OBSEVA
obstetrics & beyond

Annual Report 2018

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Letter to shareholders

Dear Shareholders,

2018 was a year of tremendous progress for ObsEva, our second year as a public company. Our pipeline of three potential best and/or first in class new chemical entities are advancing well in clinical trials, having generated important Phase 2b and Phase 3 efficacy and safety data in 2018, leading to as many as six Phase 3 trials potentially ongoing in 2019. Importantly, we have delivered our milestones both successfully and on time according to plan, through the hard work of our employees, and ObsEva is now positioned to begin the transition to a commercial stage company in 2019 with expected confirmatory Phase 3 results for nolasiban and a planned regulatory filing.

A review of our important achievements in 2018 is headlined with the first Phase 3 trial results for nolasiban, the oral oxytocin receptor antagonist for the improvement of outcomes in patients who are experiencing infertility and undergo in-vitro fertilization (IVF) procedures. The IMPLANT 2 trial of nolasiban successfully achieved primary and secondary endpoints of improved rates of 10 week pregnancy as well as live birth. We believe that the magnitude of effect, or an approximate increase of one third in the ultimate goal of taking home a baby, is an impressive outcome. Given the significant psychological, emotional, physical and financial costs that accompany IVF cycle failure, we believe improved outcomes can provide benefit to patients, IVF centers, and health care providers. Following IMPLANT 2 results we have initiated a confirmatory Phase 3 trial of nolasiban in Europe, which has the largest population undergoing IVF, approximately 800,000 cycles being performed in 2014. Assuming positive IMPLANT 4 trial results expected later this year, we plan to proceed with a Marketing Authorization Application (MAA) in Europe prior to the end of the year. In the U.S., we are discussing clinical trial design with the U.S. Food and Drug Administration (FDA), with a goal of starting this Phase 3 program in 2019.

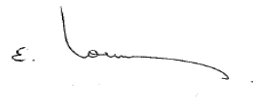
Another positive data point was reached in 2018 for linzagolix, our oral gonadotropin- releasing hormone (GnRH) receptor antagonist for the treatment of uterine fibroids and endometriosis. Primary and secondary endpoints were successfully achieved in the phase 2b EDELWEISS trial of linzagolix for the treatment of endometriosis associated pelvic pain. These trial results were highlighted by the low dose, 75mg, with sustained reduction or further improvement in patient response ratein over 70% of patients without observed significant adverse impact on bone mineral density (BMD). We are excited about the prospect of being able to treat a large majority of patients through partial estrogen suppression only, hence without the need for hormonal add back therapy (ABT) to protect from BMD loss. For this reason, we view linzagolix to be a potential best in class therapy in two populations, endometriosis and uterine fibroids, which comprise millions of women in both the U.S. and Europe. We expect Phase 3 endometriosis trials to commence in 2019, and the Phase 3 PRIMROSE 1 and 2 trials in the uterine fibroids indication are ongoing, with initial results expected later in 2019.

We believe our third compound, although earlier stage, is very promising in an area where health risks and medical costs are high, and safe and effective treatment alternatives are lacking. OBE022 is our oral prostaglandin F2 alpha receptor antagonist in development for treating acute preterm labor in pregnant women at 24–34 weeks gestation. The open label Part A of the Phase 2a PROLONG trial of OBE022 was completed in 2018, showing adequate safety and PK/PD characteristics to move to the ongoing randomized, placebo-controlled, double-blind Part B of the trial. We expect preliminary efficacy data form the PROLONG trial in a subset of patients during 2019.

In addition to our clinical trial successes in 2018, we also achieved major corporate objectives. ObsEva was listed on the SIX in Zurich and thus is now present on both the Nasdaq Global Select Market and a leading stock exchange for life science companies in Europe. We also hired a Chief Commercial Officer, Wim Souverijns, to lead our transition from a development company to a commercial company.

In 2019 we will continue to focus on executing our strategy of becoming a women's health leader by bringing innovative treatments to physicians and patients that improve upon the efficacy, tolerability and safety of existing therapeutic alternatives. We are committed to building significant long-term value for our shareholders by remaining focused and efficiently achieving relevant milestones. We are grateful for all of the support received in these endeavors, and look forward to the exciting months and years ahead.

Sincerely,



Dr. Ernest Loumaye
CEO & Co-Founder

Business Update

Business Update

We are a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for serious conditions that compromise a woman's reproductive health and pregnancy. We are advancing a pipeline of orally-administered innovative new chemical entities, or NCEs, for the treatment of symptoms associated with endometriosis and uterine fibroids, improvement of clinical pregnancy and live birth rates in women undergoing IVF and treatment of preterm labor. We have assembled a strong management team with extensive experience in successfully developing and commercializing therapeutics in our target market. Our goal is to build the leading women's reproductive health and pregnancy company focused on conditions where current treatment options are limited and significant unmet needs exist.

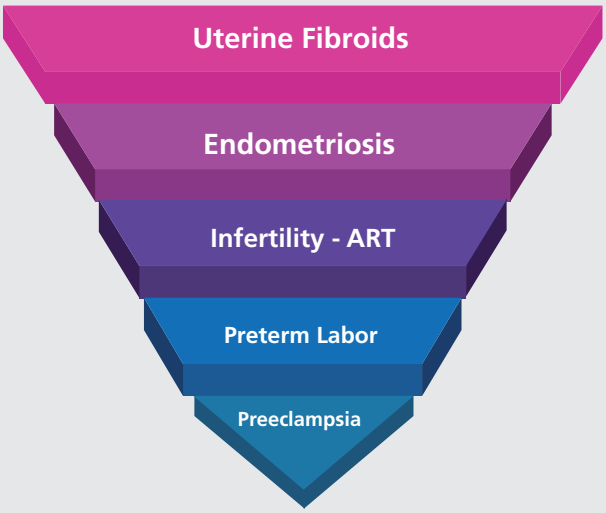
We were founded in November 2012 by former executives of PregLem SA, or PregLem, a Swiss-based specialty biopharmaceutical company dedicated to the development and commercialization of innovative drugs for women's reproductive medicine. While at PregLem, our senior management team collaborated in the clinical development and commercialization of several women's reproductive health therapeutics, including Esmya (ulipristal acetate) for the treatment of uterine fibroids. PregLem was subsequently acquired by Gedeon Richter in 2010. We believe we will be able to leverage our senior management team's long-standing experience working together and with key opinion leaders, patient groups, payors, reproductive health networks, fertility clinics, obstetricians and gynecologists, or OB/GYNs, nurses and pharmacists to identify, in-license or acquire, develop and commercialize product candidates. We are merging our passion for, and extensive experience in, the field of women's reproductive health and pregnancy, to develop therapeutics that can help women lead healthier and more fulfilling lives.

We are focused on providing therapeutic solutions for women between the ages of 15 and 49 who suffer from reproductive health conditions that affect their quality of life, ability to conceive or that complicate pregnancy and the health of newborns. There are millions of women of reproductive age affected by conditions such as endometriosis, uterine fibroids and preterm labor, or that require IVF to conceive. We believe the efficacy of current treatment options is limited and creates a significant unmet need for improved therapeutics for these women. The graphic below depicts the therapeutic focus for women's reproductive health products:

Strategic Focus
(Women ages 15–49)

ObsEva is a clinical stage biopharmaceutical company dedicated exclusively to women's health.

We are passionately focused on addressing serious, quality-of-life impacting conditions and reproductive challenges faced by women around the world.



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

- **Linzagolix for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids.** We are developing linzagolix as a novel, oral GnRH receptor antagonist, for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. Endometriosis is an often painful disorder in which the tissue that normally lines the inside of the uterus, called the endometrium, grows outside of the uterus, causing monthly bleeding and chronic inflammatory reactions inside the abdomen that may result in ovarian cyst formation, scar tissue and adhesions. The symptoms of endometriosis include significant pain during menstrual periods (dysmenorrhea), chronic pelvic pain, pain during intercourse (dyspareunia), pain during defecation (dyschezia), excessive menstrual bleeding and infertility. These symptoms can impact general physical, mental and social well-being. As of 2014, we believe that approximately 2.5 million women in the United States were diagnosed and being treated for endometriosis and that the majority of those women experience significant pain during menstrual periods. Uterine fibroids are common non-cancerous tumors that develop in the muscular wall of the uterus and have disabling symptoms such as heavy menstrual bleeding. According to a study published in the American Journal of Obstetrics & Gynecology in 2003, uterine fibroids affect an estimated 20 to 40% of women over the age of 30 in the United States based on clinical cases and women who undergo treatment.

  In previous early stage Phase 1 and Phase 2 clinical trials, linzagolix was observed to have a linear PK profile, a predictable dose-dependent suppression of estradiol and a dose range that was well-tolerated and provided symptom relief. Aimed at addressing the need of the largest possible population in each indication, our clinical trials for both of these indications are designed to assess and potentially support the registration of two regimens of administrations for linzagolix i.e. (i) a moderate dose of linzagolix without hormonal add-back therapy and (ii) a high dose of linzagolix with hormonal add-back therapy. Add-back therapy consists of co-administering estrogen and progestin with a high dose of GnRH receptor antagonist to compensate for the severe depletion of estrogen levels and thus prevent the side effects of estrogen over-suppression such as hot flushes and loss of bone mineral density.

  We have completed during the course of 2018 a 24 week treatment of the multiple-dose, placebo-controlled Phase 2b clinical trial of linzagolix in approximately 330 patients with endometriosis, or the EDELWEISS clinical trial. We are currently conducting a 6 month treatment extension phase of the EDELWEISS clinical trial, which, we expect to complete in the first half of 2019. In June 2018, we announced that the EDELWEISS clinical trial successfully met its primary endpoint, a statistically significant increase in patient response rate vs. placebo (defined as a reduction of at least 30% in combined menstrual and non-menstrual pelvic pain, recorded daily and assessed via electronic diary over the last 28 days of treatment on a verbal rating scale, or VRS of 0 (no pain) through 3(severe pain)) following 12 weeks of treatment. In September 2018, we announced positive 24-week treatment results from the EDELWEISS clinical trial, including bone mineral density (BMD) safety assessments. The data showed sustained reduction or further improvement in patient response rate at 24 weeks vs. 12 weeks for key doses which are effective at reducing menstrual and non-menstrual pain as well as at reducing pain during intercourse (dyspareunia) and during defecation (dyschezia). We believe the BMD results support our plan to pursue further development of two doses of linzagolix for the treatment of endometriosis, including a 75 mg once daily dose without low dose hormonal add-back therapy (ABT), and a 200 mg once daily dose in combination with low dose ABT (1mg E2 / 0.5mg NETA). Based on the results of our EDELWEISS trial, we believe nearly 3 out of 4 patients may achieve significant symptom relief with linzagolix 75 mg once daily with no need for ABT to mitigate BMD loss. We met with the FDA for an End of Phase 2 meeting in December 2018 to discuss the design of our planned two pivotal Phase 3 clinical trials (EDELWEISS 2 and EDELWEISS 3). Based on the feedback and meeting minutes received from the FDA, we plan to commence this clinical trial program in the first quarter of 2019.

For the uterine fibroids indication, we have completed a Phase 1 PK and PD clinical trial to assess two different doses of add-back therapy in patients receiving 100 mg and 200 mg doses of linzagolix over six weeks. The results of this clinical trial, which were announced in June 2017, support the add-back therapy dose (1mg E2 /0.5mg NETA) being utilized in the two randomized, placebo-controlled Phase 3 clinical trials that commenced in the first half of 2017. We refer to these Phase 3 clinical trials of linzagolix in patients with heavy menstrual bleeding associated with uterine fibroids as the PRIMROSE clinical trials. The PRIMROSE clinical trials each have a target enrollment of approximately 500 patients. We announced that the PRIMROSE 2 trial, being conducted in both the U.S. and Europe, completed patient recruitment in December 2018, and we expect to complete recruitment of the PRIMROSE 1 trial being conducted in the U.S. in the second quarter of 2019. We expect to report primary endpoint results following 24 weeks of treatment in the PRIMROSE 1 and 2 clinical trials in the first quarter of 2020 and fourth quarter of 2019, respectively, with a regulatory filing with the FDA based on 52 weeks treatment duration in both trials, planned prior to the end of 2020.

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

- **Nolasiban to improve IVF outcomes.** We are developing nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing IVF. Infertility is a disease of the reproductive system that impairs the body's ability to perform the basic function of reproduction. IVF helps women achieve pregnancy through 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. In Europe, nearly 800,000 IVF cycles were performed in 2014, and in the United States, approximately 230,000 IVF cycles were performed in 2015. In China, more than 700,000 ART cycles were performed in 2017, and year over year growth is double digit supported by government policies related to childbirth. We are currently assessing the regulatory development pathway in China, as well as various alternatives for future potential commercialization. We believe that nolasiban, if approved, could represent a compelling option for increasing rates of pregnancy and live birth in patients undergoing IVF treatment. In 2016, we completed our 247-patient, dose-finding, Phase 2 clinical trial (IMPLANT 1) of nolasiban in women undergoing IVF. Nolasiban did not reach the primary endpoint of a statistically significant, dose-proportional, increase in pregnancy rate at six weeks after embryo transfer. In our post-hoc analysis of the data, which excluded patients with progesterone levels in the top quartile of the patient pool, we identified a statistically significant dose-proportional increase in pregnancy rate at 10 weeks and live birth rate. We initiated a European Phase 3 clinical trial, which we refer to as IMPLANT 2, in women undergoing IVF in March 2017, announced patient enrollment completion in September 2017, and reported positive topline 10-week on going pregnancy rate results in February 2018 and positive live birth rate results in October 2018.

The IMPLANT 2 clinical trial demonstrated that Nolasiban significantly increased ongoing pregnancy rate at 10 weeks. The primary endpoint of the clinical trial was met, with an absolute increase in ongoing pregnancy rate at 10 weeks of 7.1% (placebo 28.5% and nolasiban 35.6%, p = 0.031). This represents a relative increase of 25% in the ongoing pregnancy rate after administration of nolasiban compared to placebo. Patients who underwent ET 5 days post oocyte retrieval achieved ongoing pregnancy 10 weeks post ET at a rate of 45.9% when administered nolasiban, vs. 34.7% of those who received placebo, a 32% relative increase with a p value of 0.034. The live birth rate results were consistent with the benefit seen in pregnancy rates for patients treated with nolasiban. Live birth rate, reflecting the ultimate goal of IVF procedures, taking home a baby, showed a statistically and clinically significant benefit in favor of patients receiving nolasiban, 34.8% vs. 27.7% for placebo, p=0.025. For patients undergoing Day 5 ET, the live birth rate benefit was even more pronounced for nolasiban, 44.8% vs. 33.2%, p=0.025. Nolasiban was observed to be well tolerated with a safety profile not different from placebo. 28-day neonatal safety data from the IMPLANT 2 trial did not reveal any adverse consequences from nolasiban treatment, and 6-month infant follow-up data is expected in mid-2019.

Based on feedback received in the third quarter of 2018 from regulatory authorities in Europe on our nolasiban development program, we initiated in late November 2018 an additional Phase 3 trial primarily in European, Canadian and CIS or Russian centers, or the IMPLANT 4 trial. Patients are being randomized and the IMPLANT 4 primary endpoint readout (10-week ongoing pregnancy results) is expected to support the filing of a Marketing Authorization Application (MAA) in Europe is being planned for late 2019. Feedback received from the FDA did not provide the clarity that we were hoping to see on the design of pivotal clinical trials to support an IVF indication in the United States. We are working with the FDA to reach agreement on certain elements. Upon agreement with the FDA, which we hope will be achieved in 2019, we are ready to pursue our clinical trial program in the United States that may begin in the second half of 2019. In the meantime, we do not anticipate incurring any significant cost for the U.S. clinical program.

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

  To date, only treatments with limited efficacy or restrictive safety issues are available to treat preterm labor. In the United States, no drugs are approved for acute treatment of preterm labor and recommended off-label tocolytic treatments (medications that inhibit labor) include beta-adrenergic receptor agonists, calcium channel blockers, or NSAIDs, which are used for short-term prolongation of pregnancy (up to 48 hours) to allow for the administration of antenatal steroids (e.g. betamethasone). Magnesium sulfate, used for fetal neuroprotection can also be used (up to 48 hours) to inhibit acute preterm labor. Approved tocolytic treatments in Europe include beta-adrenergic agonists, which carry severe maternal cardiovascular risks, and intravenous infusions of atosiban (an oxytocin receptor antagonist).

While prostaglandin synthesis inhibitors, such as NSAIDs, have been shown to be effective for inhibiting preterm labor, use of such drugs is limited, due to the threat of serious and sometimes life-threatening side effects in the fetus. In nonclinical studies, ObsEva has observed that OBE022 markedly reduces spontaneous and induced uterine contractions in pregnant rats without causing the fetal side effects seen with NSAIDS such as indomethacin.

Through specific antagonism of the $PGF_{2\alpha}$ receptor, OBE022 is designed to control preterm labor by reducing inflammation, decreasing uterine contractions and preventing cervical changes and fetal membrane ruptures. Based on its PK profile and efficacy observed in animal models, we believe OBE022 has the potential to become a first-in-class therapy to suppress preterm labor and delay or avoid preterm birth, without significant safety concerns for the fetus. In February 2017, we completed a Phase 1 clinical trial assessing the safety, tolerability and PK profile of OBE022 in healthy post-menopausal female volunteers after single doses of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day over 7 consecutive days. In this trial, OBE022 was observed to have a favorable PK profile, no clinically significant food effect, a favorable safety profile and to be well-tolerated at doses up to 1,300 mg after single dose administration and up to 1,000 mg per day after multiple dose administration over 7 days, each of which are above the estimated clinical effective dose. In March 2017, we completed a set of drug-drug interaction, or DDI, Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of OBE022 when combined with magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in pre-menopausal female volunteers. OBE022 in combination with those drugs was observed to have a favorable safety profile and to be well-tolerated up to 1,100 mg per day, which was the highest tested dose. In December, 2017, we announced the initiation of our Phase 2a proof-of-concept trial of OBE022, referred to as the PROLONG clinical trial. PROLONG is a proof-of-concept Phase 2a trial conducted in two parts: Part A and Part B. In this trial, OBE022 is orally administered daily for 7 days, to pregnant women, who are already receiving standard of care therapy for preterm labor, atosiban infusion for 48 hours. This clinical trial will enroll up to 120 pregnant women presenting with spontaneous preterm labor at gestational ages between 24 and 34 weeks.

In December 2018, we announced the completion of the open label Part A of the PROLONG trial in nine patients assessing OBE022 safety and pharmacokinetic (PK) profile. OBE022 was observed to be well tolerated by the mothers and their fetuses and we were able to demonstrate that the pharmacokinetics of OBE022 were similar to those previously observed in non-pregnant women. Also, 8 of the 9 treated women did not deliver during the 7 days of treatment. Based on these data, we began the randomized Part B of the trial assessing efficacy in delaying childbirth in women at 24 to 34 weeks gestation who are experiencing symptoms of preterm labor and potentially preterm delivery. Depending on the pace of patient enrollment in Part B of the trial, we expect to report interim efficacy results in 30 patients in the first half of 2019.

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

PRODUCT CANDIDATE	PRE-CLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT MILESTONES	COMMERCIAL RIGHTS
NOLASIBAN Oral oxytocin receptor antagonist			IVF – Ph3 IMPLANT 2 EU *		Primary endpoint data IMPLANT 4 Q4 2019 EU MAA filing planned late 2019 FDA feedback expected in 2019 for potential US IMPLANT 3 Initiation 2H 2019	Exclusive Worldwide
			IVF – Ph3 IMPLANT 4 EU **			
			IVF – Ph3 IMPLANT 3 US			
LINZAGOLIX (OBE2109) Oral GnRH receptor antagonist			Endometriosis – Ph2b EDELWEISS ***		52W extension data 1H 2019 EoP2 meeting completed Commencing Phase 3Q1 2019 Phase 3 PRIMROSE 1 & 2 Enrolling 24W Primary Endpoint Data Q4 2019-Q1 2020 NDA targeted end of 2020	Exclusive Worldwide (ex-Asia)
			Endometriosis – Ph3 EDELWEISS 2 US			
			Endometriosis – Ph3 EDELWEISS 3 EU & US			
			Uterine Fibroids – Ph3 PRIMROSE 1 US			
			Uterine Fibroids – Ph3 PRIMROSE 2 EU & US			
OBE022 Oral $PGF_{2\alpha}$ receptor antagonist		Preterm Labor – Ph2a PROLONG			EU Phase 2a PROLONG Interim Efficacy 1H 2019	Exclusive Worldwide

* Week 10 ongoing pregnancy primary endpoint met – Live Birth Rate secondary endpoint met
** Second Phase 3 study (EU/Canada/Russia) initiated
*** Primary and secondary endpoints met

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

Our executive team has substantial experience in developing and commercializing pharmaceutical products in this field. For example, Ernest Loumaye, M.D., Ph.D., OB/GYN, our Chief Executive Officer and co-founder, is a board certified and academically trained OB/GYN with extensive experience developing therapeutics for women's health and over 90 publications in peer-reviewed journals. Most recently he was the Chief Executive Officer and Co-Founder of PregLem. Prior to PregLem, Dr. Loumaye spent nine years as Head of Clinical Development for Reproductive Health at Serono, now Merck Serono, where he led the worldwide clinical development and contributed to the worldwide registration of Gonal-F, Luveris and Ovidrel.

In addition, Jean-Pierre Gotteland, Ph.D., our Chief Scientific Officer and Head of R&D, and Elke Bestel M.D., our Chief Medical Officer and Head of PV held the same roles at PregLem where they worked with Dr. Loumaye for six years and successfully in-licensed, developed and registered a first-in-class product, Esmya (ulipristal acetate), for the treatment of uterine fibroids.

In July 2018 we announced the hiring of a Chief Commercial Officer, Wim Souverijns, who is based at our headquarters in Geneva, Switzerland and who will lead our transition from a development company to a commercial company. Mr. Souverijns brings nearly 20 years of experience in the pharmaceutical industry and recently served as Corporate Vice President, Global Marketing, Hematology & Oncology within Celgene out of Summit, New Jersey. Previously, Mr. Souverijns developed his pharmaceutical experience through various international assignments at PwC Consulting and in different market access leadership roles at Amgen, both in Europe and the U.S.

Collectively, our management team has led the clinical development or contributed to the worldwide registration of three market-leading fertility products at Serono, Gonal-F, Luveris and Ovidrel, as well as other products including Esmya, Puregon Pen, Implanon, NuvaRing and Evamist. In addition, members of our management team bring pharmaceutical development, regulatory approval, manufacturing, reimbursement and commercialization experience from other pharmaceutical and biotechnology companies, including Merck Serono, PregLem, Organon, Allergan, Pierre Fabre, Novartis Pharma AG, Roche, SmithKline Beecham, Shire, Galderma, Speedel, Evolva SA and Acrux.

We have demonstrated an ability to successfully execute on the first part of our strategy by leveraging our extensive network in the field of women's reproductive health and pregnancy to in-license linzagolix from Kissei and nolasiban and OBE022 from Merck Serono. Additionally, we have raised USD 330.5 million in equity financing from inception to December 31, 2018 from leading healthcare investors.

Our Strengths

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

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

Our Strategy

Our goal is to build the leading women's reproductive health and pregnancy company focused on conditions where current treatment options are limited and significant unmet needs exist. The key elements of our strategy include the following:

- **Continue to advance each of our current product candidates in their respective indications.**
- **Develop a targeted commercialization strategy for any approved product candidates.** We have obtained worldwide commercial rights to our lead product candidates, except for certain countries in Asia with respect to linzagolix. As we move our product candidates through development toward regulatory approval we will evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force, entering into a joint marketing partnership with another pharmaceutical or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company. More specifically, we have assessed the IVF markets in Europe and the U.S. to be highly concentrated, likely requiring a relatively small commercial infrastructure, and we believe that nolasiban will be our first product to reach the commercial stage in Europe in 2021 assuming positive results in our ongoing IMPLANT 4 trial.
- **Pursue additional indications for our current product candidates.** We believe each of our current product candidates have application outside the indications we are currently developing and we plan to pursue additional indications for our existing product candidates in the near future. For example, we are seeking initial regulatory approvals for nolasiban in the setting of fresh embryo transfers during IVF procedures, and plan longer term to conduct clinical trials with frozen embryo transfers given the growing use of this type of procedure both in the U.S. and internationally.
- **Leverage our international product development experience and extensive network of clinical experts and pharmaceutical industry executives within women's reproductive health and pregnancy to in-license or acquire novel product candidates.** We are focused on identifying, and in-licensing or acquiring, additional clinical-stage product candidates that we believe have the potential to become best-in-class or first-in-class products for the treatment of serious conditions in women's reproductive health and pregnancy, if approved. We intend to focus on product candidates that we believe will be efficient from a capital-management standpoint, and we are exploring additional needs in our therapeutic field, such as premenstrual syndrome, fibrocystic breast disease, post-menopausal hot flashes, preeclampsia, dysmenorrhea and menopause-related auto-immune diseases.

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

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

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

Aimed at addressing the need of the largest possible population in each indication, our clinical trials for both of these indications are designed to assess and potentially support the registration of two regimens of administrations for linzagolix i.e. (i) a moderate dose of linzagolix without hormonal add-back therapy and (ii) a high dose of linzagolix with hormonal add-back therapy. We have completed the main part following 24 weeks of treatment, of the 330-patient multiple-dose, placebo-controlled Phase 2b EDELWEISS clinical trial of linzagolix in endometriosis patients across 70 sites in the United States and 15 sites in Central and Eastern Europe. We are currently conducting a 6-month treatment extension phase of the EDELWEISS clinical trial which we expect to complete by first half of 2019. In June 2018, we announced that the EDELWEISS clinical trial successfully met its primary endpoint, a statistically significant increase in patient response rate vs. placebo following 12 weeks of treatment. Patient response was measured by a reduction of at least 30% in combined menstrual and non-menstrual pelvic pain on a verbal rating scale (VRS) of 0 (no pain) through 3 (severe pain). Observed response rates were 34.5% for placebo, 61.5% for 75mg linzagolix, and 56.3% for 200mg linzagolix. Respective p values were 0.003 and 0.034.

In September 2018, we announced positive 24-week treatment results from the EDELWEISS clinical trial, including bone mineral density (BMD) safety assessments. The data showed sustained reduction or further improvement in patient response rate at 24 weeks vs. 12 weeks for key doses, with patient response in 70.8% of women at the 75mg once daily dose, and patient response in 77.3% of women at the 200mg once daily dose. The key safety endpoint of mean change in BMD at the lumbar spine, which is the site of greatest bone loss, was -0.8% at the 75mg once daily dose and -2.6% at the 200mg once daily dose. We believe the BMD results support our plan to pursue further development of two doses of linzagolix for the treatment of endometriosis, including a 75 mg once daily dose without low dose ABT, and a 200mg once daily dose in combination with low dose ABT. We met with the FDA for an End of Phase 2 meeting in December 2018 to discuss the design of our planned two pivotal Phase 3 clinical trials (EDELWEISS 2 and EDELWEISS 3). Based on the feedback received from the FDA, we plan to begin these trials in the first quarter of 2019.

In addition, we are conducting two Phase 3 clinical trials of linzagolix in patients with heavy menstrual bleeding associated with uterine fibroids, the PRIMROSE clinical trials. The PRIMROSE clinical trials each have a target enrollment of approximately 500 patients and are being conducted in the United States and in Europe. We announced that the PRIMROSE 2 trial, being conducted in both the U.S. and Europe, completed patient recruitment in December 2018. The PRIMROSE 1 and 2 clinical trials are expected to readout 6 month primary endpoint results in the first quarter of 2020 and fourth quarter of 2019, respectively, with a regulatory filing with the FDA based on 52 weeks treatment duration in both trials, planned prior to the end of 2020.

