediately following a change in control, in addition to the Accrued Obligations, the vesting and exercisability of all outstanding and unvested stock options and other stock awards held by Mr. Brown shall be accelerated and vest on the date of termination. Additionally, Mr. Brown will be entitled to receive six months of base salary continuation payments, six months of continued coverage under the health insurance plans in which Mr. Brown participates at the time of the termination and payment of any unpaid prior year's annual bonus. Lastly, Mr. Brown will be entitled to receive a one-time lump sum payment to the pro-rata portion of the annual bonus at 100% of target for the year in which the termination occurs.

Under the Employment Agreement, "cause" generally means Mr. Brown's (i) a material breach of any covenant or condition under the Employment Agreement; (ii) any act involving moral turpitude, deceit, dishonesty or fraud, (iii) conviction of, or a plea of nolo contendre or guilty to a felony crime; (iv) any act of gross misconduct or gross negligence; (v) refusal to follow or implement a clear, lawful, and reasonable directive of Company or material violation of any Company policy; (vi) material breach of fiduciary duties; or (vii) material damage to the Company's property. Under the Employment Agreement, "good reason" generally means (i) a material diminution in Mr. Brown's base salary or target annual bonus opportunity, (ii) a material diminution in Mr. Brown's title, reporting relationship, authorities, duties or responsibilities, or (iii) any other action or inaction that constitutes a material breach by the Company.

Under the agreement, Mr. Brown is subject to restrictive covenants during the term of his employment and survive termination or expiration of the Employment Agreement.

Outstanding Equity Awards at 2022 Fiscal Year-End

The following table sets forth certain information with respect to outstanding equity awards of our Named Executive Officers as of December 31, 2022.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Brian O'Callaghan	772,020	710,258 (1)	—	1.96	11/8/2030
	—	444,658 (2)	—	1.96	11/8/2030
	114,583	135,417 (3)	—	3.76	2/3/2031
	—	715,000 (4)	—	1.43	2/1/2032
Will Brown	—	450,000 (5)	—	1.99	12/31/2031

(1) One-fourth (1/4th) of the shares underlying the option vested on November 9, 2021, and the remainder of the shares underlying the option vested or will vest in 36 equal monthly installments thereafter, subject to Mr. O'Callaghan continuing to provide service through each such date.
(2) The shares underlying the option will vest on November 9, 2023, subject to Mr. O'Callaghan's continuous service.
(3) One-fourth (1/4th) of the shares underlying the option will vest on February 4, 2022, and the remainder of the shares underlying the option will vest in 36 equal monthly installments thereafter, subject to Mr. O'Callaghan continuing to provide service through each such date.
(4) One-fourth (1/4th) of the shares underlying the option will vest on February 2, 2023, and the remainder of the shares underlying the option will vest in 36 equal monthly installments thereafter, subject to Mr. O'Callaghan continuing to provide service through each such date.
(5) One-fourth (1/4th) of the shares underlying the option vested on January 1, 2023, and the remainder of the shares underlying the option will vest in 36 equal monthly installments thereafter, subject to Mr. Brown continuing to provide service through each such date.

Director Compensation

The Compensation of the Board Members consists of a fixed compensation and attendance allowances. Executive members of the Board can receive in addition compensation elements applicable to Executive Officers.

Following a proposal by the Board, the general meeting of shareholders annually and separately approves (i) the aggregate compensation of the Board until the next AGM and (ii) the aggregate compensation of the Executive Officers for the following business year. The Board can also submit at its discretion compensation proposals for other periods or for only some individuals from the Board or the executive committee. The vote of the general meeting of shareholders on the compensation proposals is binding.

We also have a policy of reimbursing our directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

Under our non-employee director compensation program, each non-employee director that qualifies under the program is eligible to receive compensation for his or her service on our board of directors or committees thereof consisting of annual cash retainers paid quarterly in arrears, as follows:

Position	Retainer
Chairperson of the Board	$ 70,000
Board Member	$ 40,000
Audit Committee Chairperson	$ 7,500
Audit Committee Member	$ 7,500
Compensation, Nominating and Corporate Governance Committee Chairperson	$ 7,500
Compensation, Nominating and Corporate Governance Committee Member	$ 7,500

The table below sets forth the compensation received by each of the individuals who served as a non-employee director during the fiscal year ended December 31, 2022.

Name	Fees earned or paid in cash ($)	Stock Awards ($)	Option Awards ($)(1)(3)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Annette Clancy	73,548	—	37,120	—	—	—	110,668
Ernest Loumaye	40,000	—	37,120	—	—	—	77,120
Ed Mathers	55,000	—	37,120	—	—	—	92,120
Anne VanLent	55,000	—	37,120	—	—	—	92,120
Catarina Edfjäll	47,500	—	37,120	—	—	—	84,620
Stephanie Brown	29,368	—	67,813	—	—	—	97,181
Frank Verwiel (2)	29,583	—	37,120	—	—	—	66,703

(1) Amounts represent the aggregate grant date fair value of stock options granted to our non-employee directors during 2022, computed in accordance with ASC Topic 718. Assumptions used in the calculation of these amounts are included in Item 8, Financial Statements and Supplementary Data. These amounts do not necessarily correspond to the actual value recognized or that may be recognized by the non-employee directors.

(2) Mr. Verwiel did not stand for re-election at the 2022 Annual General Meeting.

(3) The aggregate number of shares outstanding under all options held by our non-employee directors as of December 31, 2022 are set forth in the table below.

Name	Stock Awards (#)	Option Awards (#)
Annette Clancy	97,500	137,780
Ernest Loumaye	1,999,827	1,177,850
Ed Mathers	4,586,563	158,780
Anne VanLent	—	81,140
Catarina Edfjäll	—	81,140
Stephanie Brown	—	49,140
Frank Verwiel	—	—

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information regarding the beneficial ownership of the Company's Common Shares as of March 24, 2023 by (i) each person or group of persons known by us to beneficially own more than five percent of our Common Shares, (ii) each of our named executive officers, (iii) each of our directors and nominees for director and (iv) all of our directors and executive officers as a group.

The following table gives effect to Common Shares issuable within 60 days of March 24, 2023 upon the exercise of all options and other rights beneficially owned by the indicated shareholders on that date. Beneficial ownership is determined in accordance with Rule 13d-3 promulgated under Section 13 of the Securities Exchange Act of 1934, as amended, and includes voting and investment power with respect to shares. Percentage of beneficial ownership is based on 113,177,287 shares of Common Shares outstanding at the close of business on March 24, 2023. Except as otherwise noted below, each person or entity named in the following table has sole voting and investment power with respect to all shares of our Common Stock that he, she or it beneficially owns.

As of March 24, 2023, there was no person or group of persons known by us with beneficial ownership of more than five percent of our Common Shares.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Directors and Named Executive Officers:		
Ed Mathers (1)	4,745,343	4.19 %
Ernest Loumaye (2)	4,075,365	3.57 %
Brian O'Callaghan (3)	1,137,531	*
Will Brown (4)	121,875	*
Catarina Edfjall (5)	81,140	*
Anne VanLent (6)	60,665	*
Stephanie Brown (7)	40,950	*
All Named Executive Officers and Directors as a Group (7 persons)(8)	10,262,869	8.86 %

* Represents beneficial ownership of less than one percent of ObsEva's outstanding Common Shares.