Background of Endometriosis and Uterine Fibroids

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

According to the World Endometriosis Research Foundation, as of 2014, endometriosis affects an estimated one in ten women during their reproductive years, totaling approximately 176 million women globally between the ages of 15 and 49. As of 2014, we believe that approximately 2.5 million women in the United States were diagnosed and treated for endometriosis, and the majority of those women experience significant pain during menstrual periods.

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

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

The Role of GnRH

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

Limitations of Current Therapies for Endometriosis and Uterine Fibroids

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

Endometriosis

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

Surgery can provide short-term relief by excising the endometrial lesions, but often does not prevent the endometrial lesions from recurring. Surgery requires general anesthesia, and has a risk of scar tissue and adhesion formation in the pelvis, which could lead to infertility, make pain worse, require additional surgeries or damage other pelvic structures. Surgical treatments for endometriosis range from laparoscopy to more complex open abdominal surgery. If a woman has not responded to other medical or surgical treatments, a radical hysterectomy, which is the removal of all or part of the uterus and the ovaries may be required, resulting in definitive infertility and immediate menopause.

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

Uterine Fibroids

For heavy menstrual bleeding associated with uterine fibroids, current treatment options are limited and generally consist of oral contraceptives, GnRH agonist injections or surgery. Oral contraceptives are generally used as the first-line therapy. Upon failure of a first-line therapy or contraindication to oral contraceptives, surgical intervention is generally the next treatment option. Hysterectomy is the most commonly performed surgical treatment option. Other less invasive procedures include (1) myomectomy, which is a selective removal of the fibroid typically performed by laparoscopy, which usually preserves fertility, (2) uterine artery embolization, which is a procedure to obstruct the arteries nurturing the fibroid, performed by arterial catheterization, and (3) if the dominant symptom is bleeding, endometrial ablation, which is a procedure to remove the inner layer of the uterus performed by thermic or ultrasonic process. According to a study published in the American Journal of Obstetrics & Gynecology in 2012, approximately 200,000 hysterectomies and 30,000 myomectomies are performed annually for the treatment of uterine fibroids in the United States as of 2003. Hysterectomies are major surgeries and, according to the National Uterine Fibroids Foundation, approximately 660 women die each year in the United States from complications from a hysterectomy. Hysterectomies can be both physically and psychologically damaging, not only resulting in a woman becoming infertile, but they also can be perceived by some women as impairing their feminine integrity. Surgery also carries a risk of scar tissue and adhesions, which could lead to infertility, make pain worse, require additional surgeries or damage other pelvic structures.

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

Mechanism of Action and Limitations of GnRH Agonists

GnRH agonists are a standard pharmaceutical therapy for estrogen dependent conditions such as endometriosis and uterine fibroids as they have been demonstrated to induce a dose-dependent reduction of estradiol levels. However, GnRH agonists have significant drawbacks and limitations.

GnRH agonists act by overstimulating the GnRH receptors which initially may worsen the symptoms for several weeks (the flair effect). Subsequently it desensitizes the pituitary cells, resulting in reduced secretion of LH and FSH, and severely reduced production of estrogen, a contributing factor to endometriosis and uterine fibroids. This leads to a state referred to as pseudo-menopause, in which patients experience menopausal symptoms before ultimately experiencing symptom relief. While GnRH agonists may be effective at treating the symptoms of endometriosis and uterine fibroids, they can be accompanied with serious drawbacks and limitations including:

- **Excessive suppression of estradiol and related unfavorable side effect profile.** Because GnRH agonists cannot be titrated, they act by excessively suppressing estradiol to a post-menopausal level of less than 20 picogram/milliliter, or pg/ml. Excessive suppression of estrogen can result in multiple side effects before the patient experiences any relief, including hot flashes, vaginal dryness, and bone mineral density loss. Clinical trials of an approved GnRH agonist demonstrated that patients lose an average of up to 6% of their bone mineral density after 12 months of GnRH agonist treatment.
- **Delayed therapeutic effect and initial worsening of symptoms.** Since GnRH agonists act by overstimulating the GnRH receptors, they can cause an initial worsening of symptoms that can last for several weeks.
- **Administration by injection.** Many GnRH agonists such as Lupron (leuprolide acetate) must be injected on a monthly basis or a tri-monthly basis, which generally requires the assistance of a doctor or nurse.

- **Required add-back therapy.** To counteract the side effects of the excessive suppression of estrogen, additional administration of estrogen, referred to as "add-back therapy," may be recommended after three months of treatment and is required after six months of treatment. Add-back therapy which is standard hormone replacement therapy or HRT, used in post-menopausal women, may result in additional contraindications and adverse effects.
- **Variable and unpredictable reversibility of treatment.** After stopping treatment with injectable GnRH agonists, a patient's ovarian function can take weeks or months to return to normal. This is particularly relevant and problematic if a patient wishes to conceive after treatment or if treatment is interrupted for lack of tolerability.

Linzagolix's Mechanism of Action and Solution to GnRH Agonist Drawbacks and Limitations

Linzagolix has been designed to be a GnRH receptor antagonist with oral administration and low PK and PD variability. Linzagolix binds to and blocks the GnRH receptor in the pituitary gland, which clinical trials suggest, results in a dose-dependent reduction of LH and FSH production. This reduction in LH and FSH production in turn leads to a dose dependent reduction of estrogen levels.

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

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

- **Fast onset of therapeutic effect.** By blocking, as opposed to stimulating, the GnRH receptor, linzagolix has the potential to suppress LH and FSH within hours, lowering estradiol levels and reducing pain within days while potentially avoiding the initial worsening of symptoms which is often associated with GnRH agonist treatments.
- **Ease of administration.** linzagolix has the potential to be administered orally once daily, and regardless of food intake timing. This potential dosing regime is a more convenient treatment option than GnRH agonist intramuscular or subcutaneous injections.
- **Optionality for endometriosis and uterine fibroids treatment: stand alone or in combination with add-back therapy.** In contrast to GnRH agonists, for which hormonal add-back therapy is required when treatment exceeds six months, and may be considered earlier, we believe that the 75mg once daily dose tested in our EDELWEISS Phase 2b trial, has the potential to be utilized as a stand-alone treatment for a majority of patients with pain associated with endometriosis by maintaining estradiol levels between 20 and 60 pg/ml. The once daily 200 mg dose of linzagolix will require the addition of ABT to protect bone mineral density if used for long-term to counteract the side effects associated with full suppression of estradiol i.e. below 20 pg/ml. The doses of 75 mg without ABT and 200 mg with ABT will be tested in the confirmatory Phase 3 trials.

  For the treatment of heavy menstrual bleeding associated with uterine fibroids, we believe that the once daily 100 mg dose tested in our PRIMROSE 1 and PRIMROSE 2 Phase 3 trials also has the potential to be utilized as a stand-alone treatment for a majority of patients. Other patients may require add-back therapy, depending on the treatment dosage required to control symptoms.
- **Quick reversibility of effect.** As a result of linzagolix's observed half-life of approximately 15 hours, we believe linzagolix has the potential for ovarian function to resume within days following the end of treatment. In contrast, a patient's ovarian function can take weeks or months to return to normal after stopping treatment with injectable GnRH agonists.

Linzagolix's Potential Clinical Profile

In July 2018, AbbVie Inc. announced that their GnRH antagonist elagolix (Orilissa®) received regulatory approval in the U.S. for the treatment of pain associated with endometriosis (150mg QD up to 2-year and 400mg (200mg BID) up to 6 months). In addition, AbbVie Inc is conducting Phase 3 trials with elagolix 600mg daily dose (300mg BID) in combination with ABT only for the indication of heavy menstrual bleeding associated with uterine fibroids and publicly stated intentions to submit a regulatory application for this indication in 2019. In addition, Myovant Sciences, Inc. is conducting Phase 3 trials with the GnRH receptor antagonist relugolix 40mg daily dose in combination with ABT only for the treatment of symptoms associated with endometriosis or uterine fibroids.

We believe that linzagolix has a favorable overall clinical profile as assessed by:

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

Linzagolix Preclinical and Clinical Development for Pain Associated with Endometriosis

Prior to in-licensing linzagolix, Kissei completed a preclinical program, a Phase 1 clinical trial in healthy female volunteers of Japanese and European descent and three Phase 2a clinical trials in patients of Japanese descent with endometriosis, including one trial that included a subgroup of patients with both endometriosis and uterine fibroids. In these trials, linzagolix was observed to have a linear PK profile, a predictable dose-dependent suppression of estradiol and a dose range that was well-tolerated and provided symptom relief. Following our in-license of linzagolix from Kissei, we submitted an IND for linzagolix in May 2016, which was accepted by the FDA. We are currently completing the multiple-dose, placebo-controlled Phase 2b EDELWEISS clinical trial of linzagolix in approximately 330 endometriosis patients in the United States and Europe, from which we reported positive primary endpoint results following 12 weeks of treatment as well as 24 week efficacy and safety follow-up in 2018. We met with the FDA for an End of Phase 2 meeting in December 2018 to discuss the design of our planned two pivotal Phase 3 clinical trials (EDELWEISS 2 and EDELWEISS 3). We have received the meeting minutes, and are moving forward, commencing the Phase 3 program in the first quarter of 2019.

Preclinical Studies and Phase 1 Clinical Trial

In preclinical studies, linzagolix was observed to be a highly potent and selective antagonist of the GnRH receptor. The preclinical toxicology and safety pharmacology studies did not raise tolerance or safety concerns or potential for DDIs. In the Phase 1 clinical trial, linzagolix was observed to have a favorable safety profile and to be well-tolerated up to 400 mg once daily for seven days. Additionally, linzagolix had a linear PK profile, a half-life of approximately 15 hours and no significant differences between women of Japanese and European descent. Moreover, linzagolix was observed to have a low volume of distribution, meaning the drug remained in the blood and did not accumulate in fatty tissue, and a dose-proportional response shown in the Figure 1 below. Furthermore, in the Phase 1 clinical trial, there was no food effect observed. linzagolix was observed to induce a dose-dependent decrease in LH and FSH over time, which we believe correlates with the ability of linzagolix to control estradiol levels in a dose-dependent manner. Based on the low PK variability and lack of dose overlap observed in the Phase 1 clinical trial, we believe we will be able to more tightly control biological response with personalized doses of linzagolix. In addition, in 2016 we completed a Phase 1 trial to assess the impact of linzagolix on the potential induction of CYP3A4, which is responsible for most of the metabolism of add-back therapy. In this trial, we observed no relevant CYP3A4 induction, which we believe indicates that linzagolix will not interfere with add-back therapy.

Figure 1: Mean linzagolix Concentration Over Time

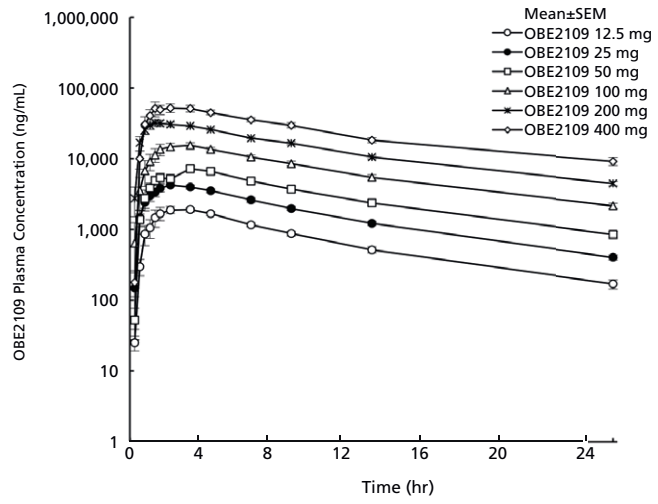
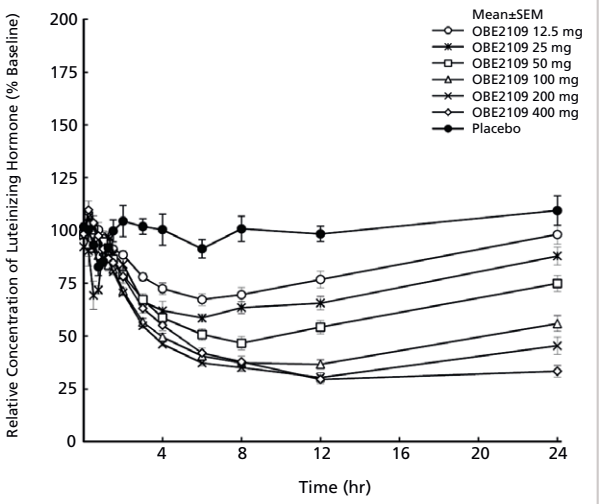


Figure 2: LH Reduction from Baseline Over Time



In 2017, we conducted a Phase 1 PK and PD clinical trial to assess two different doses of add-back therapy in patients receiving 100 mg and 200 mg doses of linzagolix over six weeks. The results of this clinical trial, which we announced in June 2017, supported our add-back therapy dose (1mg E2 / 0.5mg NETA) and linzagolix doses being utilized in the PRIMROSE clinical trials, which we are planning to utilize solely with the 200 mg dose in our Phase 3 endometriosis clinical trials that we are planning to start in the first quarter of 2019. In addition, in 2016, we completed a Phase 1 trial to assess the impact of linzagolix on CYP3A4 induction, which is responsible for most metabolism of add-back back therapy. In this trial, we observed no relevant CYP3A4 induction, which we believe suggests that linzagolix will not interfere with add-back therapy.

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

Completed Phase 2a Clinical Trials

Kissei completed three Phase 2a clinical trials of linzagolix in patients of Japanese descent with endometriosis in 2013 and 2014. Endometriosis was either diagnosed by laparoscopy or by confirmation using ultrasound of ovarian chocolate cysts, which are a particular type of ovarian cyst associated with endometriosis. Outcomes included changes in pelvic menstrual, non-menstrual and overall pain scores, analgesic use and hormone levels. The designs of these trials are summarized in the table below.

Trial	KLH1201	KLH1202	KLH1203
Trial Design	Open-label parallel-group	Placebo-controlled, double- blind, parallel-group	Open-label parallel-group
Daily Dose	50 mg (n=12) or 200 mg (n=12)	50 mg (n=29), 100 mg (n=26), 200 mg (n=28) or placebo (n=24)	75 mg (n=11) or 150 mg (n=10)
Treatment Duration	8 weeks	12 weeks	8 weeks
Trial Population	24 endometriosis patients	107 endometriosis patients	21 endometriosis patients
Demographics	• Japanese women • Average age: 35 years • Average weight: 53kg • Average duration of endometriosis: 6 years • Varying severity of endometriosis	• Japanese women • Average age: 35 years • Average weight: 54kg • Average duration of endometriosis: 4 years • Varying severity of endometriosis	• Japanese women • Average age: 35 years • Average weight: 53kg • Average duration of endometriosis: 4 years • Varying severity of endometriosis
Key Endpoints	• Severity of pelvic pain* during menstruation verbal and numerical rating scales • Severity of pelvic pain* during non-menstruation using verbal and numerical rating scales • Analgesics usage during menstruation • Analgesics usage during non-menstruation • Estradiol levels * Pelvic pain refers to any pain symptoms around the pelvic area such as lower abdominal pain and low back pain excluding temporary pains		

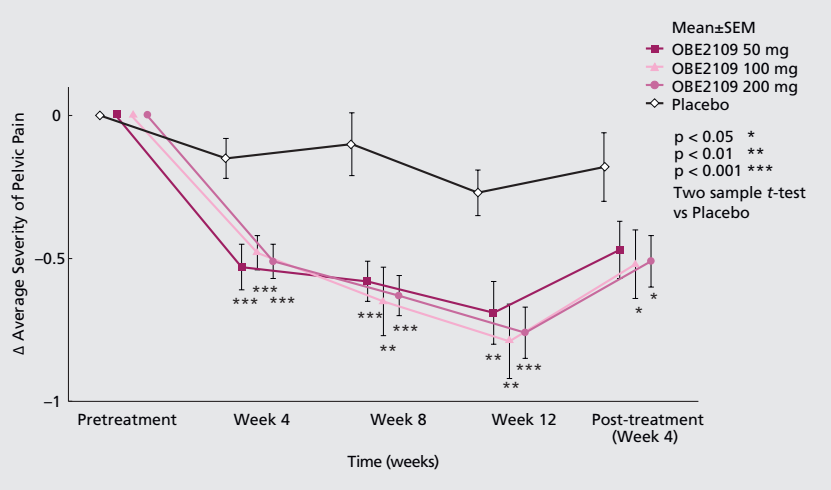
Patients reported daily whether they were bleeding, and the level of their pelvic pain using a verbal rating scale from 0 to 4, with 0 representing no pain and 4 representing unbearable pain even after using a pain relieving drug.

Improvement rate of pelvic pain severity was assessed using the proportion of pain free days during the evaluation period. Pain free is defined as the absence of pain or slight pain during menstruation and the absence of pain during non-menstruation. Across all three studies, linzagolix was observed to rapidly and consistently reduce pelvic pain scores. All doses were observed to have statistically significant reductions of both menstrual and non-menstrual pelvic pain compared to placebo. In the KLH1201 trial, the average severity of pelvic pain during menstruation in the 50 mg and 200 mg treatment groups was 1.74 +/– 0.62 (mean +/– standard deviation), and 1.42 +/– 0.61, respectively, at baseline, as compared to 0.94 +/– 0.98 and 0.00 +/– 0.00, respectively, at week 8. The average severity of pelvic pain during non-menstruation in the 50 mg and 200 mg treatment groups was 0.25 +/– 0.26 and 0.23 +/– 0.30, respectively, at baseline, as compared to 0.06 +/– 0.12 and 0.12 +/– 0.29, respectively, at week 8. As the trial was not placebo-controlled, no statistical testing was conducted.

In the KLH1203 trial, the average reduction from baseline to week 8 in severity of pelvic pain during menstruation in the 75 mg and 150 mg treatment groups was 1.39 +/– 0.79 and 2.05 +/– 0.90, respectively. The average reduction from baseline to week 8 in average severity of pelvic pain during non-menstruation in these groups was 0.46 +/– 0.68 and 0.64 +/– 0.70, respectively. As the trial was not placebo-controlled, no statistical testing was conducted.

In the placebo-controlled KLH1202 trial, there was a statistically significant reduction in pain for each of the 50 mg, 100 mg and 200 mg treatment groups, as compared to placebo at weeks 4, 8 and 12. For menstrual pain, a p-value of less than 0.001 was considered to be statistically significant for all doses. For non-menstrual pain, a p-value equal to 0.003, 0.010 and 0.005 for the 50 mg, 100 mg and 200 mg doses, respectively, was considered to be statistically significant. Patients also reported that their pelvic pain reduction was maintained four weeks after treatment. The decrease in average severity of pelvic pain (regardless of presence or absence of menstrual bleeding) and the associated p-value is shown in Figure 3 below.

Figure 3: Average Change in Severity of Pelvic Pain Over Time (Menstrual and Non-menstrual Pain Combined)

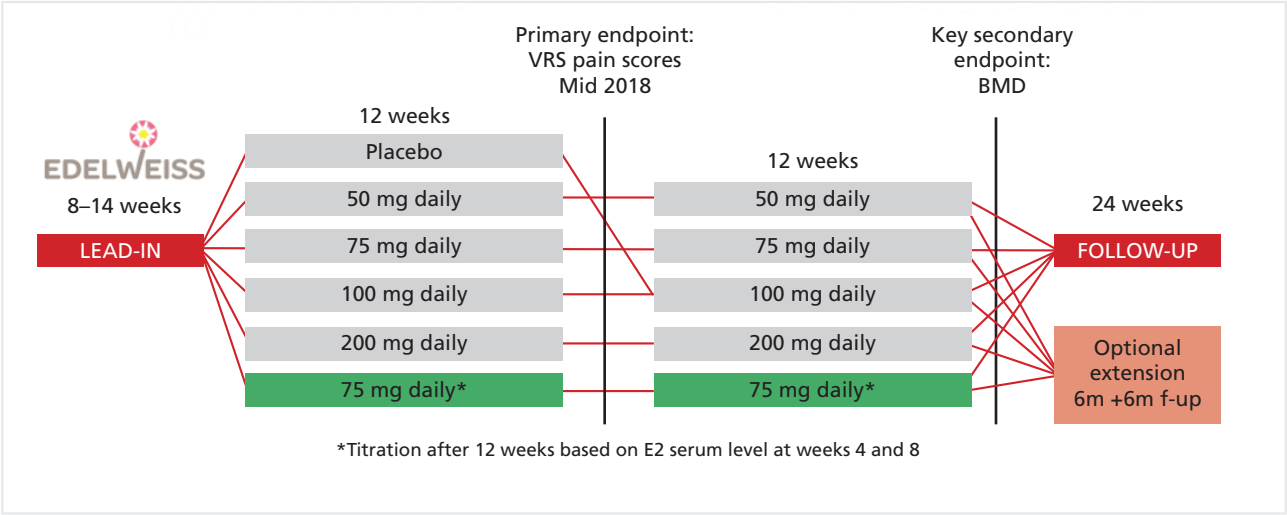


In addition, patients reported significant dose-dependent reductions in analgesic use ($p<0.001$ for all comparisons) and bleeding days. Estradiol levels were increasingly suppressed in a dose-dependent manner consistently across all three Phase 2a trials, which we believe resulted in the reduction of pelvic pain, analgesic use and bleeding days.

Clinical Development Plan–Pain Associated with Endometriosis

We are currently completing the Phase 2b EDELWEISS clinical trial in patients with endometriosis. In this trial, 328 women were enrolled with moderate-to-severe endometriosis-associated pain recruited from 64 gynecological clinics across the U.S. and Europe. Following a lead-in phase of two menstrual cycles to establish baseline pain level, patients were randomized to one of 6 treatment groups: placebo, fixed-dose groups at 50, 75, 100 and 200 mg once daily and a titrated-dose group at 75 mg once daily for up to 12 weeks, followed by 12 additional weeks of treatment. The placebo was provided for 12 weeks after which all placebo subjects were crossed-over on to active treatment (100 mg daily). In the titrated-dose arm, all subjects started on 75 mg daily for 12 weeks after which the dose was titrated up or down to 100 or 50 mg, or remain at the same dose for the following 12 weeks. Up- or down-titration depended on the mean of serum E2 assay results collected at weeks 4 and 8. The trial design is provided in Figure 4 below.

Figure 4: Design of Phase 2b EDELWEISS Clinical Trial



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

A 24-week post-treatment follow-up (PTFU) was planned after the completion of the 24 weeks of treatment or an extension trial was proposed for subjects willing to continue treatment with linzagolix. The extension trial consisted of a further 28 weeks of treatment (with the exception of patients receiving a 200 mg dose, who will be switched to a 100 mg daily dose) and a 24-week PTFU. This part of EDELWEISS trial is currently ongoing and we expect will be completed by mid-2019.

Efficacy data are summarized below in Figure 5.

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

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

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

Median serum estradiol levels at week 12 were 12 pg/ml for the 200 mg dose and 48 pg/ml for the 75mg dose, which indicates full suppression at the higher dose and partial suppression at the 75 mg dose.

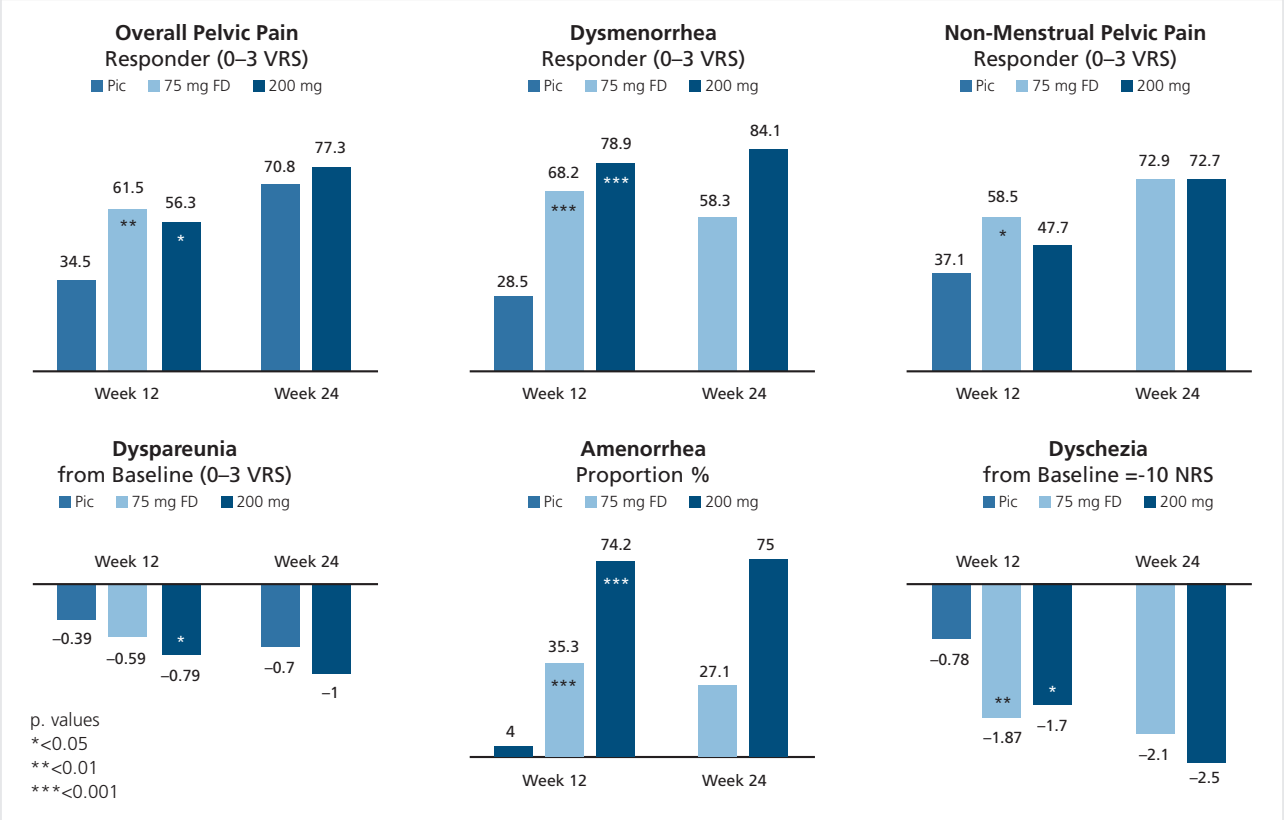
In September 2018, we announced positive 24-week treatment results from the EDELWEISS clinical trial. Overall pelvic pain, DYS and NMPP showed sustained reduction or further improvement, as compared to the positive 12-week results. Sustained efficacy was also seen in additional endpoints such as daily activity, dyschezia, and dyspareunia, as well as in the assessments of patient well- being, most notably the Patient Global Impression of Change (PGIC) and Endometriosis Health Profile-30 (EHP-30) questionnaire.

Based on the efficacy and QoL results, 75 mg daily and 200 mg daily were chosen for confirmatory testing in Phase 3.

The key safety endpoint for linzagolix is BMD loss due to suppression of estradiol. In the 75 mg treatment group, the mean BMD loss for lumbar spine at 6 months was –0.798% with the lower boundary of the 95% confidence interval of BMD reduction from baseline to week 24 at –1.57%; therefore, we believe that this dose could be given chronically with an appropriate benefit/risk ratio without the need for administering ABT. By contrast, in the linzagolix 200 mg group, the mean BMD at lumbar spine decreased by more than –2.5% after 6 months of treatment, which indicates the need for combining linzagolix with a low dose ABT. Consequently, for confirmatory testing, we are planning to combine the 200 mg dose with a low dose estrogen/progestin add-back therapy (E2 1 mg/NETA 0.5 mg) to avoid significant BMD loss during chronic administration. We believe the BMD results support our plan to pursue further development of two doses of linzagolix for the treatment of endometriosis, including a 75 mg once daily dose without low dose hormonal add-back therapy (ABT), and a 200 mg once daily dose in combination with low dose ABT. With regards to the titration scheme, although there were some numerical differences between treatment groups, we did not conclude there was sufficient benefit to continue further development, and are instead focused upon fixed dosing of linzagolix.

Overall, we believe these data support the planned development of a 75 mg once daily dose (without ABT), and a 200 mg once daily dose in combination with low dose ABT.

Figure 5: Primary and key secondary efficacy endpoints

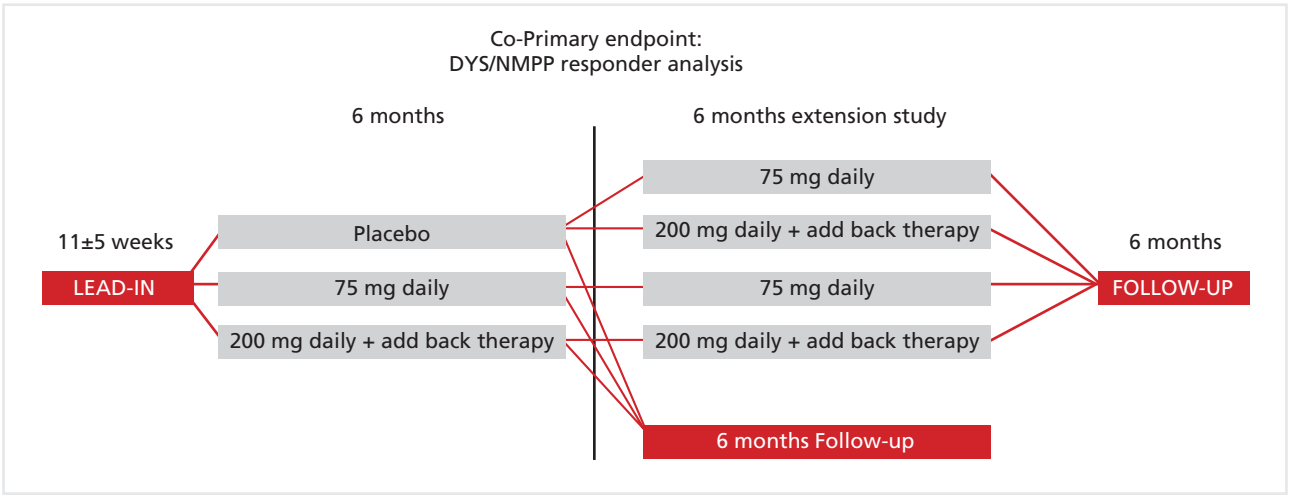


We met with the FDA for an End of Phase 2 meeting in December 2018 to discuss the design of our planned two pivotal Phase 3 clinical trials (EDELWEISS 2 and EDELWEISS 3). Based on the feedback and meeting minutes received from the FDA, we plan to commence this trial program in the first quarter of 2019.

Our Phase 3 program will consist of two clinical trials: EDELWEISS 2 will enroll approximately 420 patients in the United States. EDELWEISS 3 will enroll approximately 570 patients across sites in the U.S., as well as Canada, Europe and CIS countries. In these two double-blind, placebo-controlled trials, we will evaluate two doses of linzagolix, the 75 mg without any ABT and 200 mg with a low-dose ABT. Patients will report their pain on a daily basis with an electronic diary. The data will be analyzed at 24 weeks after initial treatment. After the initial 24-week evaluation period, an optional extension study will be proposed to patients. In this extension study, patients receiving placebo will be randomly allocated to either 75 mg without ABT or 200 mg with low-dose ABT, whereas patients on active doses of linzagolix will continue on their respective dose. The co-primary endpoint will be a responder analysis of Dysmenorrhea (DYS) and non-menstrual pelvic pain (NMPP) performed after 12-week. After treatment, all patients will be followed for at least an additional, 24-week period that will be treatment free.

Figure 6 below depicts the trial design of the Phase 3 EDELWEISS 2 and 3 clinical trials:

Figure 6: Design of Phase 3 EDELWEISS 2/3 Clinical Trials



Linzagolix Clinical Development for Heavy Menstrual Bleeding Associated with Uterine Fibroids

We are also developing linzagolix for reduction of heavy menstrual bleeding associated with uterine fibroids in adult women of reproductive age. We believe linzagolix has the potential to provide an alternative to surgery, which is the most common treatment for uterine fibroids. One of the three Phase 2a clinical trials in patients of Japanese descent with endometriosis, KLH1202, included a subgroup of 57 patients with both endometriosis and uterine fibroids.

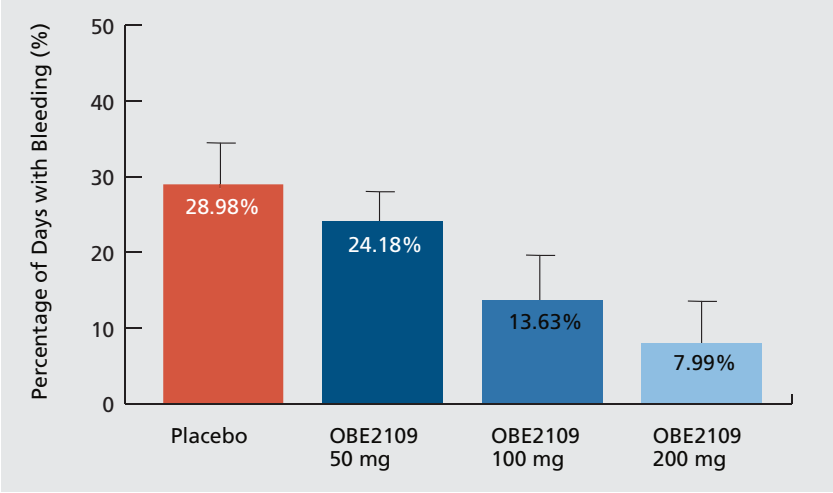
Completed Phase 2a Clinical Trial

In the KLH1202 clinical trial, 57 patients presented with uterine fibroids in addition to endometriosis. For these patients, both menstrual bleeding and uterine volume were evaluated.

Efficacy Results

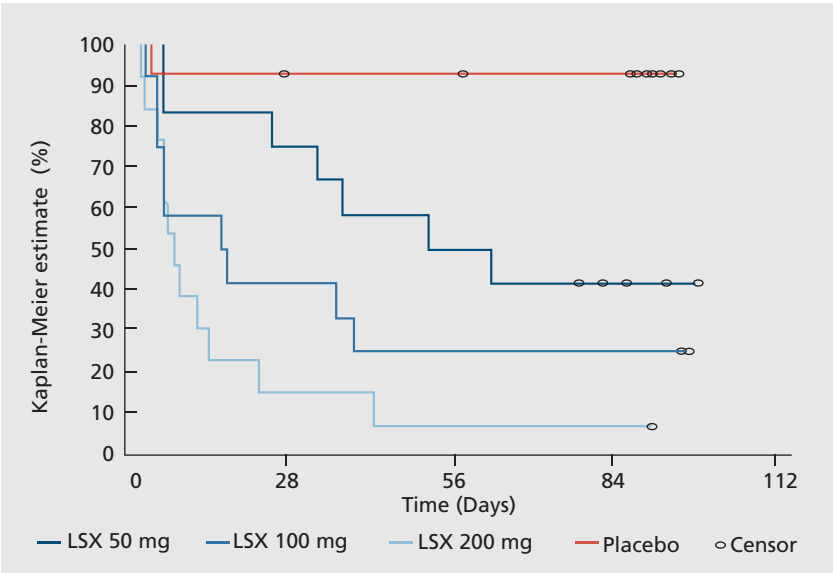
As shown in Figure 7 below, we observed a dose-dependent reduction in the percentage of days in which bleeding occurred during the 12-week treatment period in patients treated with linzagolix.

Figure 7: Percentage of Days with Bleeding During 12-Week Treatment Period



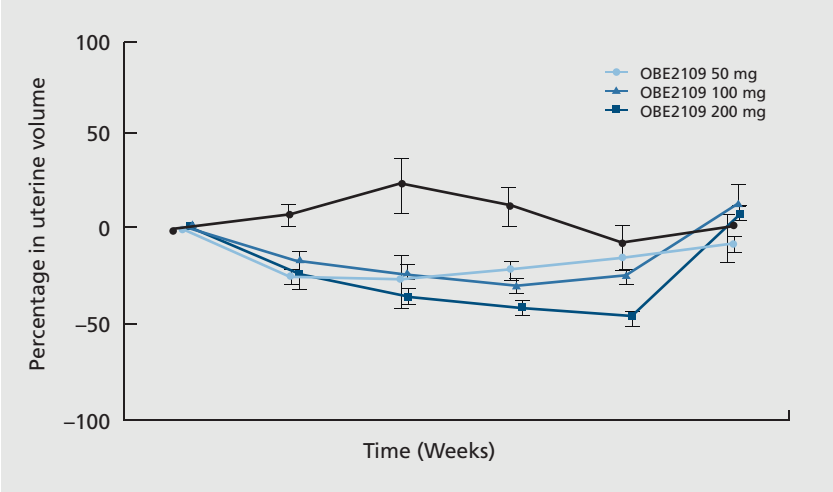
Further, in these patients with uterine fibroids, the 50 mg dose of linzagolix suppressed bleeding in approximately 55% of patients, whereas the 200 mg daily dose of linzagolix suppressed bleeding in approximately 95% of patients as shown in Figure 8 below. In addition, most patients stopped bleeding within a few weeks of treatment initiation in the 100 mg and 200 mg group, as shown in Figure 8 below.

Figure 8: Time to No Bleeding for Uterine Fibroids Patients in KLH1202 Trial



These patients experienced a dose-dependent reduction in uterine volume, while no meaningful reduction in uterine volume was observed in the placebo group, as shown in Figure 9 below. Reducing uterine volume is relevant for the treatment of uterine fibroid patients, as patients with lower uterine volume may be eligible for less invasive surgical procedures, such as a hysterectomy by vaginal route rather than abdominal route. In addition, increased uterine volume is associated with several symptoms, such as urinary incontinence at an increased frequency.

Figure 9: Change in Uterine Volume over Time

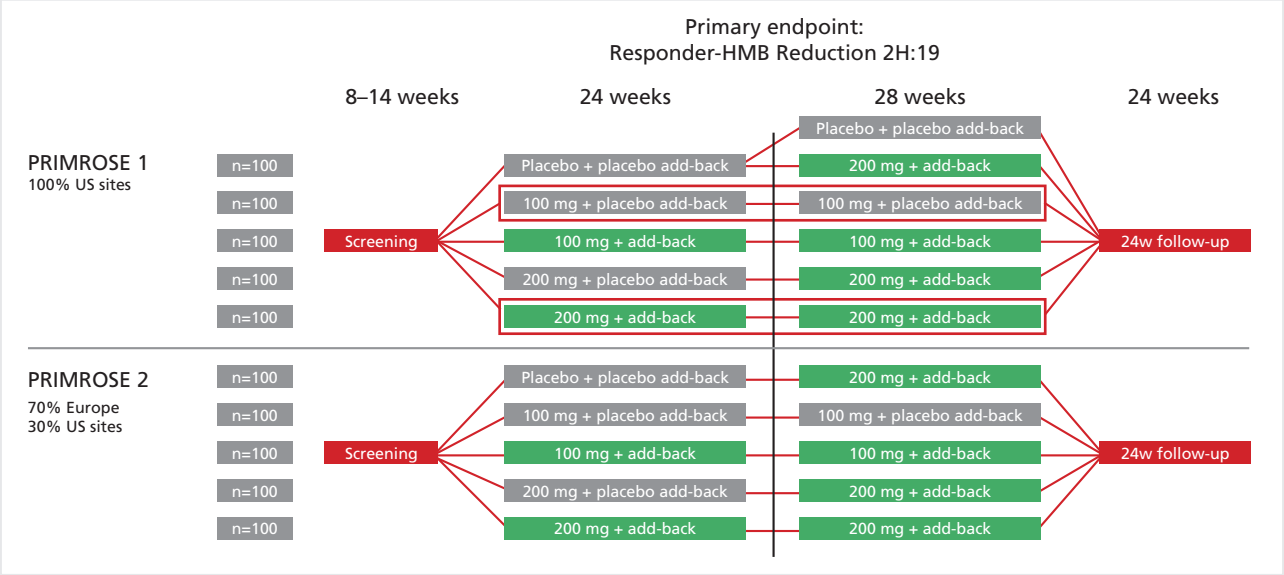


Clinical Development Plan–Heavy Menstrual Bleeding Associated with Uterine Fibroids

Based on feedback we received from the FDA in November 2016, we commenced the two PRIMROSE Phase 3 clinical trials in patients with heavy menstrual bleeding associated with uterine fibroids in the first half of 2017. The PRIMROSE clinical trials each have a target enrollment of approximately 500 patients. We announced that the PRIMROSE 2 trial, being conducted in both the U.S. and Europe, completed patient recruitment in December 2018, and we expect the PRIMROSE 1 trial being conducted in the U.S. to do so in the second quarter of 2019. We expect to report primary endpoint results following 24 weeks of treatment in the PRIMROSE 1 and 2 clinical trials in the first quarter of 2020 and fourth quarter of 2019, respectively, with a regulatory filing with the FDA based on 52 weeks treatment duration in both trials, planned prior to the end of 2020. We are assessing the efficacy of both a 100 mg dose and a 200 mg dose of linzagolix both with and without ABT in the ongoing PRIMROSE clinical trials. We believe that the 200 mg dose will require ABT to prevent excessive bone mineral density loss, while the 100mg dose may not necessitate the use of ABT.

Figure 10 below depicts the trial design of the Phase 3 PRIMROSE clinical trials:

Figure 10: Design of Phase 3 PRIMROSE Clinical Trials



Throughout the PRIMROSE clinical trials, patients will collect and deliver their used sanitary protection to a central laboratory analysis using a validated alkaline hematin method. In addition, patients will report their bleeding status on a daily basis with an electronic diary.

The PRIMROSE clinical trials will have a 52-week evaluation period. The primary endpoint of these clinical trials will be the reduction from baseline at week 24 of menstrual blood loss, defined as menstrual blood loss of less than 80 mL and equal to or greater than a 50% reduction from baseline, assessed with the alkaline hematin method. A key secondary endpoint will be the bone mineral density after 24 weeks of treatment assessed with a dual-energy x-ray absorptiometry scan. After the 52-week evaluation period, all patients will be followed for an additional, 24-week period that will be treatment free. We expect to report primary endpoint 24-week data from the PRIMROSE Phase 3 clinical trials starting in the second half of 2019, and the 52-week data are expected in 2020. If the results from these trials are favorable, we plan to submit an NDA prior to the end of 2020.

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

As of February 2019, more than 1,900 subjects have been exposed to linzagolix in completed and ongoing clinical studies and linzagolix has been generally well tolerated.

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

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

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

Over all multiple dose trials, in a very small number of subjects, an increase in transaminase values was observed under treatment, however this increase was generally reversible under treatment and was never associated with any increase in Bilirubin.

Nolasiban in IVF

We are developing nolasiban as an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing embryo transfer after IVF, including intracytoplasmic sperm injection, or ICSI. We have observed nolasiban's ability to improve uterine receptivity by, we believe, decreasing uterine contractions, improving uterine blood flow and enhancing the receptivity of the endometrium to embryo implantation. We in-licensed nolasiban from Merck Serono, which previously completed preclinical studies and Phase 1 clinical trials in 103 healthy female volunteers that evaluated the safety and PK profile of nolasiban. We completed a 247-patient Phase 2 clinical trial of nolasiban in women undergoing IVF, which we refer to as the IMPLANT 1 trial. In the IMPLANT 1 trial, nolasiban did not reach the primary endpoint of demonstrating a statistically significant increase in pregnancy rate at six weeks after ET. However, in our post-hoc analysis, which excluded patients with progesterone levels in the top quartile of the patient pool, we identified a statistically significant dose-proportional increase in pregnancy rate at 10 weeks and live birth rate. We believe that high progesterone levels can lead to a premature closing of the embryo implantation window. Based on these results, we believe that nolasiban could represent a compelling option for increasing IVF outcomes. We initiated our IMPLANT 2 European Phase 3 clinical trial in women undergoing IVF in March 2017, announced patient recruitment completion in September 2017, reported data for the primary endpoint in February 2018 and the live birth rate in October 2018. The IMPLANT 2 clinical trial demonstrated that nolasiban significantly increased ongoing pregnancy rate at 10 weeks. The primary endpoint of the clinical trial was met, with an absolute increase in ongoing pregnancy rate at 10 weeks of 7.1% (placebo 28.5% and nolasiban 35.6%, p = 0.031). This represents a relative increase of 25% in the ongoing pregnancy rate after administration of nolasiban compared to placebo. Patients who underwent ET 5 days post oocyte retrieval achieved ongoing pregnancy 10 weeks post ET at a rate of 45.9% when administered nolasiban, vs. 34.7% of those who received placebo, a 32% relative increase with a p value of 0.034. In October 2018, we announced live birth rate results from the IMPLANT 2 trial, which were consistent with the benefit seen in pregnancy rates for patients treated with nolasiban. Live birth rate, the ultimate goal of IVF procedures, taking home a baby, showed a statistically and clinically significant benefit in favor of patients receiving nolasiban, 34.8% vs. 27.7% for placebo, p=0.025. For patients undergoing Day 5 ET, the live birth rate benefit was even more pronounced for nolasiban, 44.8% vs. 33.2%, p=0.025. Nolasiban was observed to be well tolerated with a safety profile not different from placebo. 28-day neonatal safety data from the IMPLANT 2 trial did not reveal any adverse consequences from nolasiban treatment, and 6-month infant follow-up results are expected in the second quarter of 2019.

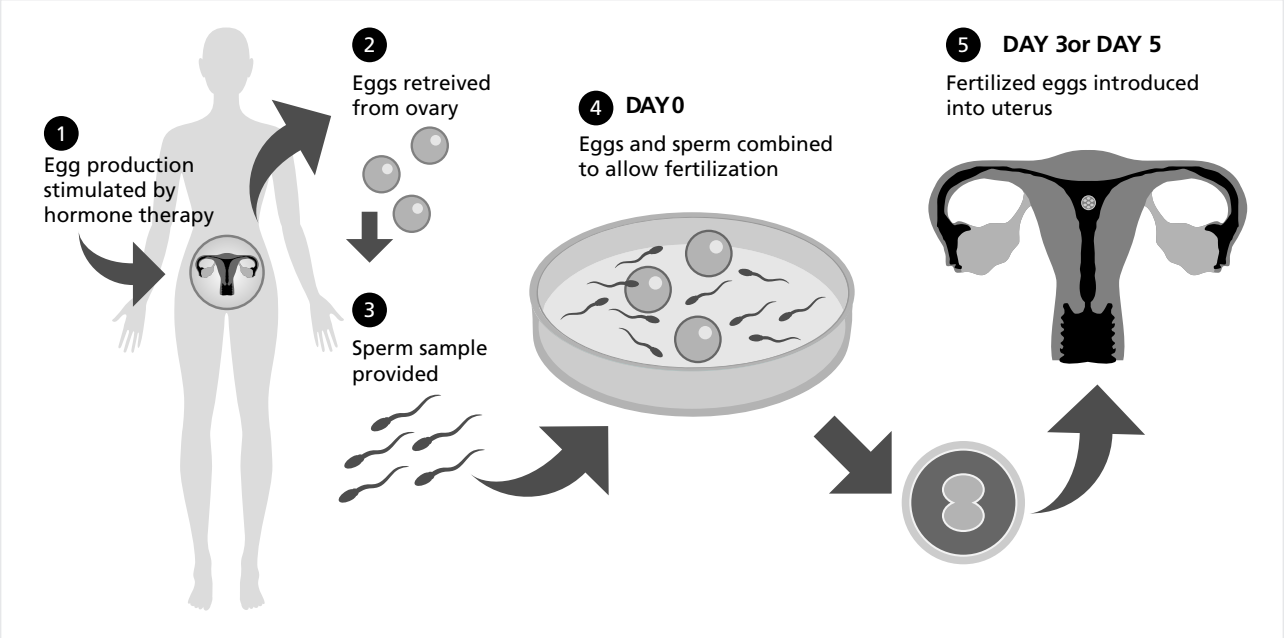
Based on the feedback we received from regulatory authorities in Europe, following scientific advice meetings on our nolasiban development program, we initiated an additional Phase 3 trial primarily in European, Canadian and CIS or Russian centers, or the IMPLANT 4 trial, in November 2018.

Background on Assisted Reproductive Technology (IVF/ICSI)

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

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

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

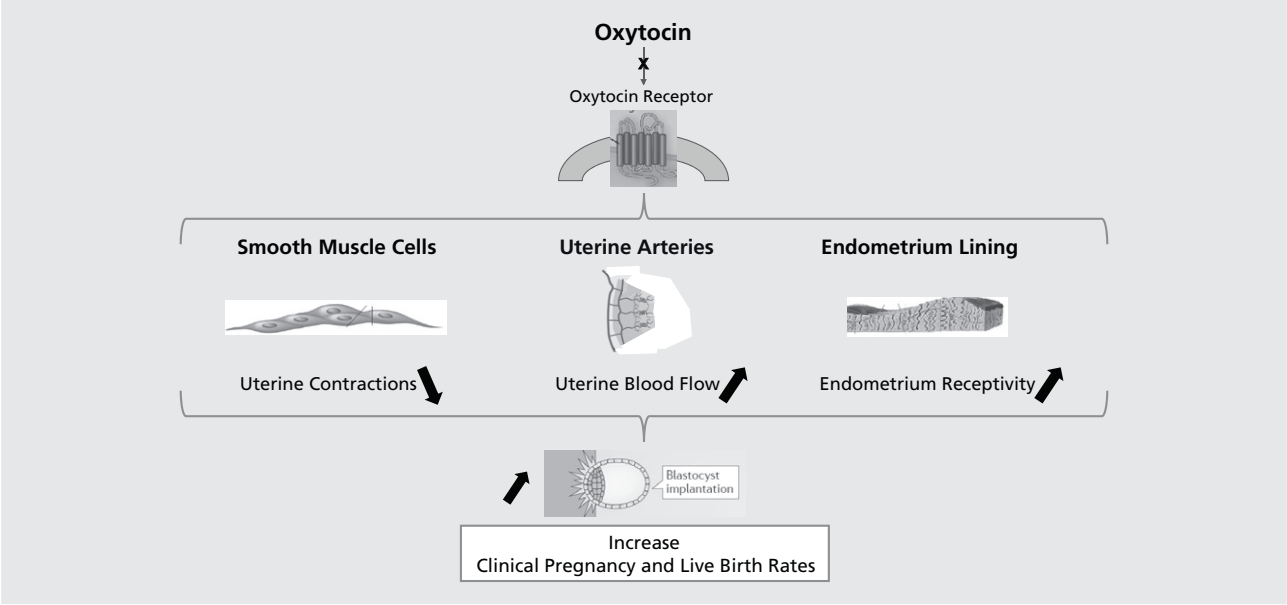


The cost of one IVF cycle varies between USD 8,000 to USD 15,000 in the United States, EUR 2,000 to EUR 10,000 in Europe and USD 3,000 to USD 6,000 in Japan. As of 2006, fertility drugs account for more than USD 2,000 of the cost of a treatment cycle. Most patients require multiple fertility treatment cycles. Data from IQVIA estimates that global sales of fertility drugs approximated USD 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 on the uterus smooth muscle cells, the endometrium and the uterus 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 the 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 the clinical pregnancy rates was significantly increased with the infusion of an oxytocin receptor antagonist at the time of embryo transfer (OR = 1.84, 95% CI: 1.31±2.57; P < 0.001), but not the live birth rate (P=0.083). Moreover, in a recent trial published in 2016 involving patients with endometriosis undergoing frozen-thawed embryo transfer, clinical pregnancy rates were approximately 20% higher after treatment with an oxytocin receptor antagonist, representing a 51% increase relative to the placebo. In addition, according to studies published in Archives of Gynecology and Obstetrics in 2011, women who received an oxytocin receptor antagonist after embryo transfer, were observed, based on three dimensional power doppler ultrasound, to have improved characteristics for uterine receptivity, including enhanced endometrial blood flow.

Limitations of Current Treatment Options

Currently, there are no oxytocin receptor antagonists approved for use in connection with IVF.

Potential Therapeutic Benefits of nolasiban

We are developing nolasiban, an oxytocin receptor antagonist, for use in connection with IVF. We believe nolasiban has the potential to offer the following therapeutic benefits:

- **Increased pregnancy and live birth rate.** In the IMPLANT 2 clinical trial, we observed that nolasiban significantly increased ongoing pregnancy rate at 10 weeks: Pooled D3/D5 (primary): Placebo 28.5%, nolasiban 35.6%, p=0.03 (7.1% absolute increase, 25% relative increase). The largest increase in ongoing pregnancy rate was seen with D5 ET, Placebo 34.7%, nolasiban 45.9%, p=0.03 (11.2% absolute increase, 32% relative increase). Live birth rate, reflecting the ultimate goal of IVF procedures, taking home a baby, showed a statistically and clinically significant benefit in favor of patients receiving nolasiban, 34.8% vs. 27.7% for placebo, p=0.025. For patients undergoing Day 5 ET, the live birth rate benefit was even more pronounced for nolasiban, 44.8% vs. 33.2%, p=0.025.
- **Convenience of administration.** Nolasiban is an oral oxytocin receptor antagonist, that is being studied as a one-time single dose oral administration which could be easily incorporated into IVF procedures and this without changing standard of care except this single oral administration prior to ET.
- **Fast and sustained therapeutic effect.** In clinical trials, nolasiban was observed to be rapidly absorbed in the body and, in the case of the 900 mg dose, to maintain effective concentrations in the body for three days after treatment, potentially allowing for a single administration at the time of embryo transfer.
- **Favorable safety profile.** In Phase 1 and Phase 2 clinical trials, single doses of nolasiban were well tolerated by patients. In addition, extensive testing in animal models around the time of embryo implantation and during pregnancy has not revealed any concerns regarding embryo toxicity. Topline IMPLANT 2 clinical trial results that were announced in February 2018 showed rates of study discontinuation and treatment emergent adverse events that were very low and comparable to placebo rates, and the few reported serious adverse event reports were numerically higher for placebo than for nolasiban, although none were reported to be related to treatment. Live birth and 28-day neonatal safety from the IMPLANT 2 trial did not reveal any adverse consequences from nolasiban treatment, and 6-month infant follow-up is expected in mid-2019.

Nolasiban Preclinical and Clinical Development

Nolasiban was discovered and initially developed by Merck Serono. Following our in-license of nolasiban from Merck Serono in 2013, we submitted an IND for nolasiban, which became effective in January 2015. Under that IND, we completed a Phase 2 clinical trial of nolasiban in 2016. Though nolasiban did not reach the primary endpoint of a statistically significant increase in pregnancy rate six weeks after the ET but based on our post-hoc analysis of the Phase 2 data, we identified a statistically and clinically significant dose-proportional increase in ongoing pregnancy rate at week 10 and live birth rate. In March 2017, we initiated our IMPLANT 2 European Phase 3 clinical trial in women undergoing IVF to further evaluate the efficacy and safety of a single oral dose of nolasiban, announced patient recruitment completion in September 2017, and reported positive primary endpoint pregnancy results in February 2018, and positive live birth results in October 2018. Based on these results, we sought feedback from regulatory authorities in Europe and the United States on any necessary additional clinical requirements, and also solicited guidance on the regulatory registration path forward. Based on the feedback we received from regulatory authorities in Europe following scientific advice meetings on our nolasiban development program, we initiated an additional Phase 3 trial primarily in European, Canadian and CIS or Russian centers, or the IMPLANT 4 trial, in November 2018. Assuming IMPLANT 4 trial results confirm IMPLANT 1 and IMPLANT 2 results, we intend to use this data to file a European marketing authorization application (MAA), which is being planned for late 2019. Feedback received from the FDA did not provide the clarity that we were hoping to see on the design of pivotal clinical trials to support an IVF indication in the United States. We are working with the FDA to reach agreement on certain elements. Upon agreement with the FDA, which we anticipate may be achieved in 2019, we are ready to pursue our clinical trial program in the United States.