(1) Consists of 4,586,563 Common Shares over which Mr. Mathers has voting control as the General Partner of NEA and 158,780 Common Shares which can be acquired upon exercise of outstanding options within 60 days of March 24, 2023.
(2) Consists of 3,023,557 Common Shares and 1,051,808 Common Shares which can be acquired upon exercise of outstanding options within 60 days of March 24, 2023.
(3) Consists of 1,137,531 Common Shares which can be acquired upon exercise of outstanding options within 60 days of March 24, 2023.
(4) Consists of 121,875 Common Shares which can be acquired upon exercise of outstanding options within 60 days of March 24, 2023.
(5) Consists of 81,140 Common Shares which can be acquired upon exercise of outstanding options within 60 days of March 24, 2023.

(6) Consists of 60,665 Common Shares which can be acquired upon exercise of outstanding options within 60 days of March 24, 2023.
(7) Consists of 40,950 Common Shares which can be acquired upon exercise of outstanding options within 60 days of March 24, 2023.
(8) Includes 7,610,120 Common Shares held by our current directors and named executive officers and 2,652,749 shares of Common Shares that can be acquired by our current directors and executive officers upon the exercise of outstanding options within 60 days of March 24, 2023.

Equity Compensation Plan Information

The following table provides information regarding the number of securities to be issued under our equity plans, the weighted-average exercise price of options issued under our equity plans and the number of securities remaining available for future issuance under our equity plans, in each case as of December 31, 2022:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights ($)	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	4,298,805	6.00	9,581,608
Equity compensation plans not approved by security holders	—	—	—
Total	4,298,805	6.00	9,581,608

On March 28, 2023, we filed a post-effective amendment to various outstanding registration statements on Form S-8, which amendment became effective immediately upon filing, to remove and withdraw from registration unissued and unsold common shares issuable to participants under our 2017 Equity Incentive Plan, as amended.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Director independence

The Company's common shares are traded on the OTC Pink Sheets, which does not require that certain of the Company's directors qualify as independent or establish a standard for the determination of a director's independence. The Board of Directors has determined to apply the independence standards under the rules of The Nasdaq Stock Market LLC ("Nasdaq") in evaluating the independence of directors. The Board of Directors has determined that each of our current directors, other than Mr. O'Callaghan and Dr. Loumaye, currently meet the independence requirements contained in the Nasdaq listing standards. Ms. Clancy, the former Chair of our board also met the independence requirements contained the Nasdaq listing standards. None of our non-employee directors has or had a relationship with the Company or its subsidiaries that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In compliance with the Nasdaq listing standards, we have a Board of Directors comprised of a majority of independent directors.

None of the non-employee directors were disqualified from "independent" status under the objective tests. In assessing independence under the subjective test, the Board took into account the standards in the objective tests, and reviewed and discussed additional information provided by the directors with regard to each director's business and personal activities as they may relate to the Company's management. Based on all of the foregoing, as required by the Nasdaq listing standards, the Board made a substantive determination as to each of the non-employee directors that no relationship exists which, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

The Board has not established categorical standards or guidelines to make these subjective determinations, but considers all relevant facts and circumstances.

In addition to Board-level standards for director independence, except as described above under "Item 10 – Board committees," the directors who serve on the Audit Committee and the CNCG Committee each satisfy standards established by the SEC and the Nasdaq listing rules, except for Dr. Loumaye, who was employed by the Company in 2020. In order to qualify as "independent" for purposes of membership on the Audit Committee or the CNCG Committee, members of such committees may not accept directly or indirectly any consulting, advisory or other compensatory fee from the Company other than their director compensation. Also, each of the directors who serve as members on the CNCG Committee has been determined to be a "non-employee director" for purposes of the applicable SEC rules and regulations, except as described above under "Item 10 – Board Committee".

Review and approval of related party transactions

Our related parties include our directors, director nominees, executive officers, holders of more than five percent of the outstanding shares of our Common Shares the foregoing persons' immediate family members. We review relationships and transactions in which the Company and our related parties are participants to determine whether such related persons have a direct or indirect material interest. As required under SEC rules, transactions since January 1, 2022 that are determined to be directly or indirectly material to a related party are disclosed in this Annual Report. In addition, the Audit Committee reviews and approves any related party transaction that is required to be disclosed.

Since January 1, 2021, there have been no related party transactions, except for the transactions disclosed below.

Director and Executive Officer Compensation

See "Item 11 – Executive Compensation" 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.

Share Purchase Agreement with Dr. Loumaye

On February 28, 2023, we entered into a share purchase agreement with Ernest Loumaye, our founder and board member, pursuant to which we sold 4,000,000 common shares, at a price of CHF 0.104, or approximately USD 0.11 per share, for an aggregate amount of CHF 416,000, or approximately USD 441,958. The shares were from our pool of treasury shares.

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.

Item 14. Principal Accountant Fees and Services

The following table sets forth the aggregate fees billed to the Company for services during the fiscal years ended December 31, 2022 and 2021 by our independent registered public accounting firm, PricewaterhouseCoopers SA (in thousands):

Fee Category	2022	2021
Audit Fees (1)	$ 838	$ 735
Tax Fees (2)	532	274
Other Fees (3)	1	511
Total	$ 1,371	$ 1,520

(1) Audit Fees consist of fees billed for professional services rendered for the annual audit of the Company's consolidated annual financial statements included in the Company's Annual Report, and review of the interim consolidated financial statements included in the Company's Quarterly Reports on Form 6-K and services that are normally provided by independent registered public accountants in connection with statutory and regulatory filings or engagements.

(2) Tax Fees were billed for services including assistance with tax compliance and tax planning and advice, including advice related to changes in tax laws.

(3) Other Fees consist of advisory services related to commercial readiness and subscriptions to knowledge tools.

Pre-Approval Policies

The Audit Committee, or a designated member thereof, pre-approves 100% of all audit, audit-related, tax and other services rendered by the independent registered public accounting firm to the Company or its subsidiaries. All fees described above for the fiscal years ended December 31, 2022 and 2021 were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibits and Financial Statement Schedules

Financial Statements

Reference is made to the Index to the Consolidated Financial Statements included in Item 8 of this report.

Financial Statement Schedules

Required information is included in the notes to the consolidated financial statements.