Preclinical Studies and Phase 1 Clinical Trials

In preclinical studies, the ability of nolasiban to inhibit uterine contraction was observed, and there were no tolerance or safety concerns. Specifically, studies were conducted focusing on the reproductive toxicology in rats and rabbits during the time of implantation, and such studies did not reveal concerns of embryo toxicity after repeated exposure to nolasiban.

In single and multiple ascending dose Phase 1 clinical trials conducted in the United Kingdom by Merck Serono, nolasiban was tested in 103 healthy female volunteers with single doses up to 1,500 mg and multiple doses up to 900 mg for seven days. There were no safety signals, trends in adverse events or negative findings from vital signs or laboratory parameters. Nolasiban was observed to be quickly absorbed, reaching maximum concentration in approximately two hours, and to have a dose-proportional PK profile and a half-life that could support once daily dosing. There was no observed food effect.

Completed Phase 2 Clinical Trial

In 2016, we completed a Phase 2, double-blind, placebo-controlled, dose ranging, clinical trial of nolasiban in women undergoing IVF, which we refer to as the IMPLANT trial. This trial enrolled 247 women across 26 fertility clinics in five European countries. Patients were between the ages of 18 and 36, were currently undergoing medically indicated IVF and had no more than one previous IVF cycle failure. The study evaluated three doses of nolasiban, 100 mg, 300 mg or 900 mg, compared to placebo. Patients received a single oral dose approximately four hours before a Day 3 fresh embryo transfer. The patients were evaluated once pregnant at weeks 2, 6 and 10 and we also evaluated the infants born for up to six months after birth. Assuming a 20% pregnancy rate in placebo and a 40% pregnancy rate in nolasiban at 900 mg, the number of patients in each arm of the trial provided an 80% chance to show a statistically significant increase in pregnancy rate from placebo through ascending doses of nolasiban using a trend test. We believed this was the appropriate trial design to determine dose effect and guide future clinical development.

The trial design is summarized below:

STUDY TOTAL DURATION PER SUBJECT: UP TO 22 WEEKS

Screening Visit: Up to 12 weeks Prior OPU	OPU Day + 3 (Baseline Visit) Dosing and Embryo Transfer					Post-Treatment Period	
	Prior to Dosing	Dosing (T0)	T+3.5 h	T+4 h	T+4.5 h	14 days	6 & 10 weeks
Key Measurements Taken	Uterine contractions OBE001 PK Estradiol, progesterone vital signs		Uterine contractions Nolasiban PK Estradiol, progesterone	Embryo transfer (ET)	Vital signs	Blood pregn. test Hemato / chemistry Vital signs Physical exam	Ultrasound to confirm pregnancy continuation: No. of gestational sac & embryo with cardiac activity

The primary endpoint of this trial was:

- the percentage of women with an intra-uterine pregnancy with positive embryo heartbeat at six weeks after the ET day.

Secondary endpoints included:

- the percentage of women with a positive blood pregnancy test at 14 days after the OPU day;
- the percentage of women with an intra-uterine pregnancy with positive embryo heartbeat at 10 weeks after the OPU day;
- the embryo-implantation rate defined as the number of intra-uterine embryos with positive heartbeat at six weeks after the ET day divided by the number of embryos transferred; and
- the absolute and relative change from baseline, prior to nolasiban or placebo administration, to the time of embryo transfer, which is about 3.5 hours after nolasiban/placebo administration and prior to embryo transfer, in the rate of uterine contractions per minute.

Efficacy Results

As shown in Figure 11 below, which we refer to as the "Full Set Analysis," the overall percentage of patients with an intra-uterine pregnancy with a positive heartbeat at six weeks after ET and the live birth rate were increased by over 9%, equivalent to a 26% increase relative to placebo. The median uterine contractions decreased by 8.7%, 4.0% and 13.3% for the 100 mg, 300 mg and 900 mg groups, respectively, compared to placebo. However, statistical significance was not reached for the primary endpoint, as indicated in the "Trend Test" column in Figure 11 below. We believe the lack of statistical significance was attributable to the limited sample size and based on the 300 mg dose group of nolasiban which had lower clinical pregnancy and live birth rates than the 100 mg and 900 mg treatment groups.

The trend test is a statistical technique that was used to determine whether there was a statistically significant linear relationship between the dose of nolasiban administered and the amplitude of the increase in ongoing pregnancy rate at six weeks after the ET day. In this Phase 2 IMPLANT trial, we considered a p-value of less than 0.10 to be statistically significant.

Figure 11

Full Set Analysis	Placebo	Nolasiban 100 mg	Nolasiban 300 mg	Nolasiban 900 mg	Nolasiban All Doses	Trend Test
Number of patients	65	62	60	60	182	
Relative change in uterine contractions	0.0%	–8.7%	–4.0%	–13.3%**		
Ongoing pregnancy rate at 6 weeks after ET day	33.8%	46.8%	35.0%	46.7%	42.9%	p=0.33
Ongoing pregnancy rate at 10 weeks after OPU day	29.2%	43.5%*	35.0%	45.0%*	41.2%	p=0.15
Live birth rate (baby born alive 24 weeks gestation)	29.2%	40.3%	35.0%	43.3%	39.6%	p=0.20

*p≤0.10 **p≤0.05

Following our receipt of the initial data, we reviewed the patients' characteristics within each of the dose groups. From this review, we discovered that patients in the 300 mg group demonstrated higher estradiol levels and higher progesterone levels prior to embryo transfer than in the other groups. We believe that high estradiol levels are responsible for the earlier expression of progesterone receptors, which induce advancement of endometrial maturation, and that high progesterone levels can lead to a premature closing of the embryo implantation window, preventing or impairing the embryo implantation. Therefore, we subsequently conducted a post-hoc analysis of the results of the Phase 2 clinical trial, removing patients with a progesterone level in the top quartile of the patient pool. There were 25 patients excluded in this post-hoc analysis from the 300 mg group, while only 16, 12 and 11 patients were excluded in this post-hoc analysis from the placebo, 100 mg and 900 mg groups, respectively, which we believe demonstrates the imbalance between the 300 mg group and the other groups.

In our post-hoc analysis, we identified a statistically significant relationship between the dose of nolasiban and the ongoing pregnancy rate at week 10 and live birth rate, with an increase from 30.6% for placebo to 51.0% for 900 mg nolasiban at week 10 and for live birth rate, equivalent to a 67% increase relative to placebo (trend test p-value < 0.05). The results of our post-hoc analysis are shown in Figure 12 below:

Figure 12

Subset Post-Hoc Analysis	Placebo	Nolasiban 100 mg	Nolasiban 300 mg	Nolasiban 900 mg	Nolasiban All Doses	Trend Test
Number of Patients	49	50	35	49	134	
Ongoing Pregnancy Rate at 6 weeks After ET day	36.7%	44.0%	48.6%	53.1%	48.5%	p=0.095*
Ongoing Pregnancy Rate at 10 weeks After OPU day	30.6%	42.0%*	48.6%	51.0%*	47.0%	p=0.035**
Live birth rate (baby born alive 24 weeks gestation)	30.6%	38.0%	48.6%	51.0%	45.5%	p=0.025**

*p≤0.10 **p≤0.05

Based on these results, we believe that a single 900 mg dose of nolasiban administered just before embryo transfer has the potential to increase clinical pregnancy and live birth rates following IVF.

Phase 2 Clinical Safety Results

In the IMPLANT 1 trial, nolasiban was well tolerated at doses up to 900 mg. Adverse events were reported through 10 weeks following the OPU day. Increased doses were not observed to result in increased occurrence of adverse events. The most common adverse events were determined to be related to pregnancy, menstrual bleeding or the IVF procedure and occurred at similar frequencies in the placebo and active treatment groups. Serious adverse events were reported in six patients and included ectopic pregnancy in three patients, and adnexal torsion, vaginal hemorrhage and ovarian hyperstimulation syndrome in one patient each. None of these serious adverse events were determined by the investigator to be related to the treatment and none caused trial discontinuation. One patient in the nolasiban 900 mg group discontinued participation in the trial due to a non-serious adverse event of ovarian hyperstimulation syndrome, which was determined by the investigator to be unrelated to treatment. Only three adverse events, which occurred in patients in the 300 mg group, were considered related to treatment (mild nausea, mild dizziness and mild rash), and the patients fully recovered from the adverse events.

In the trial, ongoing pregnancies were followed up to 28 days post-delivery. As expected with human pregnancies, some congenital malformations were observed both in the placebo group and the treatment groups. There appeared to be no relationship between the nolasiban dose and the incidence of the congenital malformations, as shown in Figure 13 below, and none were determined by the investigator to be related to treatment. In addition, nolasiban was not associated with an increase in ectopic pregnancy or in intra-uterine growth retardation.

Figure 13

Parameters	Placebo n=65	Nolasiban 100 mg n=62	Nolasiban 300 mg n=60	Nolasiban 900 mg n=60
Ectopic Pregnancy	1	1	0	1
Congenital Malformation	2*	4°	0	1§
Intra-uterine Growth Retardation	0	0	2	0

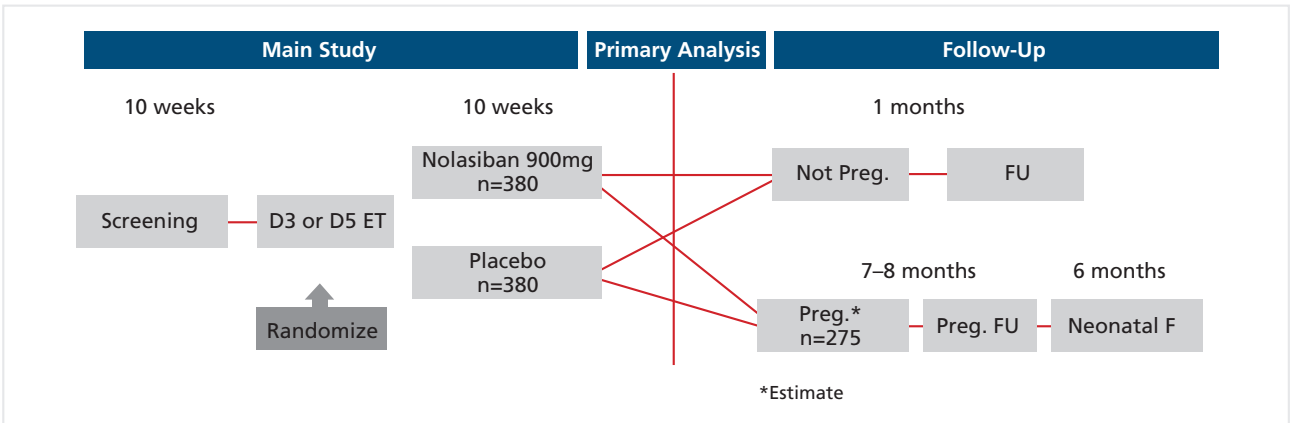
* Club-Foot/Renal hydrops
° Acrania/Turner Syndrome/Prader Willi Syndrome/Left Ventricular Hypoplasia
§ Polydactyly

Ongoing Phase 3 Clinical Trial and Clinical Development Plan

We have advanced nolasiban into Phase 3 clinical development to evaluate its potential to improve clinical pregnancy and live birth rates for women undergoing IVF. We are conducting a Phase 3 clinical trial in Europe, which we refer to as IMPLANT 2, where we believe more IVF treatments are conducted. The study included eligibility criteria to exclude patients with high progesterone level on day of hCG from entering the trial.

IMPLANT 2 is a randomized, double blind, placebo controlled clinical trial that included 778 patients from 41 fertility clinics across nine European countries. Patients received either a single 900 mg dose of nolasiban or placebo (1:1) orally on the day of ET. Recruitment included patients undergoing single, fresh ET on day 3 (D3, n=388) or on day 5 (D5, n=390) after oocyte retrieval. The primary endpoint of the trial was ongoing pregnancy as determined by ultrasound at 10 weeks following ET. The pre-defined primary analysis was conducted on the pooled population of D3 and D5 ET. Secondary endpoints include clinical pregnancy rates at six weeks after the ET day, live birth rates, maternal, newborn baby and infant follow-up. The design of this IMPLANT 2 European Phase 3 clinical trial is shown in Figure 14 below.

Figure 14



We initiated this IMPLANT 2 European Phase 3 clinical trial in March 2017, announced patient recruitment completion in September 2017, and reported data for the primary endpoint in February 2018 and for live birth rate in October 2018.

These top line results include efficacy and safety data up to week 10 of pregnancy following embryo transfer. Demographics and baseline characteristics were comparable between groups. The primary endpoint of the clinical trial was met, with an absolute increase in ongoing pregnancy rate at 10 weeks of 7.1% (placebo 28.5% and nolasiban 35.6%, p = 0.031). This represents a relative increase of 25% in the ongoing pregnancy rate after administration of nolasiban compared to placebo. In the ET D5 subgroup, the absolute increase was 11.2% in favor of nolasiban (placebo 34.7% and nolasiban 45.9%, p = 0.034). This represents a relative increase in ongoing pregnancy rate of 32% after administration of nolasiban compared to placebo. In the ET D3 subgroup, there was a statistically non-significant 3.1% absolute increase in favor of nolasiban (placebo 22.2% and nolasiban 25.3%, p > 0.05), or a 14.0% relative increase in ongoing pregnancy rate after administration of nolasiban compared to placebo. The live birth rate results were consistent with the benefit seen in pregnancy rates for patients treated with nolasiban. Live birth rate, reflecting the ultimate goal of IVF procedures, taking home a baby, showed a statistically and clinically significant benefit in favor of patients receiving nolasiban, 34.8% vs. 27.7% for placebo, p=0.025. For patients undergoing Day 5 ET, the live birth rate benefit was even more pronounced for nolasiban, 44.8% vs. 33.2%, p=0.025. The 28-day neonatal safety data did not reveal any adverse consequences from nolasiban treatment.

Figure 15

	Pooled D3 and D5			D3			D5		
	Placebo	Nolasiban 900 mg	p-value	Placebo	Nolasiban 900 mg	p-value	Placebo	Nolasiban 900 mg	p-value
Number of Patients	390	388		194	194		196	194	
Ongoing Pregnancy Rate at 10 weeks	28.5%	35.6%	**0.031**	22.2%	25.3%	0.477	34.7%	45.9%	**0.034**
Live Birth Rate	27.7%	34.8%	**0.025**	22.7%	24.7%	0.552	33.2%	44.8%	**0.025**

Overall, nolasiban was well tolerated, with low rates of study discontinuation that were comparable between treatment and placebo. The safety profile of nolasiban was also similar to placebo. Safety data from the IMPLANT 2 trial did not reveal any adverse consequences from nolasiban treatment.

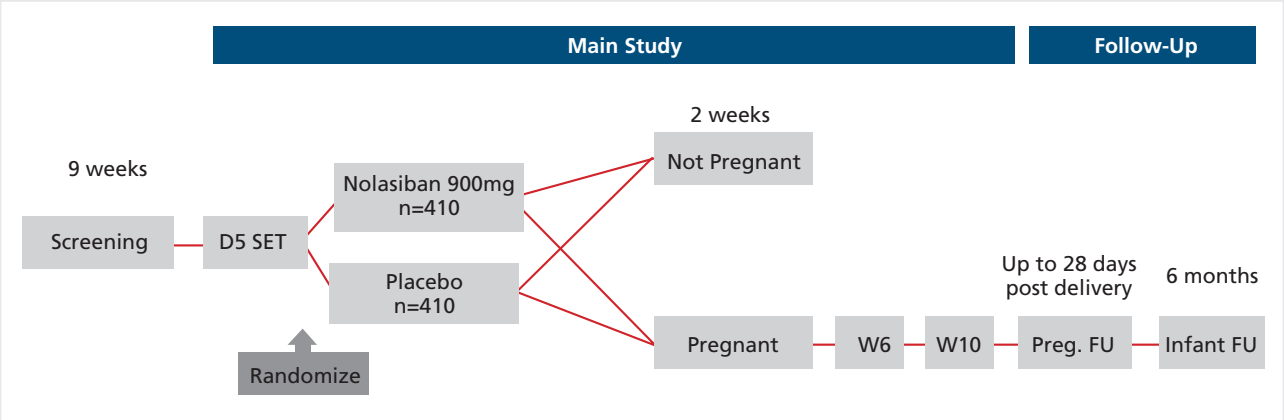
Figure 16

	Placebo	Nolasiban
Pregnant at week 2 (Safety Set)	156	174
Pregnancy loss (week 10)	44 (28.2%)	37 (21.3%)
Ectopic pregnancy	4 (2.6%)	1 (5.7%)
Other SAEs up to week 10	5 (3.2%)	4 (2.3%)
Pregnant at week 10 (Safety Set)	112	137
Pregnancy loss (week 10 to 24)	3 (2.7%)	3 (2.2%)
Congenital malformations (cumulative)	5 (4.5%)	6 (4.3%)

Based on feedback received from regulatory authorities in Europe on our nolasiban development program, we initiated an additional Phase 3 trial, or the IMPLANT 4 trial in late November 2018.

IMPLANT 4 is a randomized, double blind, placebo controlled clinical trial that will include 820 patients from about 50 fertility clinics across primarily European, Canadian and CIS or Russian centers. Patients undergoing single, fresh ET on day 5 (D5) after oocyte retrieval will be randomized to receive either a single 900 mg dose of nolasiban or placebo (1:1) orally on the day of ET. The primary endpoint of the trial will be similar to IMPLANT 2, including ongoing pregnancy as determined by ultrasound at 10 weeks following ET. The key secondary endpoint are live birth rates as well as maternal, newborn and infant follow-up. The design of this IMPLANT 4 Phase 3 clinical trial is shown in Figure 17 below.

Figure 17



OBE022: Our $PGF_{2\alpha}$ Receptor Antagonist for the Treatment of Preterm Labor (GA 24–34 weeks)

We are developing OBE022 as a potential first-in-class, once daily, oral and selective PGF2α, receptor antagonist for the treatment of preterm labor in weeks 24 to 34 of pregnancy. PGF2α is a naturally occurring prostaglandin that acts to induce labor in pregnant women. Through specific antagonism of the PGF2α receptor, OBE022 is designed to control preterm labor by reducing inflammation, decreasing uterine contractions and preventing cervical changes and membrane ruptures. Based on its PK profile and efficacy observed in animal models, we believe OBE022 has the potential to become a first-in-class therapy to suppress premature labor and delay or avoid preterm birth while also being safe for the fetus. In February 2017, we completed a Phase 1 clinical trial assessing the safety, tolerability and PK profile of OBE022 in healthy post-menopausal female volunteers after single doses of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day over 7 consecutive days. OBE022 was observed to have a favorable pharmacokinetic profile, no clinically significant food effect, a favorable safety profile and to be well-tolerated at doses up to 1,300 mg after single dose administration and up to 1,000 mg per day after multiple dose administration over 7 days, each of which are above the estimated clinical effective dose. In March 2017, we completed a set of drug-drug interaction, or DDI, Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of OBE022 when combined with magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in pre-menopausal female volunteers. OBE022 in combination with those drugs was observed to have a favorable safety profile and to be well-tolerated up to 1,100 mg per day, which was the highest tested dose. In December 2017, we announced the initiation of our Phase 2a proof-of-concept clinical trial of OBE022 known as PROLONG, which is being conducted in two parts: Part A and Part B. Part A is an open-label trial assessing the safety and pharmacokinetics of OBE022 in pregnant women, who were already receiving standard of care therapy for preterm labour, atosiban infusion. Part B, is a randomized, double-blind, placebo-controlled, parallel-group trial to assess

the efficacy, safety and pharmacokinetics of OBE022. In December 2018, following completion of the open-label Part A and based on the favorable safety and pharmacokinetics results, we announced the initiation of the randomized placebo-controlled Part B of the trial. Part B will enroll up to 120 women at 24-34 weeks gestation who are experiencing preterm labor symptom. We expect initial interim efficacy results to be available in the first 30 patients in the first half of 2019.

Background and Impact of Preterm Labor

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

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

Role of Prostaglandins in Preterm Labor

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

Limitations of Current Treatment Options

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

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

Figure 18: Weighted Percentages of Tocolytic Agents for Efficacy

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

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

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

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

OBE022 Preclinical and Clinical Development

OBE022 was discovered and initially developed by Merck Serono as a selective inhibitor of $PGF_{2\alpha}$. We in-licensed OBE022 from Merck Serono in 2015. In preclinical studies, OBE022 was observed to reduce uterine contractions and to exert a synergistic effect in combination with nifedipine to delay delivery. We advanced OBE022 into Phase 2a proof-of-concept clinical trial in December 2017 to assess the safety and efficacy of OBE022 to delay birth in women 24 to 34 weeks pregnant who face preterm labor and potentially preterm delivery. In February 2017, we completed a Phase 1 clinical trial assessing the safety, tolerability and PK profile of OBE022 in healthy post-menopausal female volunteers after single doses of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day over 7 consecutive days. OBE022 was observed to have a favorable PK profile, no clinically significant food effect, a favorable safety profile and to be well-tolerated at doses up to 1,300 mg after single dose administration and up to 1,000 mg per day after multiple dose administration over 7 days.

In March 2017, we completed a set of DDI Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of OBE022 when combined with magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in pre-menopausal female volunteers. OBE022 in combination with those drugs was observed to have a favorable safety profile and to be well-tolerated up to 1,100 mg per day, which was the highest tested dose.

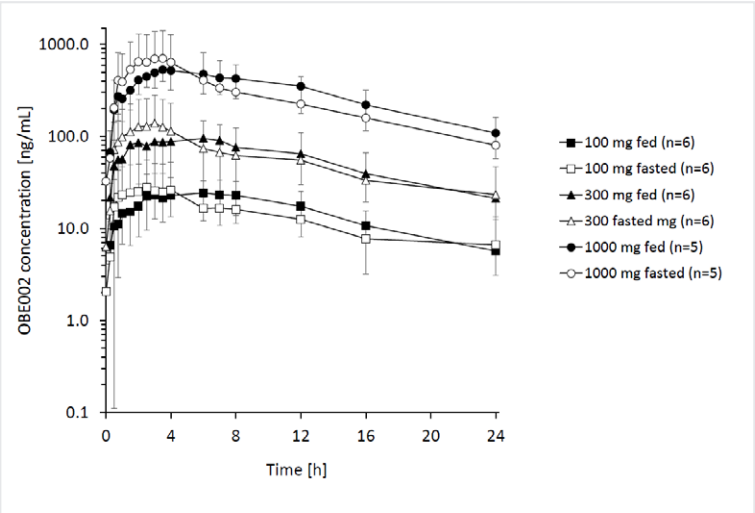
Preclinical Development

In the preclinical pharmacology, PK and toxicology studies conducted by Merck Serono, OBE022 was observed to be a highly selective, competitive and reversible $PGF_{2\alpha}$ receptor antagonist with over 100 times the affinity for it compared to other prostaglandin receptor subtypes. OBE022 has been observed to have tocolytic effects in vitro and in vivo by markedly reducing spontaneous uterine contractions in a preterm labor animal model. At the Society for Reproductive Investigations' 64th Annual Scientific Meeting in March 2017, we presented results of a non-clinical study in which we observed that OBE022 exerted a synergistic effect in combination with nifedipine on the delay of delivery in an animal model for preterm labor. The study evaluated the effect of OBE022 and nifedipine, alone and in combination with each other, on an animal model of RU486-induced birth in pregnant mice. The induction of labor by the antiprogestin RU486 results from inhibition of progesterone activation leading to the up-regulation of labor-associated proteins as seen in the case of idiopathic preterm labor. Compared to the vehicle control, we observed nifedipine (5mg/kg, taken orally), as well as OBE022 (100mg/kg, taken orally), alone resulted in statistically significant delays in RU486-induced preterm labor. We also observed a synergistic effect of combination treatment with OBE022 and nifedipine on the delay of delivery when compared to vehicle, nifedipine or OBE022 alone ($p<0.001$, $p<0.001$ and $p<0.01$, respectively). Preclinical studies have also been conducted to support oral administration of OBE022 in humans. Overall, the toxicological profile of OBE022 observed in repeated-dose toxicity studies in rats and dogs as well as reprotoxicity in rabbits and rats appeared to be benign. We also conducted safety studies to evaluate OBE022 compared to NSAIDs in pregnant rats prior to delivery. In these studies, we observed that the NSAID indomethacin induced, as expected, constriction of the blood vessel connecting the pulmonary artery to the aorta and impaired the renal function in the newborn rats, while OBE022 did not. In addition, we have observed that OBE022 does not inhibit platelet aggregation whereas the NSAIDs were confirmed to significantly inhibit it, which is considered to be a potential risk factor for neonatal tissue hemorrhagia, e.g. periventricular brain hemorrhagia. Based on the results of these preclinical studies, we believe that OBE022 has the potential to be an effective, safer tocolytic agent for the treatment of preterm labor.

Phase 1 Clinical Trials

We completed a Phase 1 clinical trial assessing the safety, tolerability and PK profile of OBE022 when administered in approximately 70 healthy post-menopausal female volunteers as single and multiple ascending doses at one site in the United Kingdom. As $PGF_{2\alpha}$ is also involved in uterine contractions and the related pain that can occur during normal menstruation in non-pregnant women, we are assessing the feasibility of measuring the ability of OBE022 to reduce the intra-uterine pressure and the pelvic pain scores in healthy female volunteers of child bearing age during menstruation. From the single doses administered of 10 mg to 1,300 mg and multiple doses between 100 mg per day and 1,000 mg per day administered over 7 consecutive days in the completed Phase 1 clinical trial, we observed that pro-drug OBE022 was readily absorbed and rapidly converted into its equally active stable metabolite OBE002. The plasma level of OBE002 increased with increasing doses of OBE022 reaching exposure levels that were anticipated to be clinically relevant within an hour following administration. There was no clinically significant food interaction with peak exposures reduced to 80% and AUC staying bioequivalent. The mean half-life of OBE002 ranged between 8 and 11 hours following administration of a single dose and between 22 to 29 hours after multiple doses (figure 19). Single and multiple administrations of OBE022 were well tolerated at all doses. There have been no serious adverse events and no clinically relevant changes in safety parameters.

Figure 19:



We also completed a set of DDI Phase 1 clinical pharmacology studies investigating the safety, tolerability and PK profile of OBE022 when combined with therapeutic doses of magnesium sulfate, atosiban, nifedipine or betamethasone (medications typically used in patients with preterm labor) in pre-menopausal female volunteers. We performed an open-label, randomized, three-period crossover trial assessing co-administration of single doses of OBE022 (1100 mg) and MgSO4 (15.5g) and also performed an open-label, single-sequence crossover trial assessing the interactions of OBE022 (1000 mg/d) at steady-state co-administered with single doses of atosiban (60.75 mg), nifedipine (20 mg) and betamethasone (12 mg). Both trials enrolled 12 healthy non-pregnant women of reproductive age at one clinical center in the United Kingdom. There were no clinically relevant pharmacokinetic interactions between OBE022 and MgSO4, betamethasone or atosiban; however, nifedipine exposure increased notably. Co-administration of OBE022 with MgSO4, betamethasone, atosiban and nifedipine was generally well tolerated.

Clinical Development Plan

Based on these Phase 1 clinical trial results, we initiated the PROLONG Phase 2a proof-of-concept clinical trial. The trial objectives are to assess the pharmacokinetic, the safety and efficacy of OBE022 when co-administered with atosiban, to delay birth after oral administration in pregnant women who face preterm labor and potentially preterm delivery. The targeted patient population will include women who are at least 24 weeks and less than 34 weeks pregnant, with intact membranes, presenting with spontaneous preterm labor for which they receive atosiban for 48 hours and no contraindications to a prolongation of pregnancy.