Exhibit Index

			Incorporated by Reference		
Exhibit	Description	Schedule/ Form	File Number	Exhibit	File Date
3.1	Articles of Association of the Registrant	Form F-3	333-262820	4.1	02/17/2022
4.1	Description of securities	Form 20-F	001-37993	2.1	03/05/2020
4.2	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
4.3	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
4.4	Registration Rights Agreement, dated as of October 12, 2021, by and between the Company and the Purchasers.	Form 6-K/A	001 37993	99.5	10/13/2021
10.1+	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
10.2+	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
10.3+	Exclusive License Agreement, by and between the Registrant and Kissei Pharmaceutical Co., Ltd., dated as of November 19, 2015, as amended pursuant to an amendment agreement dated May 29, 2017, October 16, 2017, October 12, 2021 and December 27, 2021	Form 20-F	001-37993	4.4	03/10/2022
10.4+	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
10.5	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
10.6†	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

Exhibit	Description	Schedule/ Form	Incorporated by Reference File Number	Exhibit	File Date
10.7†	Incentive Plan (including form of Issuance Agreement)	Form F-1/A	333-215383	10.6	01/06/2017
10.8†	2017 Equity Incentive Plan	Form F-1/A	333-215383	10.7	01/17/2017
10.9†	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
10.10	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
10.11+	License Agreement, dated as of July 26, 2021, by and between the Registrant and Organon International GmbH.	Form 20-F	001-37993	4.13	03/10/2022
10.12+	License Agreement between the Registrant and Theramex HQ UK Limited, dated as of February 10, 2022.	Form 20-F	001-37993	4.14	03/10/2022
10.13	Amendment Agreement, dated as of January 28, 2022, by and among the Registrant, the Subsidiary Guarantors and the Holder.	Form 6-K	001-37993	99.2	01/28/2022
10.14+	Amended and restated Securities Purchase Agreement, deemed dated as of October 12, 2021, by and among the Registrant and the Purchasers.	Form 6-K	001-37993	99.3	01/28/2022
10.15	Amendment Agreement, dated as of May 27, 2022, by and among the Company, the Subsidiary Guarantors and the Holder	Form 6-K	001-37993	99.2	05/27/2022
10.16	Amendment and Forbearance Agreement, dated as of July 31, 2022, by and among the Company, the Subsidiary Guarantors and the Holder	Form 6-K	001-37993	99.2	08/01/2022
10.17	Amendment and Forbearance Agreement, dated as of October 26, 2022, by and among the Company, the Subsidiary Guarantors and the Holder	Form 6-K	001-37993	99.2	10/26/2022
10.18	Consent and Amendment Agreement, dated as of dated November 21, 2022, by and between the Company and certain funds and accounts managed by JGB Management, Inc.	Form 6-K	001-37993	99.1	11/22/2022
10.19	Sales Agreement, dated March 5, 2021, by and between the Company and SVB Leerink LLC	Form 6-K	001-37993	1.1	03/05/2021
10.20*+	IP Acquisition Agreement, dated as of November 21, 2022, by and between the Company and XOMA (US) LLC				
21.1*	List of subsidiaries of the Registrant				
31.1*	Certification by the Principal Executive Officer and 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				

Exhibit	Description	Incorporated by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
32.1**	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema Document				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				
104	The cover page from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, formatted in Inline XBRL (Included as Exhibit 101)				

* Filed herewith.
** Furnished herewith.
† Indicates a management contract or any compensatory plan, contract or arrangement.
+ Certain portions of this exhibit (indicated by asterisks) have been omitted because they are both not material and are the type that the Registrant treats as private or confidential.

The agreements and other documents filed as exhibits to this Annual Report on Form 10-K are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

Financial Statements and Schedules of Subsidiaries and Affiliates

None.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the city of Geneva, Country of Switzerland, on the 31st day of March 2023.

OBSEVA SA

By: /s/ Will Brown
Will Brown
Interim Chief Executive Officer and Chief Financial Officer

POWER OF ATTORNEY

BY THESE PRESENTS, each person whose signature appears below constitutes and appoints Will Brown and Fabien de Ladonchamps his or her true and lawful attorney-in-fact and agents, with full power of substitution and resubstitution for him and in his or her name, place and stead, in any and all capacities to sign any and all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact or his substitute, each acting alone, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Will Brown Will Brown	Interim Chief Executive Officer and Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	March 31, 2023
/s/ Ernest Loumaye Ernest Loumaye	Interim Chair of the Board	March 31, 2023
/s/ Ann VanLent Ann VanLent	Director	March 31, 2023
/s/ Catarina Edjfäll Catarina Edjfäll	Director	March 31, 2023
/s/ Stephanie Brown Stephanie Brown	Director	March 31, 2023
/s/ Ed Mathers Ed Mathers	Director	March 31, 2023
/s/ Brian O'Callaghan Brian O'Callaghan	Director	March 31, 2023

Exhibit 10.20

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

Execution Version

IP ACQUISITION AGREEMENT

This **IP ACQUISITION AGREEMENT** (this "**Agreement**"), dated as of November 21, 2022 (the "**Effective Date**"), is made by and between **OBSEVA, SA**, a Swiss corporation having its principal place of business at Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland ("**Seller**"), and **XOMA (US) LLC**, a Delaware limited liability company having its principal place of business at 2200 Powell Street, Suite 310, Emeryville, CA 94608 ("**Buyer**").

WHEREAS, Seller wishes to sell to Buyer, and Buyer wishes to purchase from Seller, all of Seller's right, title, and interest in and to certain Acquired Patents (as defined below) and Acquired Know-How (as defined below) and obtain an assignment of the Licenses (as defined below), in each case, subject to the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Purchase of Assets and Assumption of Licenses. Subject to the terms and conditions set forth herein, Seller hereby irrevocably sells, assigns, transfers, and conveys to Buyer, and Buyer hereby accepts, all right, title, and interest in and to the following (collectively, the "**Acquired Rights**"):

(a) the patents and patent applications listed in Schedule 1, and all patents that issue from such patent applications, and all continuations, and continuations-in-part, and divisionals, and extensions, and substitutions, and reissues, and re-examinations, and renewals, of any of the foregoing, and rights to apply for new patents with respect to any of the foregoing ("**Patents**"), and any other patents or patent applications that claim a benefit or priority from any Patents, and inventions disclosed and claimed in any of the foregoing (collectively, the "**Acquired Patents**");

(b) all Know-How as defined in the Organon License (as defined below) that is owned or has been developed by Obseva relating to the subject matter of the Organon License and/or the Merck Serono License (as defined below), including, but not limited to the general description of same set forth in Schedule 2 (collectively, the "**Acquired Know-How**");

(c) those certain license agreements listed on Schedule 3 (individually, the **"Organon License"** and the "**Merck Serono License"**) and all other licenses and similar contractual rights reasonably necessary for the use, exploitation, or commercialization of the Acquired Patents (collectively with the Organon License and Merck Serono License, the "**Licenses**");

(d) all milestones, royalties, fees, income, payments, and other proceeds now or hereafter due or payable to Seller under the Licenses;

(e) all claims and causes of action with respect to any of the foregoing, whether accruing before, on, or after the date hereof, including all rights to and claims for damages, restitution, and injunctive and other legal and equitable relief for past, present, and future infringement, misappropriation, violation, breach, or default; and

(f) all other rights, privileges, and protections of any kind whatsoever of Seller accruing under any of the foregoing provided by any applicable law, treaty, or international convention throughout the world.

2. Assumption of Licenses/No Liabilities. Subject to the terms and conditions set forth herein, Buyer hereby accepts Seller's assignment of the Licenses, assumes all of Seller's duties and obligations under the Licenses, and agrees to pay, perform, and discharge, as and when due, all of the liabilities and obligations of Seller under the Licenses accruing after the Effective Date, but only to the extent that such liabilities and obligations do not relate to any breach, default, or violation by Seller on or prior to the Effective Date (the "**Assumed Liabilities**"). Other than the Assumed Liabilities, Buyer neither assumes nor is otherwise liable for any obligations, claims, or liabilities of Seller of any kind, whether known or unknown, contingent, matured, or otherwise, whether currently existing or hereafter arising (collectively, "**Excluded Liabilities**"), including, for the avoidance of doubt, any obligations, claims, or liabilities arising from or in connection with any circumstances, causes of action, breach, violation, default, or failure to perform by or of Seller with respect to the Licenses on or prior to the Effective Date.

3. Purchase Price.

(a) The aggregate purchase price for the Acquired Rights shall be FIFTEEN MILLION US Dollars (US$15,000,000) (the "**Purchase Price**").

(b) At Closing, Buyer shall pay, or cause to be paid, the Purchase Price, minus the Expense Reimbursement Amount in accordance with Section 12, to Seller. Payment shall be made in US dollars by wire transfer of immediately available funds to Seller's bank account identified in the wire transfer instructions previously provided to Buyer.

If Buyer fails to make timely and proper payment of the Purchase Price, Seller may terminate this Agreement effective immediately on written notice to Buyer.

(c) **Earn-out Payments.** As additional consideration for Buyer's purchase of the Acquired Rights, at such times as provided in Section 3(d), Buyer (or, at the direction of Buyer, a designee of Buyer so long as Buyer remains an obligor thereof) shall pay to Seller during the term of the Licenses the following amounts (each, an "**Earn-Out Payment**" and collectively, the "**Earn-Out Payments**"):

(i) [*] of all future Non-Sales Milestones payable to Buyer under section 7.2(a) of the Organon License; and

(ii) [*] of all future Sales-Based Milestones #[*] and #[*] payable to Buyer under section 7.3(a) of the Organon License (i.e., the Sales Milestones

payable upon Net Sales in a given calendar year equaling or exceeding [*] and the Sales Milestones payable upon Net Sales in a given calendar year exceeding [*]).

For purposes of this Section 3(c), terms used and not otherwise defined herein shall have the meanings set forth in the Organon License.

(d) **Timing of Payment of Earn-out Payments.** Subject to Section 3(e), each Earn-out Payment that Buyer is required to make pursuant to Section 3(c) hereof shall be paid in full no later than [*] business days following the date upon which Buyer receives any of the payments specified therein pursuant to the Organon License.

(e) **Right of Set-off**. Buyer shall have the right to withhold and set off against any amount otherwise due to be paid pursuant to this Section 3, the amount of any Losses of a Buyer Indemnified Party that are determined by a final and enforceable decision to be due and payable to such Buyer Indemnified Party by Seller in accordance with Section 8 of this Agreement.

(f) **No Security.** The parties hereto understand and agree that (i) the contingent rights to receive any Earn-out Payment shall not be represented by any form of certificate or other instrument, are not transferable and do not constitute an equity or ownership interest in Buyer or any of its affiliates, (ii) Seller shall not have any rights as a securityholder of Buyer or any of its affiliates as a result of Seller's contingent right to receive any Earn-out Payment hereunder, and (iii) no interest is payable with respect to any Earn-out Payment.

(g) **Interest on Late Payments.** If Seller does not receive payment of any sum due to it on or before the due date, interest shall thereafter accrue on the sum due to Seller until the date of payment at the per annum rate of [*] over the then-current prime rate reported in The Wall Street Journal or the maximum rate allowable by applicable laws, whichever is lower, with such interest compounded quarterly.

(h) **Audit Rights.** Following the Effective Time and continuing thereafter through the term of the Licenses, Buyer shall maintain reasonably complete and accurate records in sufficient detail to permit Seller to confirm the receipt of the milestone events under the Organon License. Upon reasonable prior written notice, in any event no less than [*] days prior written notice, such records shall be available for examination during regular business hours and in a manner that does not interfere with Buyer's business activities for a period of [*] years from the end of the calendar year to which they pertain, and not more often than once each calendar year, by an internationally-recognized independent certified public accountant selected by Seller and reasonably acceptable to Buyer, for the sole purpose of verifying the accuracy of any payments due under this Agreement. Once examined, such records shall no longer be subject to further examination. Any such auditor shall not disclose Buyer's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the amount of payments due under this Agreement. Any amounts shown to be owed but unpaid shall be paid within [*] days from the accountant's report, plus interest (as set forth in Section 3(f)) from the original due date. Seller shall bear the full cost of such audit unless such audit discloses a failure by Buyer to pay any amount due for the audited period, in which case Buyer shall bear the full cost of such audit.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

4. Closing and Deliverables. Subject to the terms and conditions of this Agreement, the consummation of the transactions contemplated by this Agreement (the "**Closing**") will occur on the date hereof, immediately after the execution of this Agreement, and will take place by the exchange and release of pdfs of manually executed signature pages delivered by e-mail or other electronic means.

(a) At or prior to the Closing, Seller shall deliver to Buyer the following:

(i) an assignment in the form of Exhibit A (the "**Assignment**") and duly executed by Seller, transferring all of Seller's right, title, and interest in and to the Acquired Rights to Buyer;

(ii) the complete prosecution files, including original granted patents, for all Acquired Patents in such form and medium as reasonably requested by Buyer, together with a list of local prosecution counsel contacts, and all such other documents, correspondence, and information as are reasonably requested by Buyer to register, prosecute to issuance, own, enforce, or otherwise use the Acquired Rights, including any maintenance fees due and deadlines for actions to be taken concerning prosecution and maintenance of all Acquired Patents in the [*] period following the date hereof;

(iii) all documents and files (whether paper or stored electronically) in Seller's possession that describe, contain or reflect (x) the Acquired Know-How and (y) the Merck Serono Know-How as defined in the Merck Serono License, including writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations experimental data and results, assay protocols, designs, formulas, experimental procedures and specifications; and

(iv) a consent in the form of Exhibit B and duly executed by JGB (Cayman) Port Ellen Ltd. with respect to the consummation of the transactions contemplated by this Agreement.

(b) Substantially simultaneously with the Closing, and in any event, no later than by the end of the business day on which the Closing occurs, Seller shall deliver to Buyer evidence reasonably satisfactory to Buyer that Seller has paid each payee of an account payable the amount set out opposite its name in Schedule 4, unless otherwise noted therein.

(c) At the Closing, Buyer shall pay to Seller the Purchase Price, minus the Expense Reimbursement Amount, in accordance with Section 3(b) and Section 12.

5. Further Assurances; Recordation; Covenants.

(a) From and after the date hereof, each of the parties hereto shall, at their own expense, execute and deliver such additional documents, instruments, conveyances, and assurances, and take such further actions as may be reasonably required to carry out the provisions hereof and give effect to the transactions contemplated by this Agreement and the documents to be delivered hereunder.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

(b) No later than the end of the business day on which the Closing occurs, Seller shall pay each payee of an account payable the amount set out opposite its name in Schedule 4 (unless otherwise noted therein) and provide confirmation of each such payoff, as applicable, to Buyer in a form acceptable to Buyer in its reasonable judgment.