The PROLONG Phase 2a trial is being conducted in two parts: Part A and Part B. Part A was an open-label trial of OBE022 administered orally, with a loading dose of 1000 mg, then 500 mg twice a day for 7 days to pregnant women with threatened preterm labor. OBE022 pharmacokinetics and maternal, fetal and infant safety were assessed. Fetal cardiac safety was monitored using Doppler ultrasound. Time to delivery was also measured. 9 patients were included in this part. Eight of the nine patients did not deliver within the 7 days of OBE022 treatment and one patient delivered the day after starting OBE022. OBE022 was observed to be well absorbed from Day 1 to Day 7 and steady-state serum concentrations and pharmacokinetics were comparable to those observed previously in non-pregnant women. OBE022 administration was observed to be well tolerated by the mother and there were no adverse events reported for the fetuses, and no clinically significant abnormal findings on the Doppler ultrasound including no constrictive effect on the ductus arteriosus. The results will be presented at the 66th Annual Scientific Meeting of the Society for Reproductive Investigation from 12th to 16th of March 2019 in Paris, France.

In January 2019, and based on the favorable safety and pharmacokinetic results we observed in Part A, we announced the initiation of Part B of the PROLONG trial, which is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of OBE022. We are planning to enroll up to 120 patients with preterm labor at a gestational age of 24 to 34 weeks. As in Part A, OBE022 or placebo will be administered orally, with 1,000 mg as a starting dose, then 500 mg twice a day for 7 days to women already receiving atosiban infusion for 48 hours.

Based on the results of this trial, and after receiving expert and regulatory feedback, we will decide whether to further develop OBE022 as a self-standing tocolytic or in combination with atosiban or another currently used tocolytic.

Commercialization
We have not yet established a sales, marketing or product distribution infrastructure. In order to commercialize any of our product candidates if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution capabilities or collaborate with third-parties that have sales and marketing experience. As we move our product candidates through development toward regulatory approval we will evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force, entering into a joint marketing partnership with another pharmaceutical or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company.

Manufacturing
We rely on CMOs to produce our product candidates in accordance with the FDA's cGMP regulations for use in our clinical trials. The manufacture of pharmaceuticals is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control. Replacement of any of our CMOs would require us to qualify new manufacturers and negotiate and execute contractual agreements with them. If any of our supply or service agreements with our CMOs are terminated, we will experience delays and additional expenses in the completion of the development of and obtaining regulatory approval for linzagolix, nolasiban and OBE022.

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

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

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

Competition

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

With respect to linzagolix, in 2018 the first compound from the oral gonadotropin-releasing hormone, or GnRH, receptor antagonist class received regulatory approval in the United States for the treatment of pain associated with endometriosis. AbbVie Inc. has been commercializing elagolix, brand named Orilissa, in the United States since August 2018, and has publicly stated intentions to submit a regulatory application for the uterine fibroids associated with heavy menstrual bleeding indication in 2019. We are aware of one other oral GnRH receptor antagonist product candidate being developed in Phase 3 clinical trials for the endometriosis and uterine fibroids indications, relugolix from Myovant Sciences, Inc. We also anticipate competing with GnRH receptor agonists, including Lupron (leuprolide acetate), marketed by AbbVie Inc. and Takeda Pharmaceuticals, Visanne (dienogest), which is approved for the treatment of endometriosis outside the United States and is marketed by Bayer. Ulipristal acetate, a Selective Progesterone Receptor Modulator (or SPRM) which is approved for the treatment of moderate-to-severe symptoms of uterine fibroids outside the United States and is marketed by Gedeon Richter in Europe and other regions, and by Allergan in Canada. Ulipristal acetate experienced severe label restrictions regarding usage in 2018 due to post marketing liver safety issues. Allergan had submitted an NDA for ulipristal acetate but disclosed receipt of a complete response letter (CRL) from the FDA in August 2018 indicating that the NDA was not approvable in its current form and requesting additional information. Recently, Bayer Schering which was conducting an exhaustive clinical development program for Vilaprisan for the treatment of uterine fibroids and endometriosis, announced that it would be stopping its development activities. In addition, oral contraceptives and nonsteroidal anti-inflammatory drugs, or NSAIDs, are routinely used as a first-line therapy for the treatment of symptoms associated with endometriosis and uterine fibroids and have a meaningful success rate at mitigating the symptoms associated with these conditions.

With respect to 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.

With respect to OBE022, 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 OBE022 given their different mechanisms of action. In terms of clinical development, it is our understanding that GlaxoSmithKline terminated the in-house development of retosiban, an oxytocin receptor antagonist, designed to delay preterm birth. Currently available prostaglandin synthesis inhibitors, such as NSAIDs may also represent competitive therapies, some of which may be used off-label as standard of care, despite risk of serious side effects for the neonates. Makena, which is registered in the USA for preventing preterm delivery in high risk patients is seen as a complement rather than a competitor for OBE022, due to its mechanism of action and regime of administration (bi-weekly administration to be initiated between week 16 and 20 of gestation).

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

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than linzagolix, nolasiban or OBE022 or any other product candidate that we may develop. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market. Any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful.

In addition, established biopharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make linzagolix, nolasiban, OBE022 or any of our future product candidates less competitive.

Intellectual Property

We have filed numerous patent applications and have licensed numerous issued patents and patent applications pertaining to our product candidates and methods of manufacture and clinical use. We strive to protect and enhance the proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining and defending our intellectual property, whether developed internally or licensed from third parties. For additional information regarding the license agreements to which we are a party, see the sections entitled "2013 License Agreement with Merck Serono," "2015 License Agreement with Merck Serono" and "License and Supply Agreement with Kissei." We also rely on trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop, strengthen and maintain our proprietary position in the field of reproductive healthcare. Additionally, we intend to rely on regulatory protection afforded through data exclusivity and market exclusivity, as well as patent term extensions, where available.

As of December 31, 2018, our patent portfolio as it pertains to certain of our product candidates included:

- four United States (U.S.) patents, projected to expire between 2034 and 2035, three 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;
- one international (PCT) application, which, if granted in the U.S., projects to expire in 2037, directed to compositions of matter containing nolasiban and uses of nolasiban in assisted reproductive technology;
- two U.S. patent applications, which, if granted, project to expire between 2037 and 2039, as well as corresponding patent applications internationally, directed to compositions of matter containing OBE022 and uses of OBE022 for the treatment of preterm labor;
- two U.S. patent applications, which, if granted, project to expire in 2039, directed to uses of linzagolix for the treatment of sex hormone-dependent diseases; and
- two PCT applications, which, if granted in the U.S., project to expire in 2038, directed to uses of linzagolix for the treatment of endometriosis and uterine fibroids

As of December 31, 2018, our in-licensed patent portfolio as it pertains to certain of our product candidates included:

- one U.S. patent, projected to expire in 2023, as well as corresponding patents and patent applications internationally, directed to nolasiban as a composition of matter;
- three U.S. patents, projected to expire between 2024 and 2036, one U.S. patent application, which, if granted, projects to expire in 2036, as well as corresponding patents and patent applications internationally, directed to OBE022 as a composition of matter and uses of OBE022 for the treatment of preterm labor; and
- three U.S. patents, projected to expire between 2030 and 2032, one U.S. patent application, which, if granted, projects to expire in 2031, as well as corresponding patents and patent applications internationally outside of specified Asian countries, directed to linzagolix as a composition of matter and uses of linzagolix for the treatment of sex hormone-dependent diseases.

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

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

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

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

2013 License Agreement with Merck Serono

In August 2013, we entered into a license agreement, or the 2013 license agreement, with Merck Serono, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including nolasiban, which we are developing for the treatment of conditions associated with ART. In consideration for the license, we issued 914,069 Series A preferred shares to Merck Serono at the time of our Series A financing, which had a fair-value of USD 4.9 million. With respect to any products we commercialize under the 2013 license agreement, we have agreed to pay Merck Serono quarterly royalties based on our annual net sales of each product at a high-single-digit percentage of annual net sales, subject to specified reductions, until the later of the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis, or ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

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

2015 License Agreement with Merck Serono

In June 2015, we entered into a second license agreement with Merck Serono, or the 2015 license agreement, which we amended in July 2016, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including OBE022, which we are developing for the treatment of preterm labor in weeks 24 to 34 of pregnancy. In consideration for the license, we agreed to issue 325,000 Series A preferred shares to Merck Serono upon the initiation of a Phase 1 clinical trial for a licensed product. With respect to any products we commercialize under the 2015 license agreement, we have agreed to pay Merck Serono quarterly royalties based on our annual net sales of each product at a mid-single-digit percentage of annual net sales, subject to specified reductions, until the later of the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

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

License and Supply Agreement with Kissei

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

In consideration for the license, we made an initial USD 10.0 million upfront payment. We also made a payment of USD 5.0 million to Kissei in 2017 related to our commencement of the PRIMROSE Phase 3 clinical trials in the uterine fibroid indication. In addition, we have agreed to make additional aggregate milestone payments of up to USD 58.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. With respect to any Product we commercialize under the Kissei license and supply agreement, we have agreed to make additional aggregate milestone payments of up to USD 125.0 million to Kissei upon the achievement of specified commercial milestones.

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

We are solely responsible, at our expense, for the development and commercialization of the Product candidates licensed under the Kissei license and supply agreement in the licensed territory. Kissei has the responsibility to maintain and prosecute the licensed patent rights in the licensed territory and we have the right to enforce any of them in the event that Kissei abandons it. The Kissei license and supply agreement terminates on the date of expiration of all royalty obligations, unless we elect to continue to purchase the Compound from Kissei after the expiration of all royalty obligations. Either party may terminate the Kissei license and supply agreement earlier for an uncured breach, subject to notice requirements and specified exceptions, including that Kissei has the option to convert the exclusive licenses granted to us to non-exclusive if we breach the agreement and fail to cure within a specified time period. We may also terminate the agreement for scientific, commercial, strategic or intellectual property reasons at any time upon advance written notice to Kissei. Kissei may also terminate the agreement if we do not fulfill certain development-related obligations for a specified period of time, or if, in connection with a change of control by us, we do not fulfill certain diligence obligations for a specified period of time. Further, under the

terms of the Kissei license and supply agreement, Kissei is obligated to have a backup supplier based on the pharmaceutical industry standard. We may only gain the right to obtain an alternative source of the supply of linzagolix upon Kissei failing to deliver a substantial percentage of the requested supply, delivering the supply late or delivering the supply of linzagolix in nonconforming manner; provided that Kissei has a specified period of time to cure any of these defects. In the event that Kissei failed to deliver a substantial percentage of requested supply of linzagolix, we may gain the right to obtain an alternative source of supply. Further, we and Kissei are each obligated to maintain a specified percentage of supply in excess of the estimate for yearly requirements that we submit to Kissei.

Government Regulation

FDA Drug Approval Process

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

Approval Process

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

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

- completion of extensive preclinical laboratory tests, animal studies and CMC studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin. The sponsor must update the IND annually;
- approval of the study by an IRB or ethics committee at each site before the study begins;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the drug for each proposed indication to the FDA's satisfaction;
- submission to the FDA of an NDA after completion of all clinical trials;
- potential review of the drug application by an FDA advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the products 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; as well as
- under protocols detailing the objectives of the trial, the safety monitoring parameters, and the effectiveness criteria to be evaluated.

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

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

Phase 2. The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy. Phase 2 trials may be denoted as Phase 2a, wherein initial dose-response relationship is explored, and Phase 2b, wherein dose ranging and proof-of-concept is targeted.

Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for labeling and product approval.

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

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

Submission of an NDA

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

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

The FDA has 60 days from its receipt of an NDA to determine whether it will accept the application for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. Once the FDA accepts the filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Under the Prescription Drug User Fee Act, the FDA has a goal of responding to standard review NDAs within ten months after the 60-day filing review period, but this timeframe is often extended. The FDA reviews most applications for standard review drugs within ten to 12 months and most applications for priority review drugs within six to eight months. 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 an REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for REMS can materially affect the potential market and profitability of the drug. Moreover, the FDA may condition approval on substantial post-approval testing and surveillance to monitor the drug's safety or efficacy.

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

Post-approval Requirements

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

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

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

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

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

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

Healthcare Reform

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

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

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two 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 January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018, or the BBA,

among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA 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 2027 unless additional Congressional action is taken.

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

At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While a number of any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a prescription drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

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. CMS may develop new payment and delivery models, such as bundled payment models. For example, the HHS moved 30% of Medicare payments to alternative payment models tied to the quality or value of services in 2016. Additionally, HHS set a goal of moving 50% of Medicare payments into these alternative payments by the end of 2018, but due a policy shift under the Trump administration, it is unclear how and when such changes will be implemented.

In the European Community, governments influence the price of products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

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

Sales and Marketing

Numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or 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, limited statutory exceptions and regulatory safe harbors, and the scarcity of guidance in the form of regulations, agency advisory opinions, sub-regulatory guidance and judicial decisions addressing industry practices, 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 fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement, individual 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 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 to on pricing and marketing information and impose registration requirements on salespersons within the jurisdiction. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources. Some states maintain anti-kickback and false claims laws that apply to claims involving healthcare items or services reimbursed by any third-party payor, including private insurers. We may also be subject to state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Many of these state laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs.

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

Foreign Regulation

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction 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 EMA issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human products that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; and officially designated orphan drugs. For products that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA as long as the product concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National Authorization Procedures

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

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

Good Manufacturing Practices

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

Data and Market Exclusivity

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

Financial Review

Financial Review

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

We are developing linzagolix as a novel, oral gonadotropin releasing hormone, or GnRH, receptor antagonist, for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids in pre-menopausal women. Aimed at addressing the need of the largest possible population in each indication, our clinical trials for both of these indications are designed to assess and potentially support the registration of two regimens of administrations for linzagolix i.e. (i) a moderate dose of linzagolix without hormonal add-back therapy and (ii) a high dose of linzagolix with hormonal add-back therapy.

In 2018 we completed a 24-week treatment of 330-patient multiple-dose, placebo-controlled Phase 2b EDELWEISS clinical trial of linzagolix in endometriosis patients across 70 sites in the United States and 15 sites in Central and Eastern Europe. We are currently conducting a 6-month treatment extension phase of the EDELWEISS clinical trial which we expect to complete in the first half of 2019. In June 2018, we announced that the EDELWEISS clinical trial successfully met its primary endpoint, a statistically significant increase in patient response rate vs. placebo following 12 weeks of treatment. In September 2018, we announced positive 24-week treatment results from the EDELWEISS clinical trial, including bone mineral density (BMD) safety assessments. We believe the BMD results support our plan to pursue further development of two doses of linzagolix for the treatment of endometriosis, including a 75 mg once daily dose without low dose ABT, and a 200 mg once daily dose in combination with low dose ABT. We met with the FDA for an End of Phase 2 meeting in December 2018 to discuss the design of our planned two pivotal Phase 3 clinical trials (EDELWEISS 2 and EDELWEISS 3). Based on the feedback and meeting minutes received from the FDA, we plan to commence this trial program in the first quarter of 2019.

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

We are also developing nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing in-vitro fertilization, or IVF. We completed randomization of 778 patients in our European Phase 3 clinical trial in women undergoing IVF, or the IMPLANT 2 clinical trial, in 2017 and reported positive results for the primary endpoint of ongoing pregnancy 10 weeks post embryo transfer in February 2018, and positive live birth rate results in October 2018. Nolasiban was observed to be well tolerated with a safety profile not different from placebo. 28-day neonatal safety data from the IMPLANT 2 trial did not reveal any adverse consequences from nolasiban treatment, and 6-month infant follow-up data is expected in the second quarter of 2019.

Based on feedback received in the third quarter of 2018 from regulatory authorities in Europe on our nolasiban development program, we initiated in late November 2018 an additional Phase 3 trial primarily in European, Canadian and CIS or Russian centers, or the IMPLANT 4 trial. Patients are being randomized and the IMPLANT 4 primary endpoint readout (10-week ongoing pregnancy results) is expected to support the filing of a Marketing Authorization Application (MAA) in Europe being planned for late 2019.

In addition, we are developing OBE022, an oral and selective prostaglandin F2α receptor antagonist, for preterm labor in weeks 24 to 34 of pregnancy. In December 2017, we announced the initiation of our Phase 2a proof-of-concept clinical trial of OBE022 known as PROLONG which is being conducted in two parts: Part A and Part B. Part A is an open-label trial assessing the safety and pharmacokinetics of OBE022 in pregnant women, who were already receiving standard of care therapy for preterm labour, atosiban infusion. Part B, is a randomized, double-blind, placebo-controlled, parallel-group trial to assess the efficacy, safety and pharmacokinetics of OBE022. In December 2018, following completion of the open-label Part A and based on the favorable safety and pharmacokinetics results, we announced the initiation of the randomized placebo-controlled Part B of the trial. Part B will enroll up to 120 women at 24-34 weeks gestation who are experiencing preterm labor symptom. We expect initial interim efficacy results to be available in the first 30 patients in the first half of 2019.

We were founded in November 2012 and our operations to date have included organizing and staffing our company, raising capital, in-licensing rights to linzagolix, nolasiban and OBE022 and conducting nonclinical studies and clinical trials. To date, we have not generated any revenue from product sales as none of our product candidates have been approved for commercialization. We have historically financed our operations exclusively through the sale of equity. To date, we have raised an aggregate of USD 330.5 million of net proceeds, including USD 88.5 million of net proceeds from our initial public offering in January 2017, USD 56.3 million of net proceeds from our private placement with institutional investors in October 2017, and USD 72.4 million in net proceeds from our underwritten public offering in June 2018. In addition, during 2018, we sold treasury shares from its "at the market" (ATM) program, generating net proceeds of USD 19.4 million.

We have never been profitable and have incurred significant net losses in each period since our inception. Our net losses were USD 76.7 million, USD 66.9 million, and USD 30.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had accumulated losses of USD 214.5 million, out of which USD 30.6 million were offset with share premium. This reclassification transaction had no impact on total equity. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We used USD 63.9 million and USD 55.7 million of cash in operations in 2018 and 2017, respectively, and we anticipate that our expenses will continue to increase significantly in connection with our ongoing activities as we:

- continue to invest in the clinical development of our product candidates and specifically in connection with our ongoing EDELWEISS, PRIMROSE 1 and 2, IMPLANT 2, IMPLANT 4 and PROLONG clinical trials, and any additional clinical trials, nonclinical studies and pre-commercial activities that we may conduct for product candidates;
- hire additional research and development, and general and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- identify and in-license or acquire additional product candidates; and
- continue to incur additional costs associated with operating as a public company.

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

We have no manufacturing facilities, and all of our manufacturing activities are contracted out to third parties. We currently utilize third-party contract research organizations, or CROs, to carry out our clinical development and trials. Additionally, we do not yet have a commercialization organization.

Strategic Licensing Agreements

Linzagolix

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

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

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

Nolasiban

In August 2013, we entered into the 2013 license agreement with Ares Trading S.A., an affiliate of Merck Serono, or Merck Serono, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including nolasiban. In consideration for the license, we issued 914,069 Series A preferred shares to Merck Serono at the time of our Series A financing, which had a fair-value of USD 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.

OBE022

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

Components of Results of Operations

Revenue

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

Operating Expenses

Research and Development Expenses

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

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

From inception through December 31, 2018, we have incurred USD 172.6 million in research and development expenses to advance the development of our product candidates. The following table provides a breakdown of our outsourced research and development expenses that are directly attributable to the specified product candidates for the years ended December 31, 2018, 2017 and 2016, respectively.

	Year Ended December 31,		
	2018	**2017**	**2016**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Linzagolix	(39,315)	(32,166)	(9,689)
Nolasiban	(7,515)	(8,873)	(2,873)
OBE022	(2,502)	(2,178)	(4,103)
Total outsourced research and development expenses	**(49,332)**	**(43,217)**	**(16,665)**

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

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

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

General and Administrative Expenses

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

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

Finance Result, Net

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

Taxation

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

In 2015, the Canton of Geneva granted us a ten-year tax holiday for all income and capital taxes on a communal and cantonal level commencing in fiscal year 2013 and valid through to 2022, subject to our Swiss domiciliation and compliance with certain reporting provisions. We remain subject to Swiss federal income tax on our profits after tax but have only incurred net losses since our inception. We are entitled under Swiss laws to carry forward any losses incurred for a period of seven years and can offset such losses carried forward against future taxes. As of December 31, 2018, we had tax loss carryforwards totaling USD 184.2 million. We do not believe it is probable that we will generate sufficient profits to avail ourselves of these tax loss carryforwards.

Our Irish subsidiary had no activity in 2017 and 2018 and our U.S. subsidiary, as a service organization to the group under cost plus arrangement, was the only entity to generate income tax expenses for the year ended December 31, 2018.

A. Operating Results

Analysis of Results of Operations

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

	Year Ended December 31,		
	2018	**2017**	**2016**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Consolidated Statements of Operations Data:			
Operating income other than revenue	15	16	22
Operating expenses:			
Research and development expenses	(62,872)	(54,912)	(23,711)
General and administrative expenses	(14,297)	(12,568)	(6,452)
Total operating expenses	(77,169)	(67,480)	(30,163)
Finance result, net	393	589	(61)
Income tax benefit / (expense)	45	(51)	–
Net loss	**(76,716)**	**(66,926)**	**(30,202)**

Years Ended December 31, 2018 and 2017

Operating Expenses

Research and Development Expenses

	Year Ended December 31,	
	2018	**2017**
(unaudited)	(in USD ,000)	(in USD ,000)
Research and development expenses by product candidate		
Linzagolix	(39,315)	(32,166)
Nolasiban	(7,515)	(8,873)
OBE022	(2,502)	(2,178)
Unallocated expenses		
Staff costs	(11,001)	(9,950)
Other research and development costs	(2,539)	(1,745)
Total research and development expenses	**(62,872)**	**(54,912)**

Research and development expenses increased by USD 8.0 million in 2018 compared to 2017 primarily due to the increased costs of USD 7.2 million resulting primarily from the ramp up of our PRIMROSE 1 and 2 clinical trials with linzagolix, and increased staff costs of USD 1.0 million associated with increased headcount, partially offset by decreased costs of USD 1.4 million for nolasiban primarily due to the completion in 2018 of our IMPLANT 2 study. Other research and development costs also contributed to the overall increase, primarily due to patent costs that were USD 0.6 million higher in 2018 compared to 2017.

General and Administrative Expenses

	Year Ended December 31,	
	2018	2017
(unaudited)	(in USD ,000)	(in USD ,000)
Staff costs	(8,536)	(8,049)
Professional fees	(3,739)	(2,793)
Other general and administrative costs	(2,022)	(1,726)
Total general and administrative expenses	**(14,297)**	**(12,568)**

General and administrative expenses increased by USD 1.7 million in 2018 compared to 2017 primarily due to increased staff costs of USD 0.5 million associated with increased headcount, and increased professional fees of USD 0.9 million resulting from our financings completed in 2018, our Swiss listing completed in July 2018, as well as increased efforts in communication and advertising.

Finance Result, Net

	Year Ended December 31,	
	2018	2017
	(in USD ,000)	(in USD ,000)
Finance result, net	393	589

Finance result, net, in 2018 and 2017 primarily consisted of foreign exchange gains and losses.

Years Ended December 31, 2017 and 2016

Operating Expenses

Research and Development Expenses

	Year Ended December 31,	
	2017	2016
(unaudited)	(in USD ,000)	(in USD ,000)
Research and development expenses by product candidate		
Linzagolix	(32,166)	(9,689)
Nolasiban	(8,873)	(2,873)
OBE022	(2,178)	(4,103)
Unallocated expenses		
Staff costs	(9,950)	(5,520)
)Other research and development costs	(1,745)	(1,526)
Total research and development expenses	**(54,912)**	**(23,711)**

Research and development expenses increased by USD 31.2 million in 2017 compared to 2016 primarily due to the increased costs of USD 22.5 million resulting primarily from our ongoing PRIMROSE 1 and 2 and EDELWEISS clinical trials with linzagolix, the increased costs of USD 6.0 million resulting from our ongoing IMPLANT 2 clinical trial with nolasiban and increased staff costs of USD 4.4 million associated with increased headcount, including a USD 2.3 million increase of share-based compensation, partially offset by decreased costs of USD 1.9 million primarily due to our Phase 1 clinical trials with OBE022.

General and Administrative Expenses

	Year Ended December 31,	
	2017	**2016**
(unaudited)	(in USD ,000)	(in USD ,000)
Staff costs	(8,049)	(1,916)
Professional fees	(2,793)	(3,959)
Other general and administrative costs	(1,726)	(577)
Total general and administrative expenses	**(12,568)**	**(6,452)**

General and administrative expenses increased by USD 6.1 million in 2017 compared to 2016 primarily due to increased staff costs of USD 6.1 million associated with increased headcount, including a USD 4.3 million increase of share-based compensation, and increased costs of USD 1.1 million resulting from other general and administrative expenses associated with operating as a public company, which were partially offset by decreased professional fees of USD 1.2 million due to fees associated with the preparation of our initial public offering in late 2016.

Finance Result, Net

	Year Ended December 31,	
	2018	**2017**
	(in USD ,000)	(in USD ,000)
Finance result, net	589	(61)

Finance result, net, in 2017 and 2016 primarily consisted of foreign exchange losses.

B. Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. We have funded our operations primarily through the sale of equity. From inception through December 31, 2018, we have raised an aggregate of USD 330.5 million of net proceeds from the sale of equity securities. In January 2017, we completed our initial public offering of 6,450,000 common shares at a public offering price of USD 15.00 per share. We received USD 88.5 million in net proceeds after deducting USD 8.3 million of underwriting discounts and commissions and other offering expenses. Additionally, in October 2017, we raised USD 56.3 million of net proceeds after deducting USD 3.7 million of placement expenses through the issuance of 7,500,000 shares at a price of USD 8.00 per share in a private placement with institutional investors.

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

In June 2018, we completed an underwritten public offering of common shares and issued 4,750,000 shares at a price of USD 15.39 per share, raising USD 68.0 million in net proceeds after deducting USD 5.1 million of underwriting discounts, commissions and other offering expenses. In July 2018, we raised additional funds for net proceeds of USD 4.4 million from the exercise of the option available to the underwriters in connection with the June 2018 offering. As of December 31, 2018, we had USD 138.6 million in cash and cash equivalents.

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

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

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

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

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

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

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

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

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

The following table shows a summary of our cash flows for the periods indicated:

	Year Ended December 31,		
	2018	**2017**	**2016**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Cash and cash equivalents at beginning of period	110,841	25,508	54,275
Net cash used in operating activities	(63,941)	(55,715)	(28,589)
Net cash used in investing activities	(271)	(5,285)	(45)
Net cash from / (used in) financing activities	91,652	145,743	(167)
Effect of exchange rates	359	590	34
Cash and cash equivalents at end of period	138,640	110,841	25,508

Operating Activities

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

During the year ended December 31, 2018, USD 63.9 million of cash was used for operating activities, primarily as the result of our net loss before tax of USD 76.8 million, as adjusted for non-cash items and changes in net working capital. Non-cash items amounted to USD 8.8 million and mainly consisted of share-based payments. Changes in net working capital included primarily a USD 8.4 million increase in accrued expenses, primarily due to the progress in our PRIMROSE 1 and 2 clinical trials (including the cost of supplies), as well as a USD 4.3 million increase in prepaid expenses, mainly attributable to upfront payments made in relation to our Phase 3 EDELWEISS 2 and 3 clinical trials announced late 2018.

During the year ended December 31, 2017, USD 55.7 million of cash was used for operating activities, primarily as the result of our net loss before tax of USD 66.9 million, as adjusted for non-cash items and changes in net working capital. Non-cash items amounted to USD 8.3 million and mainly consisted of share-based payments. Changes in net working capital included primarily a USD 1.7 million increase in accrued expenses, primarily due to the costs of our clinical trial supplies for our PRIMROSE 1 and 2 and EDELWEISS clinical trials, as well as a USD 0.7 million decrease in prepaid expenses, mainly attributable to upfront payments made in relation to our PRIMROSE 1 and 2 clinical trials during 2016.

During the year ended December 31, 2016, USD 28.6 million of cash was used for operating activities, primarily as the result of our net loss before tax of USD 30.2 million, as adjusted for non-cash items and changes in net working capital. Non-cash items amounted to USD 2.0 million and mainly consisted of share-based payments. Changes in net working capital included primarily a USD 2.0 million increase in prepaid expenses, primarily due to upfront payments made in relation to our PRIMROSE 1 and 2 clinical trials in uterine fibroids, as well as a USD 1.8 million increase in other payables and current liabilities mainly attributable to our ongoing EDELWEISS clinical trial of linzagolix in endometriosis and Phase 1 clinical trials of OBE022 during 2016.