(c) Without limiting the foregoing, and without limiting Section 4(a), Seller shall execute and deliver to Buyer, such assignments and other documents, certificates, and instruments of conveyance in a form satisfactory to Buyer and suitable for filing with the United States Patent and Trademark Office ("**USPTO**") and the registries and other recording governmental authorities in all applicable jurisdictions (including with respect to legalization, notarization, apostille, certification, and other authentication) as reasonably necessary to record and perfect the Assignment, and to vest in Buyer all right, title, and interest in and to the Acquired Rights in accordance with applicable law. As between Seller and Buyer, Buyer shall be responsible, at Buyer's expense, for filing the Assignment, and other documents, certificates, and instruments of conveyance with the applicable governmental authorities; provided that, upon Buyer's reasonable request, Seller shall take such steps and actions, and provide such cooperation and assistance, at Seller's expense, to Buyer and its successors, assigns, and legal representatives, including the execution and delivery of any affidavits, declarations, oaths, exhibits, assignments, powers of attorney, or other documents, as may be reasonably necessary to effect, evidence, or perfect the assignment of the Acquired Rights to Buyer, or any of Buyer's successors or assigns.

(d) Seller acknowledges that under the terms and conditions of the Licenses, Buyer, as the assignee thereof, is obligated to be a member of and participate in joint advisory committees, to have alliance managers, and to otherwise have skilled and knowledgeable representation with respect to its activities with its counterparties under and in furtherance of the Licenses (collectively, the "**Representative Activities**"). As such, to assist Buyer in the performance and assumption of the Representative Activities, Seller shall, at no charge to Buyer, make available to Buyer on a transition basis those of Seller's personnel who have represented Seller in connection with the Representative Activities, and, if requested by Buyer, such personnel shall represent Buyer in connection with such Representative Activities for a period of not more than [*] following the Effective Date (as may be shortened or lengthened as mutually agreed upon by the parties). In all cases such personnel shall represent Buyer in good faith, to the best of their abilities, and in the same manner as such personnel represented Seller in connection with the Representative Activities prior to the Effective Date. Such personnel shall work in conjunction and consult with Buyer in connection with their participation in all Representative Activities and will strictly follow any feedback or instructions given by Buyer with respect to the Representative Activities. Such personnel shall not undertake any activities which would cause Buyer to breach any License. Buyer shall transition all Representative Activities to personnel of Buyer within [*] after the Effective Date. All information learned or observed by Seller's personnel in the course of performing the Representative Activities is and will be deemed to be Buyer's confidential information.

(e) Within [*] after the Effective Date, Seller shall, and shall cause its affiliates to, without additional compensation, disclose and make available to Buyer or its designee, in electronic or hard copy form, as Buyer may reasonably request, all Acquired Know-How

and Merck Serono Know-How to the extent not already delivered at Closing pursuant to Section 4(a)(iii). In connection with such transfer, Seller, in a timely manner and at no charge to Buyer, shall assist Buyer in the use and understanding of the Acquired Know-How and Merck Serono Know-How, including providing technical assistance and making its technical personnel available to Buyer or its designee. Without prejudice to the generality of the foregoing, if visits of Seller's representatives to Buyer's or its designee's facilities are reasonably requested by Buyer for purposes of transferring the Acquired Know-How and Merck Serono Know-How or for purposes of Buyer acquiring expertise on the practical application of such Acquired Know-How and Merck Serono Know-How or assisting on issues arising during the exploitation of any Acquired Know-How and Merck Serono Know-How, Seller shall send appropriate representatives to Buyer's or its designee's facilities [*]. Notwithstanding the foregoing, Seller's assistance shall not exceed [*] during such [*] period without Seller's prior consent (which consent shall not be unreasonably withheld, conditioned or delayed).

(f) Notwithstanding the transfer and assignment of the Acquired Rights from Seller to Buyer, Seller shall, [*], perform any and all [*] obligations applicable to or binding on Buyer under the Licenses, including, without limitation, [*] (as such terms are defined in the Organon License) in accordance with all of the terms and conditions set forth in the Organon License as if Seller continued to be a party thereto. Seller shall continue to fulfill all of its obligations under, and shall not breach, that certain [*] Agreement between Seller and Organon International GmbH ("**Organon**") dated [*] (the "**Organon [*] Agreement**"). In connection with Seller's obligation to [*], Buyer hereby grants to Seller a royalty-free, fully paid-up, worldwide, non-exclusive license, with the right to grant sublicenses, under the Acquired Rights solely for [*] pursuant to the Organon License [*].

6. Representations and Warranties of Seller. Seller represents and warrants to Buyer that the statements contained in this Section 6 are true and correct as of the date hereof, except as set forth in the correspondingly numbered sections of the Seller disclosure schedules, attached hereto. For purposes of this Section 6, "Seller's knowledge," "knowledge of Seller," and similar phrases shall mean the actual or constructive knowledge of any director or officer of Seller, after due inquiry.

(a) Organization. Seller is a corporation duly organized, validly existing and in good standing under the laws of Switzerland and has all necessary power and authority, and all licenses, permits, franchises, authorizations, consents and approvals, required to own its property and conduct its business as now conducted. Seller is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification or good standing is required by all applicable laws, rules, regulations and orders of any governmental authority applicable to Seller or any of its properties or assets.

(b) Authority of Seller; Enforceability. Seller has the full right, power, and authority to enter into this Agreement and perform its obligations hereunder. The execution, delivery, and performance of this Agreement by Seller has been duly authorized by all necessary organizational action of Seller and no other act or proceeding on the part of Seller is necessary to authorize the execution, delivery, or performance by Seller of this Agreement or any other agreement contemplated hereby or thereby. This Agreement has

been duly executed and delivered by Seller and, assuming the due execution and delivery of this Agreement and the other agreements contemplated hereby by the other parties hereto and thereto, this Agreement constitutes, and the other agreements contemplated hereby upon execution and delivery by Seller will each constitute, a valid and binding obligation of Seller, enforceable against Seller in accordance with its and their terms.

(c) No Conflicts; Consents. The execution, delivery, and performance by Seller of this Agreement, and the consummation of the transactions contemplated hereby, do not and will not: (i) violate or conflict with the certificate of incorporation, by-laws, or other organizational documents of Seller; (ii) violate or conflict with any judgment, order, decree, statute, law, ordinance, rule, or regulation; (iii) conflict with, or result in (with or without notice or lapse of time or both), any violation of or default under, or give rise to a right of termination, acceleration, or modification of any obligation or loss of any benefit under, any contract or other instrument to which this Agreement or any of the Acquired Rights are subject (including any License); or (iv) result in the creation or imposition of any encumbrances on the Acquired Rights. No consent, approval, waiver, or authorization is required to be obtained by Seller from its stockholders or any other person, group of persons, or entity (including any legal or governmental authority) in connection with the execution, delivery, and performance by Seller of this Agreement, or to enable Buyer to register, own, and use the Acquired Rights.

(d) Ownership. Except as set forth on Schedule 1, Seller is the exclusive owner of all right, title, and interest in and to the Acquired Patents and Acquired Know-How, free and clear of all title defects or objections, liens, security interests, and other encumbrances. Seller is in full compliance with all legal requirements applicable to the Acquired Rights and Seller's ownership and use thereof.