Investing Activities

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

During 2018, net cash used in investing activities consisted primarily of USD 0.2 million in purchases of furniture and fixtures for our offices in Switzerland and the United States.

During 2017, net cash used in investing activities consisted primarily of a USD 5.0 million milestone payment to Kissei made upon initiation of the Phase 3 clinical program for linzagolix in uterine fibroids, as well as payments made for leasehold improvements and furniture for the opening of our office in the United States. Net cash used in investing activities in 2016, consisted primarily of purchase of furniture and fixtures for our office in Switzerland.

Financing Activities

Net cash from financing activities consists primarily of proceeds from the sale of equity securities.

Cash flows from financing activities in 2018 mainly consisted of the net proceeds from our underwritten public offering completed in June 2018 and our "at the market" (ATM) program, which we established in May 2018. Cash flows from financing activities in 2017 consisted mainly of the net proceeds from our initial public offering in January 2017 and from our private placement with institutional investors in October 2017. Cash flows used in financing activities in 2016 mainly consisted of payments for costs incurred in connection with our initial public offering and related issuance of new shares.

C. Research and Development

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

D. Trend Information

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

E. Off-Balance Sheet Arrangements

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

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2018:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)
Operating leases	705	1,421	948	–	3,074
Total	**705**	**1,421**	**948**	**–**	**3,074**

Under our license agreements with Kissei and Merck Serono, we may be required to pay royalties in the future. In addition, pursuant to the Kissei license and supply agreement, we have agreed to make aggregate milestone payments of up to USD 63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals, of which we had paid USD 5.0 million as of December 31, 2018. With respect to any product we commercialize under the Kissei license and supply agreement, we have agreed to make additional aggregate milestone payments of up to USD 125.0 million to Kissei upon the achievement of specified commercial milestones.

We have not included any contingent payment obligation, such as milestone payments and royalties, in the table above as the amount, timing and likelihood of such payments are not known.

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

Corporate Governance

Corporate Governance

ObsEva's articles of association (the "Articles"), organizational regulations (the "Organizational Regulations") and policies provide the basis for the principles of Corporate Governance. This Corporate Governance report has been prepared in accordance with the SIX Swiss Exchange Directive on Information Related to Corporate Governance effective as of October 1, 2014, as amended on April 1, 2016, July 1, 2017 and May 1, 2018.

1 – Group Structure and Shareholders.

Group Structure

ObsEva SA ("ObsEva", or the "Company") is a Swiss stock corporation (société anonyme) organized under the laws of Switzerland (CHE-253.914.856) and formed in 2012 with an indefinite duration. ObsEva is registered in Plan-les-Ouates, Geneva, Switzerland, with principal offices located at Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland.

ObsEva is the holding company of the ObsEva Group (the "Group") which includes two fully-owned subsidiaries:

- ObsEva USA, Inc, a limited company registered in Delaware, USA, with principal registered offices located at One Financial Center, 24th Floor, Boston MA 02111, USA, and a share capital of USD 0.50 fully-owned by ObsEva, and

- ObsEva Ireland Ltd, a limited company registered in Ireland, with principal registered offices located at Penthouse Floor, 5 Lapps Quay, Cork, Ireland, and a share capital of EUR 2.00 fully-owned by ObsEva.

The Group operates in one segment, which is the research and development of innovative women's reproductive, health and pregnancy therapeutics, with an aim to market and commercialize such therapeutics depending on, in large part, the success of the development phases. The Chief Executive Officer ("CEO") of the Company reviews the consolidated statement of operations of the Group on an aggregated basis and manages the operations of the Group as a single operating segment.

ObsEva's shares have been listed on the Nasdaq Global Select Market ("Nasdaq") since January 26, 2017 under the ticker symbol OBSV and the CUSIP number H5861P103, and on the SIX Swiss Exchange ("SIX") since July 13, 2018 under the ticker symbol OBSN, the ISIN number CH0346177709 and Swiss security number 34'617'770. On December 31, 2018, the market capitalization of ObsEva was USD 575,740,554 on the Nasdaq and CHF 570,738,069 on the SIX.

Significant Shareholders

As of December 31, 2018, based on published notifications to the SIX (unless otherwise indicated), the following shareholders own 3% or more of the Company's share capital:

Shareholder	Number of shares held [1]	% of voting rights [2]	% of capital [2]
Sofinnova Investments [3]	4,749,623	10.5%	10.5%
New Enterprise Associates 15 L.P.	4,586,563	10.1%	10.1%
Venrock Healthcare Capital Partners [4]	3,412,249	7.5%	7.5%
Ernest Loumaye [5]	3,063,098	6.8%	6.8%
OrbiMed Advisors LLC	2,605,531	5.7%	5.7%
Sofinnova Partners	1,846,649	4.1%	4.1%
FMR LLC [6]	1,800,105	4.0%	4.0%
ObsEva	1,602,601	3.5%	3.5%
Medicxi Ventures Management (Jersey) Limited	1,570,000	3.5%	3.5%
Wellington Management Group LLP	1,539,017	3.4%	3.4%
Select Biotechnology Portfolio	1,516,805	3.3%	3.3%
First Manhattan Co.	1,508,966	3.3%	3.3%
Aisling Capital [7]	1,394,838	3.1%	3.1%
HBM Healthcare Investments AG [8]	1,386,598	3.1%	3.1%

(1) This table presents the shares held by the shareholders listed therein, or in respect of which the persons or entities mentioned have been granted voting discretion. The derivative holdings held by such shareholders are not included.

(2) Based on the share capital registered in the Swiss Commercial Register as of December 31, 2018 (i.e. CHF 3,490,865 and 7/13th of a franc, divided into 45,381,252 registered shares).

(3) Beneficial owners of shares reported under Sofinnova Investments are Dr. Anand Mehra, Dr. James I. Healy and Dr. Michael F. Powell, which are acting in concert and form an organized group within the meaning of Article 121 of the Swiss Financial Market Infrastructure Act ("FMIA") pursuant to a shareholders' agreement.

(4) Beneficial owners of shares reported under Venrock Healthcare Capital Partners are Mr. Bong Koh and Mr. Nimish Shah, which are acting in concert and form an organized group within the meaning of Article 121 FMIA pursuant to fund agreements.

(5) According to the Company's share register, Dr. Ernest Loumaye held 3,063,098 shares, or 6.8% of the Company's share capital and voting rights, as of December 31, 2018.

(6) The positions held by FMR LLC are positions of third parties over which FMR LLC has the discretion to exercise the voting rights pursuant to Article 120 para. 3 FMIA. The positions are disclosed by the entity that decides how voting rights are exercised (and not on a consolidated basis within the meaning of Article 10 para. 2 sentences 2 and 3 FMIO-FINMA).

(7) Beneficial owners of shares reported under Aisling Capital are Dr. Drew Schiff and Mr. Steve Elms, which are acting in concert and form an organized group within the meaning of Article 121 FMIA pursuant to a shareholders agreement.

(8) According to a Schedule 13 G filed with the United Stated Securities and Exchange Commission ("SEC") on February 14, 2019, HBM Healthcare Investments AG held 1,386,598 shares, or 3.1% of the Company's share capital and voting rights, as of December 31, 2018.

For a comprehensive list of notifications of shareholdings received during 2018 pursuant to article 120 and seq. FMIA and its implementing ordinances, refer to the SIX website (https://www.six-exchange-regulation.com/en/home/publications/significant-shareholders.html).

Cross Shareholdings
There are no cross-shareholdings in terms of capital or voting rights in excess of 5%.

2 – Capital Structure.

Capital
As of December 31, 2018, the Company's share capital registered with the Swiss Commercial Register amounted to CHF 3,490,865 and 7/13th of a franc, consisting of 45,381,252 registered shares (or "common shares") with a par value of 1/13th of a Swiss franc each, and the issued share capital amounted to CHF 3,498,241 and 4/13th of a franc, consisting of 45,477,137 common shares with a par value of 1/13th of a Swiss franc each. As of December 31, 2018, the Company directly held 1,602,601 of its own shares, recorded as treasury shares.

Authorized Share Capital
As of December 31, 2018, according to the Articles, the Board of Directors (the "Board") is authorized at any time until May 9, 2020 to increase the share capital by a maximum aggregate amount of CHF 1,197,355 and 5/13th of a franc, which equates to approximately 34% of the existing share capital, through the issuance of not more than 15,565,620 common shares, which will have to be fully paid-in, with a par value of 1/13th of a Swiss franc each. Increases in partial amounts are permitted. The Board may issue new shares also by means of underwriting or in any other manner by one or more banks and subsequent offer to shareholders or third parties. The Board determines the type of contributions, the issue price, the time of the issue, the conditions for the exercise of the pre-emptive rights, the allocation of pre-emptive rights which have not been exercised, and the date on which the dividend entitlement starts. The Board is authorized to permit, to restrict or to exclude the trading of pre-emptive rights.

If pre-emptive rights are granted, but not exercised, the Board shall use the relevant shares in the interest of the Company.

The Board is authorized to withdraw or limit the pre-emptive rights of the shareholders, and to allocate them to third parties or to the Company, in the event of use of the shares for the purpose of: (i) expanding the shareholder base in certain capital markets or in the context of the listing, admission to official trading or registration of the shares at domestic or international stock exchanges; (ii) granting an over-allotment option ("greenshoe") to one or several underwriters in connection with a placement of shares; (iii) share placements, provided the issue price is determined by reference to market price; (iv) the participation of employees, members of the Board or consultant of the Company or of one of its subsidiaries according to one or several equity incentive plans adopted by the Board; (v) the acquisition of companies, company assets, participations, the acquisition of products, intellectual property rights, licenses or new investment projects or for public or private share placements for the financing and/or refinancing of such transactions; (vi) for raising equity capital in a fast and flexible manner as such transaction would be difficult to carry out, or could be carried out only at less favorable terms, without the exclusion of the pre-emptive rights of the existing shareholders; or (vii) the acquisition of a participation in the company by a strategic partner (including in the case of a public takeover offer).

Conditional Share Capital for Financing Purposes

As of December 31, 2018, according to the Articles, the Company's share capital may be increased by a maximum aggregate amount of CHF 1,107,154, which equates to approximately 32% of the existing share capital, through the issuance of not more than 14,393,002 common shares, which will have to be fully paid-in, with a par value of 1/13th of a Swiss franc each, by the exercise of option and conversion rights which are granted in connection with bonds, similar debt instruments, loans or other financial market instruments or contractual obligations of the Company or one of its subsidiaries, and/or by the exercise of option rights issued by the Company or one of its subsidiaries (the "Financial Instruments"). The pre-emptive rights of shareholders are excluded. The right to subscribe for the new shares shall be held by the holders of the Financial Instruments. The Board determines the terms of the Financial Instruments.

When issuing Financial Instruments, the Board has the right to limit or exclude the right of shareholders to subscribe for the Financial Instruments by preference: a) for the purpose of financing or refinancing the acquisition of enterprises, divisions thereof, or of participations, products, intellectual property rights, licenses, cooperations or of newly planned investments of the Company; b) if the issuance is made on domestic or international capital markets, including by means of private placements; or c) for purposes of an underwriting of the Financial Instruments by a banking institution or a consortium of banks with subsequent offering to the public.

To the extent that the right of shareholders to subscribe for the Financial Instruments by preference is excluded, (i) the Financial Instruments shall be placed at market conditions; (ii) the exercise period, the conversion period or the exchange period of the Financial Instruments shall not exceed 10 years as of the date of the issue; and (iii) the conversion price, the exchange price or other exercise price of the Financial Instruments shall be determined by reference to market prices.

Conditional Share Capital for Equity Plans

As of December 31, 2018, according to the Articles, the Company's share capital may be increased by a maximum aggregate amount of CHF 455,586, which equates to approximately 13% of the existing share capital, through the issuance of not more than 5,922,618 common shares, which will have to be fully paid-in, with a par value of 1/13th of a Swiss franc each, by issuance of shares upon the exercise of options or pre-emptive rights thereof, which have been issued or granted to employees, members of the Board or consultant of the Company or of one of its subsidiaries under the terms of one or more equity incentive plans or regulations adopted by the Board. The pre-emptive rights of shareholders are excluded. The Board determines the terms of the equity incentive plans or regulations and of the issuance of the shares.

Changes in Capital

Before its Initial Public Offering ("IPO") on the Nasdaq in January 2017, the Company had three categories of shares which were common shares, preferred shares and non-voting shares. Effective upon the IPO, the preferred and non-voting shares were converted into common shares. Since then, the Company has had only common shares.

On July 29, 2016 and November 22, 2016, the Company issued 279,500 and 817,492 non-voting shares, respectively, at par value of 1/13th of a Swiss franc per share, from its authorized non-voting share capital, to its employees, members of the Board and consultants under its equity incentive plan.

On September 28, 2016, the Company issued 325,000 preferred shares at par value of 1/13th of a Swiss franc per share. The shares were subscribed by Merck Serono under the terms of a licensing agreement for a product candidate of the Company.

On January 25, 2017, the Company executed its IPO on the Nasdaq and all existing preferred shares and non-voting shares were converted into common shares at a 1 for 1 ratio.

On January 30, 2017, upon completion of the IPO, the Company issued 6,450,000 common shares at a subscription price of USD 15.00 per share and a par value of 1/13th of a Swiss franc per share.

On October 13, 2017, the Company completed a private placement with institutional investors and issued 7,500,000 common shares at a subscription price of USD 8.00 per share and a par value of 1/13th of a Swiss franc per share.

On March 16, 2018, the Company issued 3,499,990 common shares at par value of 1/13th of a Swiss franc per share. The shares were subscribed by the Company and held as treasury shares. On May 17 and 25, 2018, the Company sold 1,000,851 and 600,000 of these treasury shares, respectively, at a price of USD 12.50 per share.

On June 22, 2018, the Company completed an underwritten public offering and issued 4,750,000 common shares at a subscription price of USD 15.39 per share and a par value of 1/13th of a Swiss franc. Subsequent to the initial closing of this follow-on offering and the exercise of an overallotment (i.e. "greenshoe") option granted in this context, the Company issued an additional 306,721 common shares on July 19, 2018, at a subscription price of USD 15.39 per share and a par value of 1/13th of a Swiss franc.

In 2018, 95,885 options granted to employees under equity incentive plans of the Company have been exercised and 95,885 new shares have been issued from the conditional capital for equity plans at par value of 1/13th of a Swiss franc per share. Changes to articles (5) Par Value and Number of Shares and (5c) Conditional Share Capital for Equity Plans in the Articles have not been recorded yet with the Swiss Commercial Register as of the reporting date to reflect these exercises and issuances.

For further information on changes in capital in 2018, 2017 and 2016, including changes in reserves, refer to the consolidated statements of changes in equity as well as to note 11 of the consolidated financial statements on pages 100 and 115, respectively, of this annual report.

Shares and Participation Certificates

ObsEva has one class of shares, which is common shares, i.e. registered shares, with a par value of 1/13th of a Swiss franc per share. Each share is indivisible towards the Company, which only recognizes one legal owner for each share. Each share confers the right to a portion of the profit resulting from the balance sheet and the proceeds of liquidation, in proportion to the payments made to pay-in the share capital. Each share conveys the right to one vote.

The Company's shares are uncertificated securities (in terms of the Swiss Code of Obligations) and intermediated securities (in terms of the Swiss Federal Intermediated Securities Act). Any shareholder registered in the Company's share register may request from the Company a statement his/her common shares at any time. Shareholders are not entitled to request printing and delivery of certificates. However, the Company may, at any time and at its option: (i) print and deliver certificates for shares; (ii) withdraw uncertificated shares from the custodian system where they have been registered; and (iii) with the consent of the shareholder, cancel issued certificates that are returned to the Company. If the Company decides to print and deliver share certificates, the share certificates shall bear the signatures of two duly authorized signatories of the Company, at least one of which shall be member of the Board. These signatures may be facsimile signatures.

The Company has no participation certificates.

Dividend-Right Certificates
The Company has no dividend-right certificates.

Limitations on Transferability and Nominee Registrations
The Articles do not contain clauses limiting the transferability of the Company's shares and do not provide restrictions to the registration of nominee shareholders.

Convertibles Bonds and Options
As of December 31, 2018, the Company has no convertible bonds outstanding, and has 3,028,275 options issued under the Company's equity incentive plans outstanding, corresponding to an amount of CHF 232,944 and 3/13th of a franc of share capital, and equating to approximately 7% of the existing share capital. Such options have a 1:1 subscription ratio, vest under a 3-year or 4-year vesting schedule, have a 10-year expiration term and have a strike price in US Dollars equivalent to the closing share price of OBSV on Nasdaq at grant date. For information on the equity incentive plans operated by the Company and details of grants made and options outstanding as of December 31, 2018, refer to note 18 of the consolidated financial statements on page 122 of this annual report.

3 – Board of Directors.

The following table sets forth the name, nationality, year joined the Board, terms of office, position and directorship term, as well as committee memberships, of each member of the Board, followed by a short description of each member's business experience, education and activities. The directors are appointed individually, for one-year terms, which expire on the occasion of each annual general meeting, and can be re-elected indefinitely. Accordingly, the terms of the directors set forth below will expire at the closing of the 2019 annual general meeting of shareholders. All members of the Board, to the exception of Dr. Ernest Loumaye, Co-Founder and CEO of the Company, are non-executive members. None of these non-executive members have held management roles in the Group in the three financial years preceding the period under review, nor have had significant business connections with any entity of the Group.

Name	Nationality	First Appointment	Board	AC [1]	CNCGC [2]
Frank Verwiel	Dutch	2016	Chair	Member	–
Ernest Loumaye	Belgian	2012	Member, CEO	–	–
Annette Clancy	British	2013	Member	–	Chair
Barbara Duncan	American	2016	Member	Chair	–
Ed Mathers	American	2016	Member	Member	–
Jim Healy	American	2013	Member	–	Member
Rafaèle Tordjman	French	2013	Vice-Chair	–	Member
Jacky Vonderscher	French	2013	Member	–	–

(1) Audit Committee
(2) Compensation, Nominating and Corporate Governance Committee

Frank Verwiel has served as a member of the Board since March 2016 and as its Chairperson since December 2016. Dr. Verwiel was the President and Chief Executive Officer of Aptalis Pharma Inc. from 2005 to 2014, where he also served on the board of directors. He also currently serves as a member of the board of directors of the public companies Achillion Pharmaceuticals, Inc. (since 2015), a pharmaceutical company, Bavarian Nordic A/S (since 2016), a biotechnology company and Intellia Inc. (since 2017), also a biotechnology company. Dr. Verwiel previously served on the board of directors of InterMune, Inc. from 2012 to 2014 and Avexis, Inc., a biotechnology company from 2015 to 2018. Dr. Verwiel was also a director of the Biotechnology Industry Organisation from 2013 to 2014. Dr. Verwiel received his M.D. from Erasmus University, Rotterdam, The Netherlands, and his M.B.A. from INSEAD in Fontainebleau, France.

Ernest Loumaye is a Co-Founder of the Company and has served as its Chief Executive Officer and member of the Board since its inception in November 2012. Previously, Dr. Loumaye co-founded PregLem SA, a Swiss specialty biopharmaceutical company and served as its Chief Executive Officer from 2006 to 2012. Prior to founding PregLem SA, Dr. Loumaye held various senior positions at Ipsen, Paris, and Serono, Geneva and Boston. Dr. Loumaye also served as Chairman of the Swiss biotechnology company GenKyoTex from 2015 to 2016. Dr. Ernest Loumaye holds a M.D. and a Ph.D., with a specialization in Obstetrics and Gynaecology, from Louvain University, Belgium. He was a research fellow at the National Institute of Child Health and Human Development in the US and is the author of over 90 publications in peer-reviewed journals.

Annette Clancy has served as a member of the Board since November 2013 and served as its Chairperson from November 2013 to December 2016. From 2009 to 2017, Ms. Clancy has been a senior advisor at Frazier Healthcare Ventures, a U.S.-based healthcare venture capital firm. Prior to joining Frazier Healthcare Ventures, Ms. Clancy held various senior positions at GlaxoSmithKline, a global healthcare company. Ms. Clancy is currently serving as member of the board of directors of Swedish Orphan Biovitrum AB (since 2014), a public biopharmaceutical company, as well as Chairperson of the Board of Directors of Enyo SA (since 2016) and Lysogene (since 2014), two European Biotech Companies developing innovative therapeutics for severe medical needs. Ms. Clancy also served as member of the boards of directors of Silence Therapeutics (from 2008 to 2012) and Clavis Pharma (from 2010 to 2013), and Chairperson of the board of directors of Genable Therapeutics (from 2013 to 2016). Ms. Clancy holds a B.Sc. in Pharmacology from Bath University and a series of American Management Association diplomas in finance and marketing.

Barbara Duncan has served as a member of the Board since December 2016. From May 2009 through June 2016, Ms. Duncan served as the Chief Financial Officer of Intercept Pharmaceuticals, Inc., a biopharmaceutical company. Prior to joining Intercept Pharmaceuticals, Inc., Ms. Duncan served as the Chief Financial Officer and then Chief Executive Officer of DOV Pharmaceutical, Inc., or DOV, from 2001 to April 2009. Prior to joining DOV, Ms. Duncan served as a vice president of Lehman Brothers Inc. in its corporate finance division from August 1998 to August 2001. From September 1994 to August 1998, Ms. Duncan was an associate and director at SBC Warburg Dillon Read, Inc. in its corporate finance group. Ms. Duncan serves on the board of directors of Aevi Genomic Medicine, Inc. (since 2015), Adaptimmune Therapeutics plc (since 2016), Jounce Therapeutics, Inc. (since 2016) and Ovid Therapeutics Inc. (since 2017), publicly traded biopharmaceutical companies. She also served as member of the board of directors of Edgemont LLC (from 2010 to 2017). Ms. Duncan received her B.S. from Louisiana State University in 1985 and her M.B.A. from the Wharton School, University of Pennsylvania, in 1994.

Ed Mathers has served as a member of the Board since February 2016. Mr. Mathers is a Partner of NEA since August 2008 and is focused on biotechnology and specialty pharmaceuticals investments. He is a director of Liquidia Technologies (Nasdaq: LQDA), Ra Pharmaceuticals (Nasdaq: RARX – Chairman), Rhythm Pharmaceuticals, Envisia Therapeutics, Synlogic (Nasdaq: SYBX), Lumos Pharma, Amplyx Pharmaceuticals, Senti Biosciences, Inozyme, Reneo Pharma, Akouos (since 2017), Trevi Therapeutics and Mirium Pharmaceuticals (since 2018). Previously he was a board member of 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, and the Biotechnology Industry Organization (BIO). 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.

James I. Healy has served as a member of the Board since August 2013. Dr. Healy has been a general partner at Sofinnova Investments, Inc. (previously Sofinnova Ventures, Inc.) since 2000. Prior to this, Dr. Healy held various positions at Bayer Healthcare Pharmaceuticals, Sanderling Ventures, and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Ascendis Pharma A/S (since 2014), Coherus BioSciences, Inc. (since 2014), Iterum Therapeutics (since 2015), Natera, Inc. (since 2014), NuCana plc (since 2014), Y-mAbs Therapeutics (since 2017) and several private companies. Previously, Dr. Healy served as a board member of Amarin Corporation plc (from 2008 to 2016), Anthera Pharmaceuticals (from 2006 to 2014), Auris Medical Holdings AG (from 2013 to 2017), Durata Therapeutics, Inc. (from 2009 to 2012), Edge Therapeutics, Inc. (from 2015 to 2018), Hyperion Therapeutics, Inc. (from 2007 to 2012), InterMune, Inc. (from 1999 to 2014), KaloBios Pharmaceuticals, Inc. (from 2001 to 2014), Movetis NV (from 2006 to 2009) and a number of private companies. Dr. Healy holds a B.A. in Molecular Biology and a B.A. Scandinavian Studies from the University of California at Berkeley, and an M.D. and Ph.D. in Immunology from Stanford University School of Medicine.

Rafaèle Tordjman has served as a member of the Board since August 2013. Dr. Tordjman joined the French based venture capital firm Sofinnova Partners in 2001 until March 2017 where she served as Managing Partner specializing in life sciences investments. Dr. Tordjman serves on the board of directors of the public company Nucana (since 2011), a clinical-stage pharmaceutical company. Dr. Tordjman has also served on the boards of directors at several life sciences companies including, DBV Technologies SA (from 2005 to 2015), a French publicly traded company specializing in allergy therapies, Ascendis Pharma (from 2007 to 2017), Flexion Therapeutics, Inc. (from 2009 to 2015), Lysogene (from 2014 to 2018), publicly traded companies in clinical-stage pharmaceuticals, as well as a private company, and PregLem (from 2006 to 2010), a company that specialized in reproductive female medicine. Previously, Dr. Tordjman was a research scientist at the Institut National de la Santé et de la Recherche Médicale (INSERM) in Cochin Hospital, Paris, France. Dr. Tordjman has also practiced as a medical doctor, specializing in clinical hematology and internal medicine. Dr. Tordjman received an M.D. and completed a fellowship in hematology and internal medicine at the Paris University Hospitals. She received a Ph.D. in hematopoiesis and angiogenesis from and completed a post-doctoral fellowship in immunology at the University of Paris VII.

Jacky Vonderscher has served as a member of the Board since October 2013. Since September 2013, Dr. Vonderscher has served as the Chief Executive Officer of Vonderscher & Co GmbH, a consultancy company, and since January 2014, as the President of ENYO Pharma, a biopharmaceutical company. Dr. Vonderscher has also served as the Chief Executive Officer of ENYO Pharma since July 2016. Prior to joining ENYO Pharma, Dr. Vonderscher served as a Senior Vice President of Hoffmann-La-Roche Ltd from 2008 to December 2013. From 1979 to 2008, Dr. Vonderscher held a variety of senior positions at Novartis Pharma AG. Dr. Vonderscher also serves on the boards of directors of Inatherys SAS (since 2013) and Step Pharma SAS (since 2016). Dr. Vonderscher holds an engineering degree in Biological Chemistry from the National Institute of Applied Sciences (INSA-Lyon, France) and a Ph.D. in Biochemistry from the University of Geneva.

Restrictions on Mandates held outside the Company

The Articles provide certain restrictions to the number of mandates that members of the Board may have in the supreme governing bodies of legal entities registered in the Swiss commercial register or similar foreign register. As such no member of the Board may hold more than six additional mandates in the highest supervisory or management bodies of third party companies whose equity securities are listed on a stock exchange and ten additional mandates in the highest management bodies of other companies. The following mandates are not subject to these limitations: (i) mandates in companies which are controlled by the Company or which control the Company; and (ii) mandates in the highest supervisory bodies of associations, charitable organizations, foundations, trust and employee welfare foundations. No member of the Board shall hold more than ten such mandates.

Other Activities and Vested Interests

The Articles provide certain restrictions to the number of mandates that members of the Board may have in the supreme governing bodies of legal entities registered in the Swiss commercial register or similar foreign register. As such no member of the Board may hold more than six additional mandates in the highest supervisory or management bodies of third party companies whose equity securities are listed on a stock exchange and ten additional mandates in the highest management bodies of other companies. The following mandates are not subject to these limitations: (i) mandates in companies which are controlled by the Company or which control the Company; and (ii) mandates in the highest supervisory bodies of associations, charitable organizations, foundations, trust and employee welfare foundations. No member of the Board shall held more than ten such mandates.

Internal Organizational Structure

Responsibilities of the Board

The Board is entrusted with the ultimate direction of the Company and the supervision of management. The Board's duties include:

(i) the ultimate supervision of the Company and the issuing of all necessary directives;
(ii) the establishment of the Company's organization, including the enactment and amendment of the Organizational Regulations;
(iii) the structuring of the Company's accounting, financial control and financial planning systems, including the approval of the annual budget;

(iv) the appointment and removal of the persons entrusted with the management and the representation of the Company, as well as the determination of their signatory authority;
(v) the ultimate supervision of the persons entrusted with the management of the Company, in particular with regard to compliance with the law, the articles of association and the Company's internal regulations and policies;
(vi) the preparation of the annual report as well as the preparation of the general meeting of shareholders and the implementing of its resolutions;
(vii) the notification of the court in the event that the Company is overindebted;
(viii) the other powers and duties that Swiss law requires to be assumed or discharged by the Board; and
(ix) the adoption of a code of business conduct and ethics for the Company.

Additionally, the Board keeps the power to resolve itself on the following duties:
(i) approve any loans by the Company to executive officers (to the extent permitted by applicable law and the Articles) and loans by the Company to employees that are not executive officers, where the amount of any such loan exceeds USD 10,000, such duty being also delegated to the compensation, nominating and corporate governance committee: and
(ii) administer the Company's share and equity incentive plans, such duty being also delegated to the compensation, nominating and corporate governance committee and subject to further delegation to the executive committee under certain circumstances, as described in the Compensation Report on page 149 of this annual report.

The Board may also pass resolutions on all matters not reserved to the general meeting of shareholders or another corporate body by law or the Articles.

Working method of the Board

The Board of the Company is composed of not more than eight members. The Chairman of Board is appointed by the general meeting of shareholders for a term of office expiring after completion of the subsequent annual general meeting of shareholders.

The meetings of the Board are called and chaired by the Chairman as often as business requires, and may be held by telephone or videoconference. At the first meeting following the annual general meeting of shareholders, the Board appoints one or more Vice-Chairperson and a Secretary. It is not mandatory that the Secretary be a member of the Board. The notice convening a Board meeting is made in writing (including via telefax or email) and mentions the day, the time and the place of the meeting, as well as its agenda. The relevant documentation relating to the forthcoming meeting is delivered reasonably in advance. Except in case of emergency, resolutions on items that were not mentioned in the agenda may only be taken if all members of the Board have been consulted. Resolutions of the Board are made with a majority of the members present at a meeting. No quorum requirement applies for resolutions regarding the completion of a previously decided capital increase and the amendment of the Articles evidencing such capital increase.

The discussions and resolutions are kept in minutes signed by the Chairman and the Secretary. Resolutions may also be made by written consent to a proposed motion, provided no member requests that it be debated orally. Such resolutions by written consent shall be entered in the minutes of the next meeting.

The Board meets at least four times per year, on a quarterly basis, for regular face-to-face sessions. In 2018, the Board held four meetings in person, which lasted on average five hours, and one teleconference, which lasted approximately one hour. A vast majority of the Board Members were present at each Board meeting and teleconference. Members of the Executive Committee are usually invited to attend the meetings of the Board but are required to leave them for the non-Executive session that concludes every meeting.

Committees of the Board of Directors

The Board has two established committees: an audit committee and a compensation, nominating and corporate governance ("CNCG") committee. Both committees present reports to the Board on their activities at every regular session of the Board.

Audit Committee

The audit committee, which consists of Barbara Duncan, Ed Mathers and Frank Verwiel, 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. Duncan serves as chair of the audit committee. The audit committee consists exclusively of members of the Board who are financially literate, and Ms. Duncan is considered an "audit committee financial expert" as defined by the SEC.

The audit committee is governed by a charter and is responsible, among other things, for:

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

The audit committee meets as often as it determines is appropriate to carry out its responsibilities, but in any event meets at least four times per year. In 2018, the audit committee held five meetings, which lasted on average one to two hours. A vast majority of the audit committee members were present at each audit committee meeting. The Company's auditors are invited and systematically attend the audit committee meetings. The Chief Financial Officer and V.P. Finance are invited to attend the meetings of the audit committee too, but are required to leave them for the non-Executive session that concludes every meeting.

Compensation, Nominating and Corporate Governance Committee

The CNCG committee consists of three members, Annette Clancy, Rafaèle Tordjman and James I. Healy. The chair of the CNCG committee is Ms. Clancy. 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.

The CNCG committee has the responsibility to, among other things:

(i) review and approve, or recommend that the Board approves the compensation of the executive officers based on the aggregate compensation approved by the shareholders;
(ii) review and approve, or recommend that the Board approves the compensation of the members of the Board based on the aggregate compensation approved by the shareholders;
(iii) review and approve, or recommend that the Board approves the terms of compensatory arrangements with the executive officers;
(iv) administer the Company's share and equity incentive plans, subject to further delegation to the executive committee under certain circumstances, as described in the Compensation Report on page 149 of this annual report;
(v) select independent compensation consultants and assess whether there are any conflicts of interest with any of the committees' compensation advisers;
(vi) review and approve, or recommend that the Board approves incentive compensation and equity plans, and any other compensatory arrangements for the executive officers and other senior management, as appropriate;
(vii) review and establish general policies relating to compensation and benefits of the employees and reviewing the Company's overall compensation philosophy;
(viii) identify, evaluate and select, or recommend that the Board approves, nominees for election to the Board;
(ix) evaluate the performance of the Board and of individual directors;
(x) consider and make recommendations to the Board regarding the composition of its committees;
(xi) review developments in corporate governance practices;
(xii) evaluate the adequacy of the Company's corporate governance practices and reporting;
(xiii) review management succession plans;
(xiv) approve any loans by the company to executive officers (to the extent permitted by applicable law and the Articles) and loans by the company to employees that are not executive officers, where the amount of any such loan exceeds USD 10,000;
(xv) develop and make recommendations to the Board regarding corporate governance guidelines and matters; and
(xvi) oversee periodic evaluations of the Board's performance.

The CNCG committee meets as often as it determines is appropriate to carry out its responsibilities. In 2018, the CNCG committee held six meetings, which lasted on average one hour. A vast majority of the CNCG committee members were present at each CNCG committee meeting. The Chief Executive Officer is invited to attend the meetings of the CNCG committee but is required to leave them for the non-Executive session that conclude every meeting.

Definition of Areas of Responsibility

Subject to responsibilities reserved to the Board and its committees, as set forth in this section 3 of this Corporate Governance report, and except to the extent required by law, the Articles or the Organizational Regulations, the Board has delegated all areas of management of the Group's business to the Executive Committee.

Information and Control Measurements vis-à-vis the Executive Committee

The Board elects the members and appoints the head of the Executive Committee (the CEO), and ensures that it receives sufficient information from the CEO to perform its supervisory duty and to make the decisions that are reserved to the Board. At each Board meeting the Board receives reports from the CEO on the status of finance, business, research and development. These reports focus on the main risks and opportunities related to the Group. In addition, the Board is provided with other ad hoc reports on significant matters related to the Group's operations, as business requires, as well as with monthly financial reporting and unaudited consolidated financial statements for the Company on a quarterly basis. The Board receives a written report from the auditors on the results of the audit which includes any findings with respect to internal control risks arising as a result of the audit procedures.

For further information on controls measures, refer to section 9 of this corporate governance report.

4 – Executive Committee.

In accordance with the Articles and the Organizational Regulations, the Board has delegated the operational management to the Executive Committee which conducts the operational management of the Company pursuant to the Organizational Regulations and reports to the Board on a regular basis.

The following table sets forth the name, nationality, position and year of appointment, of each member of the Executive Committee, followed by a short description of each member's business experience, education and activities.

Name	Nationality	Function	Appointment
Ernest Loumaye	Belgian	Chief Executive Officer	2013
Tim Adams	American	Chief Financial Officer	2017
Jean-Pierre Gotteland	French	Chief Scientific Officer and Head of R&D	2015
Wim Souverijns	Belgian	Chief Commercial Officer	2018
Elke Bestel	German	Chief Medical Officer	2015
Ben T.G. Tan	Dutch	V.P. Commercial & B.D.	2014
Fabien de Ladonchamps	French	V.P. Corporate Affairs & Finance	2013

Ernest Loumaye is a Co-Founder of the Company and has served as its Chief Executive Officer and member of the Board since its inception in November 2012. For further information on Dr. Loumaye biographic details refer to section 3 of this corporate governance report.

Timothy Adams has served as Chief Financial Officer since January 2017. From June 2014 to September 2016, Mr. Adams served as the Chief Financial Officer of Demandware, Inc. Mr. Adams served as Senior Vice President and Chief Financial Officer of athenahealth, Inc. from January 2010 to June 2014. Previously, Mr. Adams served as Chief Investment Officer of Constitution Medical Investors, Inc., a private investment firm focused on health-care-sector-related acquisitions and investments, as well as Senior Vice President of Corporate Strategy for Keystone Dental, Inc., a provider of dental health products and solutions. Earlier in his career, Mr. Adams was Chief Financial Officer at a number of other publicly traded companies. Mr. Adams began his career in public accounting at PricewaterhouseCoopers LLP, formerly Price Waterhouse, and is a Certified Public Accountant. Mr. Adams has been serving as a member of the board of directors of Model N, a public revenue management solutions company, since December 2016. Mr. Adams has also served as a member of the board of directors of ABILITY Network, a private healthcare technology company, from 2014 to 2018. Mr. Adams obtained a B.S. from Murray State University and an M.B.A. from Boston University.

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

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

Elke Bestel has served as Chief Medical Officer and Head of Pharmacovigilance since September 2015. Prior to joining the Company, Dr. Bestel worked at PregLem SA, initially as a Global Project Director from 2008 to 2009, then as the Vice President Clinical Operations from 2009 to August 2012 and finally as the Chief Medical Officer from September 2012 to August 2015. Dr. Bestel studied at the Georg-August University Medical School of Göttingen, Germany and the Ludwig-Maximilian University Medical School of Munich, Germany. Dr. Bestel holds an M.D. from the University of Göttingen.

Ben T.G. Tan has served as Vice President of Commercial & Business Development since September 2014. Prior to joining the Company, Mr. Tan worked at Evolva SA, as Director, Business Development Pharmaceuticals from April 2012 to March 2014. Prior to joining Evolva SA, Mr. Tan worked at Novartis as Global Program Strategic Director, Cardiovascular and Metabolic Diseases from 2008 to 2011. Prior to joining Novartis, Mr. Tan worked at Speedel as Head of Business Development & Licensing from 2001 to 2008. Prior to joining Speedel, Mr. Tan worked at Devgen, as Executive Vice President of Business from 2000 to 2001. Prior to joining Devgen, Mr. Tan worked at Organon, as Global Head of Licensing from 1997 to 2000. Prior to joining Organon, Mr. Tan worked at Roche, as Global Business Leader/International Product Manager from 1994 to 1997, and at Roche Netherlands, as Head of Medical Marketing from 1990 to 1993. Mr. Tan holds an M.S. from the Vrije Universiteit Amsterdam.

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

Restrictions on Mandates held outside the Company

The Articles provide certain restrictions to the number of mandates that members of the Executive Committee may have in the supreme governing bodies of legal entities registered in the Swiss commercial register or similar foreign register. As such no member of the Executive Committee may hold more than six additional mandates in the highest supervisory or management bodies of third party companies whose equity securities are listed on a stock exchange and ten additional mandates in the highest management bodies of other companies. Members of the Executive Committee shall only accept such mandates with the prior consent of the Board. The following mandates are not subject to these limitations: (i) mandates in companies which are controlled by the Company or which control the Company; and (ii) mandates in the highest supervisory bodies of associations, charitable organizations, foundations, trust and employee welfare foundations. No member of the Executive Committee shall hold more than ten such mandates.

Management Contracts
There are no management contracts between the Company and third parties not belonging to the Group.

5 – Compensation, Shareholdings and Loans.

For a discussion on compensation and shareholdings of the members of the Board and of the Executive Committee, and loans granted to these individuals, refer to the Compensation Report section of this Annual Report on page 149.

6 – Shareholders' Participation Rights.

Voting Rights Restrictions and Representation
Voting rights may be exercised only after a shareholder has been recorded in the Company's share register as a shareholder or usufructuary with voting rights. A shareholder may be represented by his legal representative, the independent proxy or by a duly authorized person who does not need to be a shareholder. Subject to the registration of shares in the share register within the deadline set from time to time by the Board before the general meetings of shareholders, the Articles do not impose any restrictions on the voting rights of shareholders. Specifically, there is no limitation on the number of voting rights per shareholder.

A general meeting of shareholders is duly convened and capable of passing resolutions regardless of the number of shares represented. Resolutions of a general meetings of shareholders generally require the approval of the absolute majority of the votes cast at the shareholders meeting (more than 50% of the share votes cast at such meeting). Such resolutions include amendments to the Articles, elections of the members of the Board and statutory and group auditors, election of the chairman of the Board and of the members of the Compensation Committee, election of the independent proxy, approval of the annual financial statements, setting the annual dividend, approval of the compensation of the Board and executive committee pursuant to the Articles, decisions to discharge the members of the Board and executive committee for liability for matters disclosed to the general meeting of shareholders and the ordering of an independent investigation into specific matters proposed to the shareholders' meeting.

However, a qualified majority of at least two-thirds of the votes represented and the absolute majority of the nominal share capital is required by law or the Articles for resolution pertaining to: (i) changes to the business purpose; (ii) the creation of shares with privileged voting rights; (iii) restrictions on the transferability of registered shares; (iv) an increase of the authorized or conditional share capital; (v) an increase in the share capital by way of conversion of capital surplus, through contribution in kind, or for purposes of an acquisition of assets or the granting of special privileges; (vi) the withdrawing or limitation of pre-emptive rights of shareholders; (vii) a relocation of the registered office; (viii) the dissolution of the Company; (ix) an abrogation or amendment of the Articles regarding the limitations of outside mandates for the Board members; or (x) the removal of a serving member of the Board. Furthermore, any decision related to a merger, demerger or conversion of the Company shall be taken in accordance with the Swiss Federal Act on Mergers, De-Mergers, Transformations and Transfers of Businesses.

Independent Proxy
Article 18 of the Articles provides the basis for election of the independent proxy. The general meeting of shareholders of May 9, 2018, elected Perréard de Boccard SA, a law firm located at Rue de la Coulouvrenière 29 in Geneva, Switzerland, as the independent proxy of shareholders of the Company.

Quorums Required by the Articles
There is no other provision in the Articles requiring a majority for shareholders' resolutions beyond the majority requirements set out by applicable legal provisions other than those disclosed under the above "Voting Rights Restrictions and Representation" section.

Convocation of the General Meeting of Shareholders
The general meeting of shareholders is the highest authority of the Company and under Swiss law, the ordinary general meeting of shareholders takes place annually within six months after the close of the business year. General meetings of shareholders are convened by the Board or, if required by law or the Articles, by the auditors, the liquidators of the Company or the representatives of the bonds holders, if any. Furthermore, the Board is required to convene an extraordinary general meeting of shareholders if so requested by holders of shares representing at least 10% of the share capital or having a total par value of one million Swiss francs. Such request must be made in writing not less than sixty days ahead of the meeting and shall include a brief description of the items to be discussed and the proposals.

Annual or extraordinary meetings of the shareholders are called by notice in the "Swiss Official Gazette of Commerce" not less than twenty days before the date fixed for the meeting. A general meeting of shareholders may also be called by means of a notice sent to the shareholders at their address registered in the share register. The notice of the meeting shall state the items on the agenda the proposals of the Board and of the shareholders that requested that a general meeting be convened or that items be included in the agenda. No resolution shall be passed at a general meeting of shareholders on matters which do not appear on the agenda except for a resolution convening an extraordinary general meeting, the setting up of a special audit or the election of auditors. No prior notice is required to bring motions related to items already on the agenda or for the discussion of matters on which no resolution is to be taken.

Inclusion of Items in the Agenda
Shareholders representing shares of a total par value of one million Swiss francs may require that items be included in the agenda of the meeting. Such request must be made in writing not less than sixty days ahead of the meeting and shall include a brief description of the items to be discussed and the proposals.

Entries in the Share Register
The Board determines the relevant deadlines for registration in the share register giving the right to attend and to vote at the general meetings of shareholders. Such deadlines are published by the Company in its annual report and are mentioned in the invitation to the general meeting of shareholders published in the Swiss Official Commercial Gazette. The registration deadline for the general meeting of shareholders of May 8, 2019 has been set as April 2, 2019 at 22:00 CET. The Company has not enacted any rules on the granting of exceptions in relation to these deadlines.

7 – Changes of Control and Defense Measures.

Duty to Make an Offer
Swiss law provides for the possibility to have the Articles contain a provision which would eliminate the obligation of an acquirer of shares, exceeding the threshold of 33 1/3% of the voting rights (whether exercisable or not), to proceed with a public tender offer to acquire 100% of the listed equity securities of the company (opting-out provision pursuant to Article art. 125 para. 3 FMIA) or which would increase such threshold to 49% of the voting rights (opting-up provision pursuant to Article art. 135 para. 1 FMIA). The Articles do not contain an opting-out or an opting-up provision.

Clauses of Changes of Control

The following agreements and schemes executed by the Company contain provisions in respect of changes in the Company's shareholder base:

(i) the equity incentive plan dated 2013 contains provisions such as all equity instruments granted under that plan, consisting of 1,844,319 outstanding shares as of December 31, 2018, shall be immediately retransferred to the Company in case of a change of control at the shares' fair market value at the time and for the purpose of the change of control;

(ii) 25% of the unvested portion of stock-options granted under the equity incentive plan dated 2017 to an employee that is not a member of the Executive Committee, or an aggregate 178,915 unvested stock-options for all such employees as of December 31, 2018, shall vest immediately if, within three months before or 12 months following a change in control, (a) the employee is terminated without cause, or (b) the employee resigns for good reason; and

(iii) all of the unvested portion of stock-options granted under the equity incentive plan dated 2017 to a member of the Executive Committee, or an aggregate of 1,538,622 unvested stock-options for all members of the Executive Committee, as of December 31, 2018, shall vest immediately if, within three months before or 12 months following a change in control, (a) the member of the Executive Committee is terminated without cause, or (b) the member of the Executive Committee resigns for good reason.

8 – Auditors.

Duration of the Mandate and Term of Office of the Lead Auditor

The Articles provide the basis for election of the Company's auditors. The general meeting of shareholders of May 9, 2018, elected PricewaterhouseCoopers SA as the Company's Auditors and Independent Registered Public Accounting Firm for the fiscal year 2018. PricewaterhouseCoopers SA has served as auditor of the Company since 2013, and PricewaterhouseCoopers SA's lead auditor, Mike Foley, has been serving in this capacity since the business year 2016. The Company, through its audit committee, has not adopted a policy regarding the rotation of audit firms yet.

Auditing Fees

Auditing fees charged for 2018 by the auditor amounted to USD 502 thousands and consisted of fees billed for the annual audit of the Company's consolidated financial statements, and the statutory audit of the Company's consolidated and standalone financial statements. Audit Fees also include services that only the independent external auditor of the Company can reasonably provide, such as the review of documents filed with the U.S. stock exchange.

Additional Fees

Additional fees charged for 2018 by the auditor amounted to USD 188 thousands and consisted of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the financial statements or that are traditionally performed by the external auditor, and mainly include services such as comfort letters issued in connection with securities offerings, due diligence and agreed-upon or expanded audit procedures.

Information Instruments Pertaining to the External Audit

The audit committee assumes the task of supervising the auditors, and in this regard meets with the auditors at least four times a year to discuss the scope and the results of the audit and reviews performed by them, as well as other communications as may be required by applicable auditing standards. The auditors prepare an audit report to inform the audit committee of the result of the annual audit and quarterly reviews, as applicable, and to provide it with observations arising from the audit or reviews that are significant to the financial reporting process. The auditors also communicate once a year to the audit committee an overview of the overall audit strategy and timing of the audit. Other instruments available to the audit committee to obtain information on the activities of the auditors include a written disclosure by the auditors prior to their engagement on the assessment of their independence, including a delineation of all relationships between them, or their affiliates, and the Group. Furthermore, the quality of the auditors' service is assessed at least once a year by the audit committee.

9 – Controls and Procedures.

Management's Annual Report on Internal Control over Financial Reporting
The Audit Committee oversees the Company's financial reporting process on behalf of the Board. The management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of such. Under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, management assessed the internal control over financial reporting and concluded that such was effective as of December 31, 2018.

Conduct of a Risk Assessment
The Company conducts risk management processes to identify and mitigate risks at an early stage. The responsibility for risk assessment and management is allocated to the Executive Committee and to other specialized corporate functions such as the finance and administrative functions of the Group. Financial risk management is described in more details in note 3 to the Consolidated IFRS Financial Statements for the year ended December 31, 2018.

Insider policy
The Board has issued an insider policy and implemented procedures to prevent insiders from benefiting from confidential information. The policy defines guidelines on how to deter corporate insiders from making use of confidential information. The Board has established blocking periods to prevent insiders from trading during sensitive periods.

Ethical business conduct
As a pharmaceutical business, the Group is operating in a highly regulated business environment. Strict compliance with all legal and health authority requirements, as well as requirements of other regulators, is mandatory. The Group expects its employees, contractors and agents to observe the highest standards of integrity in the conduct of the Group's business. The Code of Business Conduct and Ethics sets forth the Group's policy embodying the highest standards of business ethics and integrity required of all directors, executives, employees and agents when conducting business affairs on behalf of the Group.

10 – Information Policy.

The Company publishes financial results in the form of an Annual Report and quarterly interim reports. In addition, the Company informs shareholders and the public regarding the Group's business through press releases, conference calls, as well as roadshows and Key Opinion Leaders meetings. Where required by law or the Company's Articles, publications are made in the Swiss Official Commercial Gazette. The Annual Report, usually published no later than March of the following year, and the quarterly interim reports, usually published no later than in May, August and November, respectively, are announced by press release. Annual Reports, quarterly interim reports and press releases are available on request in printed form to all registered shareholders, and are also made available on the Group's website at www.obseva.com. The Group's website, which is the Group's permanent source of information, also provides other information useful to investors and the public, including information on the Group's research and development programs as well as contact information. Additionally, the latest versions of the Articles, Organizational Regulations, charter of the audit committee, charter of the CNCG committee, as well as the Company's Code of Business Conduct and Ethics and whistleblower policy can be found and downloaded in the Corporate Governance section of the Investors tab of the Group's website. The Board has issued a disclosure policy to ensure that investors are informed in compliance with all applicable regulations. The Group's investor relations department is available to respond to shareholders' or potential investors' queries under IR@obseva.com, through the address and telephone number of ObsEva's principal executive office in Geneva, Chemin de Aulx 12, 1228 Plan-les-Ouates, telephone number +41 22 552 38 40, or via the U.S. office at 1 Financial Center in Boston, MA, telephone number +1 (857) 972-9366.

Consolidated IFRS Financial Statements

Consolidated IFRS Financial Statements for the year ended December 31, 2018

Consolidated Balance Sheet

	Notes	As at December 31, 2018	2017
		(in USD ,000)	(in USD ,000)
ASSETS			
Current assets			
Cash and cash equivalents	4	138,640	110,841
Other receivables	5	885	783
Prepaid expenses	6	5,715	1,490
Total current assets		**145,240**	**113,114**
Non-current assets			
Furniture, fixtures and equipment	7	319	323
Intangible assets	8	21,608	21,608
Other long-term assets	9	273	190
Total non-current assets		**22,200**	**22,121**
Total assets		**167,440**	**135,235**
LIABILITIES AND EQUITY			
Current liabilities			
Current tax liability	16	–	51
Other payables and current liabilities	5	2,766	2,865
Accrued expenses	6	14,163	6,514
Total current liabilities		**16,929**	**9,430**
Non-current liabilities			
Post-employment obligations	10	3,547	3,099
Other long-term liabilities	9	48	55
Total non-current liabilities		**3,595**	**3,154**
Shareholders' equity			
Share capital	11	3,420	2,864
Share premium	11	314,565	219,335
Reserves	11	12,858	7,119
Accumulated losses	11	(183,927)	(106,667)
Total shareholders' equity		**146,916**	**122,651**
Total liabilities and shareholders' equity		**167,440**	**135,235**

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

Consolidated Statement of Comprehensive Loss

		Year ended December 31,		
	Notes	2018	2017	2016
		(in USD ,000, except per share data)	(in USD ,000, except per share data)	(in USD ,000, except per share data)
Operating income other than revenue	**12**	**15**	**16**	**22**
OPERATING EXPENSES				
Research and development expenses	13	(62,872)	(54,912)	(23,711)
General and administrative expenses	13	(14,297)	(12,568)	(6,452)
Total operating expenses		**(77,169)**	**(67,480)**	**(30,163)**
OPERATING LOSS		**(77,154)**	**(67,464)**	**(30,141)**
Finance income	15	393	590	36
Finance expense	15	–	(1)	(97)
NET LOSS BEFORE TAX		**(76,761)**	**(66,875)**	**(30,202)**
Income tax benefit / (expense)	16	45	(51)	–
NET LOSS FOR THE YEAR		**(76,716)**	**(66,926)**	**(30,202)**
Net loss per share				
Basic	17	(1.91)	(2.25)	(1.40)
Diluted	17	(1.91)	(2.25)	(1.40)
OTHER COMPREHENSIVE LOSS				
Items that will not be reclassified to profit and loss				
Remeasurements on post-employment benefit plans		(544)	(142)	(599)
Items that may be reclassified to profit or loss				
Currency translation differences		–	–	(83)
TOTAL OTHER COMPREHENSIVE LOSS		**(544)**	**(142)**	**(682)**
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		**(77,260)**	**(67,068)**	**(30,884)**

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

Consolidated Statement of Cash Flows

	Notes	Year ended December 31, 2018	2017	2016
		(in USD ,000)	(in USD ,000)	(in USD ,000)
NET LOSS BEFORE TAX FOR THE YEAR		**(76,761)**	**(66,875)**	**(30,202)**
Adjustments for:				
Depreciation expense	7	109	70	46
Post-employment cost / (benefit)		(96)	7	(384)
Share-based compensation expense	18	9,152	8,856	2,237
Income tax paid		(11)	–	–
Finance (income) / expense, net		(359)	(589)	61
Increase in other receivables		(96)	–	(714)
Decrease / (increase) in prepaid expenses, deferred costs and other long term-assets		(4,225)	721	(2,033)
Increase / (decrease) in other payables and current liabilities		(16)	399	1,788
Increase in accrued expenses and other long-term liabilities		8,362	1,696	612
NET CASH FLOWS USED IN OPERATING ACTIVITIES		**(63,941)**	**(55,715)**	**(28,589)**
Cash used for rental deposits		(83)	(96)	–
Payments for plant and equipment	7	(188)	(189)	(45)
Acquisition of a license	8	–	(5,000)	–
NET CASH FLOWS USED IN INVESTING ACTIVITIES		**(271)**	**(5,285)**	**(45)**
Proceeds from issuance of shares	11	97,861	156,786	46
Payment of share issuance costs	11	(6,881)	(11,042)	(33)
Proceeds from exercise of stock-options	11	672	–	–
Payment of deferred costs of financing activities		–	–	(206)
Interest paid		–	(1)	(8)
Interest received		–	–	34
NET CASH FLOWS FROM / (USED IN) FINANCING ACTIVITIES		**91,652**	**145,743**	**(167)**
Net increase / (decrease) in cash and cash equivalents		27,440	84,743	(28,801)
Cash and cash equivalents as at January 1,		**110,841**	**25,508**	**54,275**
Effects of exchange rate changes on cash and cash equivalents		359	590	34
Cash and cash equivalents as at December 31,	**4**	**138,640**	**110,841**	**25,508**

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

Consolidated Statement of Changes in Equity

	Notes	Share capital	Share premium	Share-based payments reserve	Foreign currency translation reserve	Total reserves	Accumulated losses	Total
		(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)
December 31, 2015		**1,694**	**99,597**	**3,227**	**(406)**	**2,821**	**(39,437)**	**64,675**
Loss for the year		–	–	–	–	–	(30,202)	(30,202)
Other comprehensive loss		–	–	–	(83)	(83)	(599)	(682)
Total comprehensive loss		**–**	**–**	**–**	**(83)**	**(83)**	**(30,801)**	**(30,884)**
Issuance of non-voting shares		20	675	(675)	–	(675)	–	20
Acquisition of license		26	2,366	(2,366)	–	(2,366)	–	26
Share issuance costs		–	(33)	–	–	–	–	(33)
Share-based remuneration	18	–	–	2,237	–	2,237	–	2,237
Offset of accumulated losses with share premium		–	(30,639)	–	–	–	30,639	–
December 31, 2016		**1,740**	**71,966**	**2,423**	**(489)**	**1,934**	**(39,599)**	**36,041**
Loss for the year		–	–	–	–	–	(66,926)	(66,926)
Other comprehensive loss		–	–	–	–	–	(142)	(142)
Total comprehensive loss		**–**	**–**	**–**	**–**	**–**	**(67,068)**	**(67,068)**
Issuance of shares – IPO	11	496	96,254	–	–	–	–	96,750
Issuance of shares – PIPE	11	592	59,408	–	–	–	–	60,000
Issuance of shares – Incentive Plan	11	36	3,671	(3,671)	–	(3,671)	–	36
Share issuance costs		–	(11,964)	–	–	–	–	(11,964)
Share-based remuneration	18	–	–	8,856	–	8,856	–	8,856
December 31, 2017		**2,864**	**219,335**	**7,608**	**(489)**	**7,119**	**(106,667)**	**122,651**
Loss for the year		–	–	–	–	–	(76,716)	(76,716)
Other comprehensive loss		–	–	–	–	–	(544)	(544)
Total comprehensive loss		**–**	**–**	**–**	**–**	**–**	**(77,260)**	**(77,260)**
Issuance of shares – Incentive Plan	11	27	2,947	(2,947)	–	(2,947)	–	27
Issuance of shares – June 2018 offering	11	392	77,431	–	–	–	–	77,823
Issuance of shares – ATM program	11	130	19,881	–	–	–	–	20,011
Share issuance costs		–	(6,160)	–	–	–	–	(6,160)
Exercise of stock-options	18	7	1,131	(466)	–	(466)	–	672
Share-based remuneration	18	–	–	9,152	–	9,152	–	9,152
December 31, 2018		**3,420**	**314,565**	**13,347**	**(489)**	**12,858**	**(183,927)**	**146,916**

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

Notes to the Consolidated Financial Statements

1. General information

ObsEva SA (the "Company") was founded on November 14, 2012, and its address is 12 Chemin des Aulx, 1228 Plan-les-Ouates, Geneva, Switzerland. The terms "ObsEva" or "the Group" refer to ObsEva SA together with its subsidiaries included in the scope of consolidation (note 2.2).