(e) Patents and Applications. Schedule 1 contains a correct, current, and complete list of all patents and patent applications related to the Licenses, including the Acquired Patents and the Merck Serono Patents (as defined in the Merck Serono License), specifying as to each, as applicable, the title, the record owner, the jurisdiction in which it has been issued or filed, the patent number or application serial or publication number, and the issue or application filing date. All required filings and fees related to the Acquired Patents listed on Schedule 1 have been timely filed with and paid to the USPTO and other relevant governmental authorities and authorized registrars, and all such patents and patent applications have at all times been and remain in good standing. Seller has provided Buyer with true and complete copies of all documents, certificates, office actions, responses, correspondence, and other filings and materials related to all such Acquired Patents. Seller has satisfied, and will continue to satisfy, all of its obligations to the inventors of the Acquired Patents (if any).

(f) Know-How. Seller has taken commercially reasonable steps to protect the rights of Seller in the Acquired Know-How and, except under confidentiality obligations contained in the Licenses, there has not been any disclosure by Seller of any Acquired Know-How to any third party.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

(g) Validity and Enforceability. No claim in any of the Acquired Patents has been deemed invalid by a court of competent jurisdiction, and the Acquired Patents are subsisting, and enforceable by Seller in all applicable jurisdictions. The Acquired Patents are not subject to any pending or threatened (in writing) challenge or claim to their validity, subsistence, or enforceability. Without limiting the foregoing, neither the inventors of the Acquired Patents nor their counsel (i) intentionally failed to disclose any material, non-cumulative prior art references to the United States Patent and Trademark Office (the "PTO") or any foreign patent offices requiring such disclosure in connection with the prosecution of any Acquired Patents, (ii) made any material misstatements or misrepresentations to the PTO or any foreign patent offices in connection with the prosecution of any of the Acquired Patents, or (iii) engaged in any act or omission inconsistent with the duty of candor to the PTO. The inventions and discoveries described in the Acquired Patents were made solely by the inventors named in the Acquired Patents, without misappropriation of any trade secrets, confidential information, or other rights of any person. The inventors named in the Acquired Patents that are employees or agents of Seller had no obligation to assign the inventions claimed by the Acquired Patents to any third party based on any form of employment and/or consulting agreement or relationship. Seller is not aware of any prior art that must be disclosed to any governmental office in which a given patent application has been filed (based on relevant disclosure obligations). Seller and those authorized by Seller to make, offer for sale, sell or import into the United States any article covered by the Acquired Patents have complied with the marking provisions of 35 U.S.C. section 287(a) with respect to the Acquired Patents.

(h) Legal Actions. There are no actions (including any US Patent Trial and Appeal Board proceedings or European Opposition Proceedings) settled, pending, or threatened in writing (including in the form of offers to obtain a license): (i) alleging any infringement, misappropriation, or other violation of the intellectual property rights of any third party based on the use or exploitation of any Acquired Rights; (ii) challenging the validity, patentability, enforceability, issuance, inventorship or ownership of any Acquired Patents or Acquired Know-How or Seller's rights with respect thereto; or (iii) by Seller alleging any infringement, misappropriation, or other violation by any third party of any Acquired Rights.

(i) Licenses. Seller has provided Buyer with true and complete copies of all Licenses (or in the case of any oral agreements, a complete and accurate written description thereof), including all modifications, amendments, and supplements thereto and waivers thereunder. Each License is valid, binding, in full force and effect, and enforceable between Seller and the other parties thereto, and neither Seller nor, to Seller's knowledge, any other party thereto is in breach of or default under (or is alleged to be in breach of or default under) any License, or has provided or received any written notice of breach of, default under, or any actual or intended termination of any License, nor to Seller's knowledge, is there any basis to provide or receive any such notice. Seller has not received any written notice from Organon or any affiliate thereof that Organon intends to wind-down, limit, or suspend its commercialization activities under the Organon License or otherwise take any action that would adversely effect the sale of Licensed Products (as defined in the Organon License), nor is Seller aware of any basis for such conduct or any such notice. Seller has not waived or relinquished any rights under any License.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

(j) Accounts Payable. There are no liabilities, debts, claims or obligations of any nature of Seller, whether known, unknown, accrued, absolute, direct or indirect, contingent, determined, determinable or otherwise, whether due or to become due, except (i) the convertible notes issued to JGB (Cayman) Port Ellen Ltd. and (ii) the accounts payable set forth on Schedule 4.

7. Representations and Warranties of Buyer. Buyer represents and warrants to Seller that the statements contained in this Section 7 are true and correct as of the date hereof, except as set forth in the correspondingly numbered sections of the Buyer disclosure schedules, attached hereto.

(a) Organization. Purchaser is a limited liability company, duly organized, validly existing and in good standing under the laws of the State of Delaware, and has all powers and authority, and all licenses, permits, franchises, authorizations, consents and approvals of all applicable governmental authorities, required to own its property and conduct its business as now conducted.

(b) Authority of Buyer; Enforceability. Buyer has the full right, power, and authority to enter into this Agreement and perform its obligations hereunder. The execution, delivery, and performance of this Agreement by Buyer have been duly authorized by all necessary organizational action of Buyer, and no other act or proceeding on the part of Buyer is necessary to authorize the execution, delivery, or performance by Buyer of this Agreement or any other agreement contemplated hereby or thereby. This Agreement has been duly executed and delivered by Buyer and, assuming the due execution and delivery of this Agreement and the other agreements contemplated hereby by the other parties hereto and thereto, this Agreement constitutes, and the other agreements contemplated hereby upon execution and delivery by Buyer will each constitute, a valid and binding obligation of Buyer, enforceable against Buyer in accordance with its and their terms.

(c) No Conflicts; Consents. The execution, delivery, and performance by Buyer of this Agreement, and the consummation of the transactions contemplated hereby, do not and will not: (i) violate or conflict with the certificate of incorporation, by-laws, or other organizational documents of Buyer; (ii) violate or conflict with any judgment, order, decree, statute, law, ordinance, rule, or regulation; or (iii) conflict with, or result in (with or without notice or lapse of time, or both), any violation of or default under, or give rise to a right of termination, acceleration, or modification of, any obligation or loss of any benefit under, any contract or other instrument to which this Agreement is subject. No consent, approval, waiver, or authorization is required to be obtained by Buyer from any person or entity (including any governmental authority) in connection with the execution, delivery, and performance by Buyer of this Agreement.

8. Indemnification.

(a) Survival. Subject to Section 8(a)(i) and 8(a)(ii) hereto, all representations and warranties contained herein and all related rights to indemnification shall continue in full force and effect until 11:59 p.m. (Eastern time) on the date that is [*] from Closing.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

The covenants and agreements contained in this Agreement shall survive the Closing until fully performed in accordance with their respective terms.

(i) The representations and warranties of Seller in [*] shall survive [*] following the Closing; and

(ii) The representations and warranties of Buyer in [*] shall survive [*] following the Closing.

Notwithstanding the foregoing or anything to the contrary in this Agreement, (i) if an indemnification claim is made prior to the expiration of the applicable survival period in accordance with the terms of this Section 8, then such applicable representation, warranty, covenant or agreement shall survive as to such claim until all Losses (as defined below) arising out of or resulting from such claim have been fully paid in accordance with the terms of this Agreement, and (ii) none of the survival periods or limitations contained in this Section 8 shall apply to any claims relating to fraud or intentional misrepresentation.

(b) Agreement to Indemnify. Each party (the "**Indemnifying Party**") shall defend, indemnify, and hold harmless the other party, its affiliates, and their respective shareholders, directors, officers, and employees (each, an "**Indemnified Party**") from and against all losses, damages, liabilities, deficiencies, claims, actions, judgments, settlements, interest, awards, penalties, fines, fees, costs, or expenses of whatever kind, including reasonable attorneys' fees, the cost of enforcing any right to indemnification hereunder, and the cost of pursuing any insurance providers (collectively, "**Losses**") arising out of or in connection with (i) any breach or alleged breach of any representation, warranty or certification made by the Indemnifying Party in, or pursuant to, this Agreement, (ii) any breach or default by the Indemnifying Party in respect of any covenant or agreement made by the Indemnifying Party in this Agreement, (iii) any Excluded Liabilities, and (iv) any third-party claim, suit, action, or proceeding (each, a "**Third-Party Claim**") arising on or after the date hereof and asserted against the Indemnified Party relating to the transactions contemplated in this Agreement, as applicable.

(c) Limitations. Notwithstanding anything in this Agreement to the contrary, the aggregate amount required to be paid by the Indemnifying Party to the Indemnified Party under Section 8(b)(i) for any breach or alleged breach of any representation, warranty or certification, or pursuant to, this Agreement shall not exceed an amount equal to [*], provided, however, that the limitation set forth in this Section 8(c) shall not be applicable to claims for fraud or intentional misrepresentation.

(d) Indemnification Procedures.

(i) Notice of Claim. An Indemnified Party may assert a claim for indemnification, whether for its own Losses or for Losses incurred by any other Indemnified Party by giving the Indemnifying Party written notice thereof ("**Notice of Claim**"). Each Notice of Claim given pursuant to this Section 8(d) shall contain a description, in reasonable detail to the extent known to the Indemnified Party, of the facts, circumstances or events giving rise to such claim, together with (to the extent in the Indemnified Party's possession and permitted by applicable law)

copies of any formal written demand or complaint from any third party claimant and an estimate of the amount, if reasonably practicable, of the Losses that have been or may be sustained by the Indemnified Party. No failure or delay on the part of the Indemnified Party in giving the Indemnifying Party a Notice of Claim shall relieve, waive or otherwise release Seller from any of its obligations under this Section 8 unless (and then only to the extent that) the Indemnifying Party is adversely and materially prejudiced thereby in terms of the amount of Losses for which such Indemnifying Party is obligated to indemnify the Indemnified Party, and then, only to the extent of such prejudice.

(ii) Direct Claims. Any claim by an Indemnified Party on account of Losses which do not result from a Third-Party Claim (a "**Direct Claim**") shall be asserted by the Indemnified Party giving the Indemnifying Party Notice of Claim with respect thereto. The Indemnifying Party shall have [*] days after its receipt of such Notice of Claim to respond in writing to such Direct Claim. During such [*]-day period, the Indemnified Party shall allow the Indemnifying Party and its professional advisors to investigate the matter or circumstance alleged to give rise to the Direct Claim and whether and to what extent any amount is payable in respect of the Direct Claim, and the Indemnified Party shall reasonably cooperate with the Indemnifying Party's investigation by giving such information and assistance (including the right to examine any documents or records exclusively related to such Direct Claim) as the Indemnifying Party or any of its professional advisors may reasonably request. If Seller does not so respond within such [*]-day period, the Indemnifying Party shall be deemed to have rejected such Direct Claim, in which case the Indemnified Party shall be free to pursue such remedies as may be available to the Indemnified Party on the terms and subject to the provisions of this Agreement. To object to all or a portion of any Direct Claim made in a Notice of Claim, the Indemnifying Party must deliver a written objection to the Buyer Indemnified Party within [*] business days after receipt of such Notice of Claim expressing such objection and explaining in reasonable detail and in good faith the basis therefor (an "Objection Notice"). Following receipt by the Indemnified Party of the Objection Notice, if any, the Indemnified Party and the Indemnifying Part shall promptly, and within [*] business days, meet to attempt to resolve the rights of the respective parties that is the subject of the Objection Notice. If the Indemnifying Part and the Indemnified Party resolve the dispute, then as promptly as practicable (and in any event within [*] Business Days) following the resolution of the Direct Claim, the Indemnified Party and the Indemnifying Part shall execute and deliver a memorandum setting forth the aggregate Dollar amount of such Losses payable to the Indemnified Party (the "Stipulated Amount"), and such Stipulated Amount shall be paid in the manner set forth in Section 8(e). In the event that the Indemnified Party and the Indemnifying Part do not execute a memorandum as contemplated above within [*] business days of receipt by the Indemnified Party of the Objection Notice, then the Buyer Indemnified Party may commence an action to resolve such dispute and enforce its rights with respect thereto in any court available therefor (such action, a "Litigated Dispute"). Upon the resolution of a Litigated Dispute, the amount awarded to the Indemnified Party,

if any, in such Litigated Dispute (the "Award Amount") shall be paid in the manner set forth in Section 8(e).

(iii) Third-Party Claims. Any claim by an Indemnified Party on account of Losses resulting from a Third-Party Claim shall be asserted by the Indemnified Party giving the Indemnifying Part a Notice of Claim with respect thereto. The Indemnifying Part shall promptly assume control of the defense and investigation of the Third-Party Claim, with counsel reasonably acceptable to the Indemnified Party, and the Indemnified Party shall fully cooperate with the Indemnified Party in connection therewith, in each case at the Indemnified Party's sole cost and expense. The Indemnified Party may participate in the defense of such Third-Party Claim, with counsel of its own choosing and at its own cost and expense. the Indemnifying Party shall not settle any Third-Party Claim without the Indemnified Party's prior written consent (which consent shall not be unreasonably withheld, conditioned, or delayed). If the Indemnifying Part fails or refuses to assume control of the defense of such Third-Party Claim, the Indemnified Party shall have the right, but no obligation, to defend against such Third-Party Claim, including settling such Third-Party Claim after giving notice to Seller, in each case in such manner and on such terms as the Indemnified Party may deem appropriate. Neither the Indemnified Party's failure to perform any obligation under this Section 8(d), nor any act or omission of the Indemnified Party in the defense or settlement of any Third-Party Claim shall relieve Seller of its obligations under this Section 8, including with respect to any Losses, except to the extent that Seller can demonstrate that it has been materially prejudiced as a result thereof.

(e) Payment of Losses. With respect to any Losses for which an Indemnified Party is entitled to indemnification, any and all payments in respect of such Losses shall be satisfied, in whole or in part and at such Indemnified Party's election, by: (i) in the case of the Seller, setting off such Losses against any Earn-out Payments that become payable to Seller in accordance with the provisions of Section 3(e), as applicable, or (ii) wire transfer of immediately available funds from the Indemnifying Party within ten (10) business days after such amounts are finally determined to be due and payable to such Indemnified Party.

9. Equitable Remedies. Each party acknowledges that (a) a breach or threatened breach by such party of any of its obligations under this Agreement would give rise to irreparable harm to the other party for which monetary damages would not be an adequate remedy; and (b) if a breach or a threatened breach by each party of any such obligations occurs, the other party will, in addition to any and all other rights and remedies that may be available to such party at law, at equity, or otherwise in respect of such breach, be entitled to equitable relief, including a restraining order, an injunction, specific performance, and any other relief that may be available from a court of competent jurisdiction, without any requirement to (i) post a bond or other security; or (ii) prove actual damages or that monetary damages will not afford an adequate remedy.

10. Confidentiality.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

(a) Confidentiality and Use. Seller agrees: (i) not to use any information that is of a sensitive, proprietary, or confidential nature, whether written or oral, concerning the Acquired Rights, other than as strictly necessary to exercise its rights or perform its obligations under this Agreement; (ii) not to use any such information, directly or indirectly, in any manner to the detriment of Buyer or to obtain any competitive advantage relative to Buyer; and (iii) to maintain such information in strict confidence, and not to disclose such information without Buyer's prior written consent. Both parties agree to comply with the confidentiality obligations contained in the Licenses. The Mutual Non-Disclosure Agreement between Buyer and Seller dated [*], is hereby superseded in its entirety by the provisions of this Section 10.

(b) Compelled Disclosures. If either party is compelled to disclose any information with respect to the financial terms of this Agreement, or Seller is compelled to disclose any information that is of a sensitive, proprietary, or confidential nature concerning the Acquired Rights, by judicial or administrative process or by other requirements of law, such party shall: (i) promptly notify the other party in writing; (ii) disclose only that portion of such information that it is advised by counsel in writing is legally required to be disclosed; and (iii) use reasonable best efforts to obtain an appropriate protective order or other reasonable assurance that confidential treatment will be accorded such information.

(c) Permitted Disclosures. Notwithstanding anything to the contrary in this Section 10, each party shall be permitted to disclose any information with respect to this Agreement (i) to the extent required by applicable law, applicable regulations, or applicable rules of any stock exchange or quotation system on which Buyer, Seller, or any of their respective affiliates lists or trades securities from and after the date hereof, and (ii) to their respective representatives as necessary in the ordinary course of business (as long as such persons agree to or are bound by contract or professional obligation to keep the terms of this Agreement confidential and not use any such terms except as necessary in connection with such ordinary conduct).

11. Miscellaneous.

(a) Interpretation. For purposes of this Agreement, (i) the words "include," "includes," and "including" are deemed to be followed by the words "without limitation"; (ii) the word "or" is not exclusive; and (iii) the words "herein," "hereof," "hereby," "hereto," and "hereunder" refer to this Agreement as a whole. Unless the context otherwise requires, references herein: (x) to Sections, Schedules, and Exhibits refer to the Sections of, and Schedules and Exhibits attached to, this Agreement; (y) to an agreement, instrument, or other document means such agreement, instrument, or other document as amended, supplemented, and modified from time to time to the extent permitted by the provisions thereof; and (z) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement is intended to be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted. The Schedules and Exhibits referred to herein are intended to

be construed with, and as an integral part of, this Agreement to the same extent as if they were set forth verbatim herein.

(b) Notices. All notices, requests, consents, claims, demands, waivers, and other communications hereunder shall be in writing and shall be deemed to have been given: (i) when delivered by hand (with written confirmation of receipt); (ii) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (iii) on the date sent by facsimile or email of a PDF document (with confirmation of transmission) if sent during normal business hours of the recipient; and (iv) on the day after the date mailed, by certified or registered mail (in each case, return receipt requested, postage prepaid). Such communications must be sent to the respective parties at the following addresses or at such other address for a party as shall be specified in a notice given in accordance with this Section 11(b):

If to Seller:	Address:	Chemin des Aulx, 12, 1228 Plan-les-Outes, Geneva, Switzerland
	Facsimile:	+41 (0)22 884 1556
	Email:	[*]
	Attention:	Chief Financial Officer
If to Buyer:	Address:	2200 Powell Street, Suite 310
	Email:	[*]
	Attention:	Chief Financial Officer

(c) Entire Agreement. This Agreement, together with Licenses and the documents to be delivered hereunder, and all related exhibits and schedules, constitute the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein and therein, and supersede all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter.

(d) Severability. If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction.

(e) Successors and Assigns. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and assigns.

(f) Governing Law; Venue. All matters arising out of or relating to this Agreement shall be governed by and construed in accordance with the internal laws of the State of New York without giving effect to any choice or conflict of law provision or rule. Any legal suit, action, or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby shall be instituted in the federal courts of the United States of America or the courts of the State of New York in each case located in the Borough of Manhattan and County of New York, and each party irrevocably submits to the exclusive jurisdiction of such courts in any such legal suit, action, or proceeding.

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

(g) Amendment and Modification. This Agreement may only be amended, modified, or supplemented by an agreement in writing signed by each party hereto.

(h) Waiver. No waiver by any party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the party so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any right, remedy, power, or privilege arising from this Agreement shall operate or be construed as a waiver thereof; and any single or partial exercise of any right, remedy, power, or privilege hereunder shall not preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.

(i) Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, email, or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

12. Expense Reimbursement. Seller agrees to reimburse Buyer for up to [*] of expenses incurred by Buyer in connection with the transactions contemplated by this Agreement (the "**Expense Reimbursement Amount**"). Such Expense Reimbursement Amount shall be set off from the Purchase Price in accordance with Section 3(b).

[SIGNATURE PAGE FOLLOWS]

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) is the type that the registrant treats as private or confidential.

IN WITNESS WHEREOF, Seller and Buyer have caused this Agreement to be executed as of the date first written above by their respective duly authorized officers.

OBSEVA S.A.
By: /s/ Will Brown
Name: Will Brown
Title: Chief Financial Officer
XOMA (US) LLC
By: /s/ James R. Neal
Name: James R. Neal
Title: Chief Executive Officer

Exhibit 21.1

ObsEva SA
List of Subsidiaries

Subsidiary	Jurisdiction
ObsEva USA, Inc.	Delaware
ObsEva Ireland Limited	Ireland
ObsEva Europe B.V.	The Netherlands

Exhibit 31.1

CERTIFICATIONS

I, Will Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K 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 registrant as of, and for, the periods presented in this report;

4. I am 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 registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 registrant's disclosure controls and procedures and presented in this report my conclusion 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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 31, 2023

By: /s/ Will Brown
Will Brown
Interim Chief Executive Officer and Chief Financial Officer
Principal Executive Officer and Principal Financial Officer

Exhibit 32.1

CERTIFICATIONS

In connection with this Annual Report on Form 10-K of ObsEva SA (the "Company") for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officer of the Company hereby certifies, pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 31, 2023

By: /s/ Will Brown
Will Brown
Interim Chief Executive Officer and Chief Financial Officer