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

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

These consolidated financial statements were authorized for issue by the Company's Board of Directors (the "Board of Directors") on March 5, 2019.

2. Accounting principles applied in the preparation of the consolidated financial statements

2.1 Basis of preparation

These consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). The consolidated financial statements are based on a historical cost basis.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies. The areas involving a higher degree of judgement or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements, are disclosed in note 2.5.

Due to rounding, numbers presented throughout these consolidated financial statements may not add up precisely to the totals provided. All ratios and variances are calculated using the underlying amount rather than the presented rounded amount.

2.2 Scope of consolidation

Subsidiaries are all entities over which the Group has control. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power to direct the activities of the entity. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date that control ceases.

The Company currently consolidates the financial operations of its two fully-owned subsidiaries, ObsEva Ireland Ltd, which is registered in Cork, Ireland and organized under the laws of Ireland, and ObsEva USA Inc., which is registered and organized under the laws of Delaware, USA. ObsEva Ireland Ltd had no operations and no results of operations to report as of December 31, 2018 and 2017.

2.3 Standards and interpretations published by the IASB

The IASB and the International Financing Reporting Standards Interpretations Committee have recently issued new standards and interpretations to be applied to the Group's consolidated financial statements.

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

On January 1, 2018, the Group adopted IFRS 15 Revenue from Contracts with Customers which replaces IAS 11 Construction Contracts and IAS 18 Revenue and related interpretations. The adoption of the standard had no material impact on the Group's consolidated financial statements.

No other new standards and amendments applied by the Group in 2018 had a material impact on its consolidated financial statements.

In 2019, the Group will adopt the following new relevant standard:

IFRS 16 Leases, effective for annual periods beginning on or after January 1, 2019
In January 2016, the IASB issued IFRS 16 Leases, which replaces IAS 17 Leases and related interpretations. The new standard will require lessees to recognize a lease liability reflecting future lease payments and a right-of-use asset for virtually all lease contracts, removing the distinction between operating and finance leases. As at December 31, 2018, the Group has non-cancellable operating lease commitments of USD 3 million (excluding short-term and low-value leases) and has recognized right-of-use assets and lease liabilities of USD 2.7 million on January 1, 2019. The Group does not expect a significant impact on the net profit after tax resulting from the adoption of IFRS 16.

The Group will apply the standard from its mandatory adoption date of January 1, 2019. The Group intends to apply the simplified transition approach and will not restate comparative amounts for the year prior to first adoption. Right-of-use assets for property leases will be measured on transition as if the new rules had always been applied. All other right-of-use assets will be measured at the amount of the lease liability on adoption (adjusted for any prepaid or accrued lease expenses).

Other new standards and amendments published but not yet effective are not expected to have any material impact on the consolidated financial statements of the Group.

2.4 Significant accounting policies

Cash and cash equivalents
Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the balance sheet.

Current assets
Other receivables and other current receivables or prepaid expenses are carried at their nominal value.

Individual receivables that are known to be uncollectible are written off by reducing the carrying amount directly. The Group considers that there is evidence of impairment if any of the following indicators are present:

- significant financial difficulties of the debtor;
- probability that the debtor will enter bankruptcy or financial reorganization; and
- default or delinquency in payments (more than 30 days overdue).

The Group applies the IFRS 9 simplified approach to measuring expected credit losses which uses a lifetime expected loss allowance for all receivables.

Receivables for which an impairment provision was recognized are written off against the provision when there is no expectation of recovering additional cash.

Furniture, fixtures and equipment

Furniture, fixtures and equipment are carried at cost less depreciation and impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the items. Depreciation is calculated using the straight-line method, on the basis of the following useful lives:

l	furniture	5 years
l	hardware	3 years
l	leasehold improvement	duration of lease

Furniture, fixtures and equipment are reviewed for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable, on an individual basis. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount.

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

Intangible assets

Separately acquired patents, licenses and other intangible assets are recorded at historical cost and subsequently measured at cost less accumulated amortization and any impairment losses.

The acquisition of certain intangible assets, mainly licenses, may involve additional payments contingent on the occurrence of specific events or milestones. Unless the Group already has a present obligation to make the payment at a future date, the initial measurement of the intangible asset does not include such contingent payments. Instead, such payments are subsequently capitalized as intangible assets when the contingency or milestone occurs.

Estimated useful life is the lower of legal duration and economic useful life, which does not exceed 20 years. The estimated useful life of the intangible assets is annually reviewed, and if necessary, the future amortization charge is accelerated.

For licenses, the amortization starts when the assets become available for use, generally once proper regulatory and marketing approval are obtained.

Intangible assets are subject to impairment testing annually, and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Post-employment benefits

Group companies operate two pension schemes.

All employees of ObsEva SA participate in a retirement defined benefit plan. A defined benefit plan is a pension plan that defines an amount of pension benefit that an employee will receive on retirement, usually dependent on one or more factors such as age, years of service and compensation. The liability recognized in the balance sheet in respect of defined benefit pension plans is the present value of the defined benefit obligation at the end of the reporting period less the fair value of plan assets. The defined benefit obligation is calculated annually by an independent actuary, using the projected unit credit method. The present value of the defined benefit obligation is determined by discounting the estimated future cash outflows using interest rates of high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating to the terms of the related pension obligation.

Actuarial gains and losses arising from experience adjustments and changes in actuarial assumptions are charged or credited to equity in other comprehensive income in the period in which they arise. Past-service costs are recognized immediately in the consolidated statement of comprehensive loss.

During 2017, ObsEva USA, Inc established a 401K, defined contribution plan, for the employees of the company. A defined contribution plan is a pension plan under which the amounts paid by the employer are fixed in advance. The plan assets are held by a third party custodian. ObsEva USA, Inc. contributions to the defined contribution plan are charged to the income statement as incurred. The Group has no further obligation once the contributions have been paid.

Equity

Incremental costs directly attributable to the issuance of common shares and options are recognized as a deduction from equity, net of any tax effects.

Research and development

Research expenses are charged to the consolidated statement of comprehensive loss as incurred. Development expenses are capitalized as intangible assets when it is probable that future economic benefits will flow to the Group, and the following criteria are fulfilled:

- it is technically feasible to complete the intangible asset so that it will be available for use or sale;
- management intends to complete the intangible asset and use or sell it;
- there is an ability to use or sell the intangible asset;
- the asset will generate probable future economic benefits and demonstrate the existence of a market;
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

In the opinion of management, due to uncertainties inherent in the development of the Group's product candidates, the criteria for development costs to be recognized as an asset as defined by IAS 38 Intangible Assets are not met.

Foreign currencies

Functional and presentation currency

Items included in the consolidated financial statements of the Group are measured using the currency of the primary economic environment in which each Group's entity operates (the "functional currencies").

Until December 31, 2016, the functional currency of the Company was the Swiss franc (CHF). As from January 1, 2017, due to a change of its primary economic environment, the functional currency of ObsEva SA became the US dollar (USD), which is also the functional currency of ObsEva USA, Inc. and the presentation currency of the Group.

Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates at the dates of the transactions or valuation where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at year end exchange rates are recognized in profit or loss.

Foreign exchange gains and losses that relate to borrowings are presented in the consolidated statement of comprehensive loss, within finance costs. All other foreign exchange gains and losses are presented in the consolidated statement of comprehensive loss on a net basis within other income or other expenses.

The following rates have been used for the translation from the functional currency to the presentation currency:

	Income statement Average rate		Balance sheet Closing rate as of December 31,	
	2016	**2015**	**2016**	**2015**
	(CHF)	(CHF)	(CHF)	(CHF)
USD	0.9850	0.9624	1.0160	1.0010

Share-based compensation
The Group operates two equity incentive plans.

A share-based, equity-settled, plan was formally set-up by the Group in 2013 (the "2013 EIP"). Participants eligible for awards under the 2013 EIP are executives, directors, employees, agents and consultants. The fair value of the shares granted under the 2013 EIP is determined at each grant date by using either an option pricing method that uses a Black-Scholes model or a hybrid method, as appropriate, both based on a combination of the discounted cash flow method, under the income approach, and the backsolve method.

A share-based, equity-settled, plan was formally set-up by the Group in 2017 (the "2017 EIP"). Participants eligible for awards under this plan are executives, directors, employees, agents and consultants. The fair value of the stock-options granted under the 2017 EIP is determined at each grant date by using a Black-Scholes model.

When the equity instruments granted do not vest until the counterparty completes a specified period of services, the Group accounts for those services as they are rendered by the counterparty, during the vesting period, with a corresponding increase in equity.

Deferred income taxes
Deferred income tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, if the deferred income tax arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit and loss, it is not accounted for. Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Leases
Leases of assets under which all the risks and rewards of ownership are effectively retained by the lessor are classified as operating leases, and payments made are charged to the statement of comprehensive loss on a straight-line basis.

Segment information

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

The Group currently generates no revenue from the sales of therapeutics products.

The Group's activities are not affected by any significant seasonal effect.

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

	As at December 31,	
	2018	**2017**
	(in USD ,000)	(in USD ,000)
Switzerland	21,954	21,832
USA	246	289
Total non-current assets	**22,200**	**22,121**

The geographical analysis of operating expenses is as follows:

	Year ended December 31,		
	2018	**2017**	**2016**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Switzerland	73,050	63,956	30,163
USA	4,119	3,524	–
Total operating expenses	**77,169**	**67,480**	**30,163**

2.5 Critical accounting estimates and judgments

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

Critical accounting estimates and assumptions

The Group makes estimates and assumptions concerning the future. The resulting accounting estimates will not necessarily equal to related actual outcome. The following areas involve a higher degree of judgement or complexity or are areas where assumptions and estimates can have a significant impact on the consolidated financial statements:

- Post-employment obligations: the actuarial valuation involves making assumptions about discount rates, future salary increases, mortality rates and future pension increases. Due to the long-term nature of these plans, such estimates are subject to significant uncertainty (note 10);
- Share-based compensation: the determination of the fair value of the equity instruments granted involves the use of certain assumptions subject to judgement (note 18);

- Commencement of depreciation and amortization: the depreciation and amortization starts when the assets are available for use in the manner intended by management, which requires judgement (notes 7 and 8);
- Research and development costs: the Group recognizes expenditure incurred in carrying out its research and development activities until it becomes probable that future economic benefits will flow to the Group, which results in recognizing such costs as intangible assets, involving a certain degree of judgement (note 13);
- Deferred taxes: the recognition of deferred tax assets requires assessment of whether it is probable that sufficient future taxable profit will be available against which the deferred tax assets can be utilized (note 16);
- Impairment of assets: as part of impairment tests, the recoverable amounts of tested assets have been determined based on fair value calculations requiring the use of certain assumptions, subject to judgement (note 8).

3. Financial risk management

3.1 Financial risk factors

The Group's activities expose it to a variety of financial risks such as foreign exchange risk, credit risk, interest rate risk and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance. Financial risk management is carried out by the Group`s finance department subject to and pursuing policies approved by the Board of Directors.

Foreign exchange risk

The Group operates internationally and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the Swiss franc (CHF), Euro (EUR) and British Pound (GBP). Foreign exchange risk arises from future commercial transactions (e.g. costs for clinical services) and recognized assets and liabilities. Management has set up a policy to manage the foreign exchange risk against their functional currency. To manage its foreign exchange risk arising from future commercial transactions and recognized assets and liabilities, the Group's finance department maintains foreign currency cash balances to cover anticipated future requirements.

The sensitivity of profit or loss to changes in the exchange rates in the reported periods are as follows:

EUR positions	Increase /decrease exchange rate vs USD	Effect on profit before tax	Effect on shareholders' equity
		(in USD ,000)	(in USD ,000)
2018	+5%	770	770
	–5%	(770)	(770)
2017	+5%	924	924
	–5%	(924)	(924)

GBP positions	Increase /decrease exchange rate vs USD	Effect on profit before tax	Effect on share-holders' equity
		(in USD ,000)	(in USD ,000)
2018	+5%	110	110
	–5%	(110)	(110)
2017	+5%	98	98
	–5%	(98)	(98)

CHF positions	Increase /decrease exchange rate vs USD	Effect on profit before tax	Effect on share-holders' equity
		(in USD ,000)	(in USD ,000)
2018	+5%	607	607
	–5%	(607)	(607)
2017	+5%	474	474
	–5%	(474)	(474)

Credit risk

Cash and cash equivalents are deposited with top tier banks and institutions with a short term rating of "A-1" or "P-1" with Standard & Poor's and Moody's, respectively.

The maximum credit risk exposure the Group faces in connection with its financial assets, being cash and cash equivalents and other receivables, is the carrying amounts of these balances as shown in the consolidated balance sheet.

Interest rate risk

The Group's exposure to interest rate fluctuations is limited because the Group has no interest-bearing indebtedness.

Liquidity risk

The Group's principal source of liquidity is the cash reserves which are obtained through the issuance of new shares. The Group's policy is to invest these funds in low risk investments including interest bearing deposits. The ability of the Group to maintain adequate cash reserves to sustain its activities in the medium term is subject to risk as it is highly dependent on the Group's ability to raise further funds from the sale of new shares.

3.2 Capital management

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern in order to ensure the financing of successful research and development activities so that future profits can be generated and to maintain sufficient financial resources to mitigate against risks and unforeseen events.

The Group is also subject to capital maintenance requirements under Swiss law. To ensure that statutory capital requirements are met, the Group monitors capital periodically.

3.3 Fair value estimation and financial instruments

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

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

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

4. Cash and cash equivalents

	As at December 31,	
	2018	**2017**
	(in USD ,000)	(in USD ,000)
Bank deposits	138,640	110,841
Interest bearing deposits	–	–
Total cash and cash equivalents	**138,640**	**110,841**

Split by currency:

	2018	**2017**
CHF	5%	6%
USD	89%	93%
EUR	5%	1%
GBP	1%	–

5. Receivables and payables

As at December 31, 2018 and 2017, other receivables consist mainly of reimbursements to be received from third parties, including VAT, insurance premiums and shared-costs of research and development studies, and other payables and other current liabilities include mainly costs of clinical services. All receivables and payables are due from and to third parties and carried at amortized cost.

All payables have a contract maturity within 1 year.

6. Prepaid and accrued expenses

As at December 31, 2018 and 2017, prepaid expenses mainly consist of advance or milestone payments made as part of our ongoing clinical trials. The balance as at December 31, 2018 includes USD 4.3 million attributable to the upfront payment made in relation to the Company's Phase 3 EDELWEISS 2 and 3 clinical trials expected to be initiated in the first quarter of 2019.

As at December 31, 2018 and 2017, accrued expenses consisted of the following:

	As at December 31,	
	2018	**2017**
	(in USD ,000)	(in USD ,000)
Accrued research and development expenses	10,734	3,192
Accrued compensation-related expenses	2,364	1,994
Accrued other expenses	1,065	1,328
Total accrued expenses	**14,163**	**6,514**

7. Furniture, fixtures and equipment

	2018	**2017**
	(in USD ,000)	(in USD ,000)
Net book value as at January 1	**323**	**121**
Additions	105	272
Depreciation charge	(109)	(70)
Currency translation effects	–	–
Net book value as at December 31	**319**	**323**
Total cost	600	495
Accumulated depreciation	(281)	(172)

Furniture, fixtures and equipment assets mainly consist of office furniture and leasehold improvements.

8. Intangible assets

	2018	**2017**
	(in USD ,000)	(in USD ,000)
Net book value as at January 1	**21,608**	**16,608**
Additions	–	5,000
Amortization charge	–	–
Currency translation effects	–	–
Net book value as at December 31	**21,608**	**21,608**
Total cost	21,608	21,608
Accumulated amortization	–	–

As at December 31, 2018, the Group holds a number of licenses to operate several biopharmaceutical product candidates, the value of which is recorded at USD 21.6 million (2017: USD 21.6 million).

Merck Serono licenses
On August 28, 2013, the Group in-licensed nolasiban for USD 4.9 million from Ares Trading S.A., an affiliate of Merck Serono ("Merck Serono").

In June 2015, the Group acquired the in-license for OBE022 from Merck Serono for an amount of USD 2.4 million.

Kissei license
On November 19, 2015, the Group entered into an exclusive in-license and supply agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei") to acquire the product candidate linzagolix (formerly OBE2109) for which Kissei successfully completed a Phase 2 trial in Japan. This in-license agreement grants the Group an exclusive license to use, develop and commercialize the product candidate worldwide excluding certain Asian countries. This in-license was acquired for an upfront cash consideration of USD 10 million, with additional contingent payments upon occurrence of certain milestones (note 19).

On April 25, 2017, the Group announced the initiation of its Phase 3 clinical program for linzagolix in uterine fibroids and related activation of sites and start of recruitment. This event triggered the recognition and payment of a USD 5.0 million milestone to Kissei during the second quarter of 2017, that was accounted for as an intangible asset.

The Group has concluded that the Merck Serono licenses and the Kissei license acquisitions do not qualify as business combinations per IFRS 3, as the Group did not acquire processes that are capable of producing outputs given the in-licensed compounds are very early-stage.

Amortization and impairment
The licenses are currently not amortized as no regulatory and marketing approvals were obtained.

In accordance with IAS 38, the licenses have been reviewed for impairment by assessing the fair value less costs of disposal ("FVLCOD"). The valuation is considered to be Level 3 in the fair value hierarchy due to unobservable inputs used in the valuation. No impairment was identified.

The key assumptions used in the valuation model (income approach) to determine the FVLCOD of the licenses are as follows:

- Expected research and development costs;
- Probabilities of achieving development milestones based on industry standards;
- Reported disease prevalence;
- Expected market share;
- Drug reimbursement, costs of goods and marketing expenses; and
- Expected patent life.

The valuation model covers a 20-year period due to the length of the development cycle for assets of this nature. A discount factor of 15%, based on the assumed cost of capital for the Group, has been used over the forecast period.

Based on sensitivity analysis performed, including changes in discount rates and peak sales assumptions, no reasonably possible change in assumption would cause the carrying value of the licenses to exceed their recoverable amount.

9. Other long-term assets and liabilities

The Group's other long-term assets mainly consist of security rental deposits for the Group's offices.
The Group's other long-term liabilities consist of long-term components of rent costs for ObsEva USA Inc.
10. Post-employment benefits

In accordance with the mandatory Swiss pension fund law, all employees of the Company participate in a retirement defined benefit plan. Swiss based pension plans are governed by the Swiss Federal Law on Occupational Retirement, Survivors' and Disability Pension Plans (the "LPP"), which stipulates that pension plans are to be managed by independent, legally autonomous units. Under the terms of the pension plan, participants are insured against the financial consequences of old age, disability and death. The various insurance benefits are governed by regulations, with the LPP specifying the minimum benefits that are to be provided. The employer and employees pay contributions to the pension plan. In the event the pension plan's statutory funding falls below a certain level, various measures can be taken to increase funding above such level, such as increasing the current contribution, lowering the interest rate on the retirement account balances or reducing the additional prospective benefits. The employer can also make additional restructuring contributions. Since the risks of death and disability are fully reinsured by an insurance group, the savings plan must be qualified as a defined benefit plan. As required by IAS 19 Employee Benefits, the projected unit credit method has been used in the calculation of present value of the benefit obligations and the related current service cost.

The investment risk is borne by the insurer and the reinsurer respectively, and the investment decision is taken by the board of trustees of the collective insurance.

In 2018, the pension fund changed the pension conversion rates, what has been considered as an amendment of the pension plan.

	2018	2017
	(in USD ,000)	(in USD ,000)
Change in defined benefit obligation		
Defined benefit obligation at January 1,	**(12,230)**	**(9,201)**
Current service cost	(1,046)	(795)
Interest cost	(101)	(72)
Net benefits paid	(888)	(1,604)
Currency translation effects	137	(403)
Remeasurements:		
Impact of plan amendment	172	–
Effect of changes in demographic assumptions	–	–
Effect of changes in financial assumptions	96	155
Effect in experience assumptions	(642)	(310)
Defined benefit obligation at December 31,	**(14,502)**	**(12,230)**

	2018	2017
	(in USD ,000)	(in USD ,000)
Change in plan assets		
Fair value of plan assets at January 1,	**9,131**	**6,369**
Interest income	80	55
Employer contributions	479	403
Employee contributions	479	403
Net benefits paid	888	1,604
Currency translation effects	(104)	284
Remeasurements: return on plan assets (excluding interest income)	2	13
Fair value of plan assets at December 31,	**10,955**	**9,131**

	Year ended December 31,	
	2018	2017
	(in USD ,000)	(in USD ,000)
Components of defined benefit cost		
Current service cost	1,046	795
Interest expense on defined benefit obligation	101	72
Interest income on plan assets	(80)	(55)
Employee contributions	(479)	(403)
Impact of plan amendment	(172)	–
Total included in staff costs (note 14)	**416**	**409**

	Year ended December 31,	
	2018	2017
	(in USD ,000)	(in USD ,000)
Remeasurements recognized in other comprehensive loss		
Effect of changes in demographic assumptions	–	–
Effect of changes in financial assumptions	96	155
Effect in experience assumptions	(642)	(310)
Return on plan assets (excluding interest income)	2	13
Total remeasurements recognized as other comprehensive loss	**(544)**	**(142)**
Cumulative amount of remeasurements immediately recognized in other comprehensive loss	(4,125)	(3,581)

	As at December 31,	
	2018	2017
	(in USD ,000)	(in USD ,000)
Amounts recognized in the statement of financial position		
Defined benefit obligation	(14,502)	(12,230)
Fair value of plan assets	10,955	9,131
Net liability	**(3,547)**	**(3,099)**

	2018	2017
	(in USD ,000)	(in USD ,000)
Change in defined benefit liability		
Net defined benefit liability at January 1,	**(3,099)**	**(2,832)**
Defined benefit cost included in statement of comprehensive loss	(416)	(409)
Total remeasurements included in other comprehensive loss	(544)	(142)
Employer contributions	479	403
Currency translation effects	33	(119)
Net defined benefit liability at December 31,	**(3,547)**	**(3,099)**

As of the date of preparation of these consolidated financial statements, the annual report for 2018 of the pension fund has not yet been issued, and therefore the detailed structures and assets held at December 31, 2018, are not currently available for presentation. The detailed structures and assets held at December 31, 2017, are as follows:

Plan assets	As at December 31, 2017
Cash	2.2%
Bonds	64.3%
Shares	9.3%
Real estate	16.4%
Mortgages	7.7%
Alternative investments	0.1%
Total	**100.0**

The principal actuarial assumptions used were as follows:

	2018	2017
Discount rate	0.85%	0.80%
Salary increase (including inflation)	1.00%	1.00%
Rate of pension increases	0.25%	0.25%
Post-employment mortality table	LPP 2015 G	LPP 2015 G

Sensitivity analysis illustrates the sensitivity of the Group defined benefit obligation at December 31, 2018 by varying the discount rate and the salary increase rate by plus / minus 50 basis points:

(in USD ,000)	Discount rate	Discount rate	Salary increase	Salary increase	Rate of pension increase	Rate of pension increase
Sensitivity analysis	plus 50bps	minus 50bps	plus 50bps	minus 50bps	plus 25bps	minus 25bps
Discount rate	1.35%	0.35%	0.85%	0.85%	0.85%	0.85%
Salary increase	1.00%	1.00%	1.50%	0.50%	1.00%	1.00%
Rate of pension increases	0.25%	0.25%	0.25%	0.25%	0.50%	0.00%
Defined benefit obligation	**(13,238)**	**(15,986)**	**(14,611)**	**(14,398)**	**(14,885)**	**(14,139)**

Average duration of the defined benefit obligation	**2018**	**2017**
Duration in years	18.9	18.8

The methods and types of assumptions used in preparing the sensitivity analysis did not change compared to the prior period.

Expected contributions by the employer to be paid to the post-employment benefit plans during the annual period beginning after the end of the reporting period amount to approximately USD 531,000.

11. Shareholders' equity

	Number of shares					in USD ,000		
	Common shares	Preferred A shares	Preferred B shares	Non-voting shares	Total shares	Share capital	Share premium	Total
January 1, 2017	**2,215,434**	**8,031,777**	**11,079,549**	**611,637**	**21,938,397**	**1,740**	**71,966**	**73,706**
Conversion of preferred and non-voting shares	19,722,963	(8,031,777)	(11,079,549)	(611,637)	–	–	–	–
Issuance of shares – IPO	6,450,000	–	–	–	6,450,000	496	96,254	96,750
Issuance of shares – PIPE	7,500,000	–	–	–	7,500,000	592	59,408	60,000
Issuance of shares – Incentive Plan	454,548	–	–	–	454,548	36	3,671	3,707
Share issuance costs	–	–	–	–	–	–	(11,964)	(11,964)
December 31, 2017	**36,342,945**	**–**	**–**	**–**	**36,342,945**	**2,864**	**219,335**	**222,199**

	Number of common shares	Share capital	Share premium	Total
		(in USD ,000)	(in USD ,000)	(in USD ,000)
January 1, 2018	**36,342,945**	**2,864**	**219,335**	**222,199**
Issuance of shares - Incentive Plan	347,509	27	2,947	2,974
Issuance of shares – June 2018 offering	5,056,721	392	77,431	77,823
Issuance of shares – ATM program	1,600,851	130	19,881	20,011
Share issuance costs	–	–	(6,160)	(6,160)
Exercise of stock-options	95,885	7	1,131	1,138
December 31, 2018	**43,443,911**	**3,420**	**314,565**	**317,985**

Share capital and share premium

As at December 31, 2018, the total outstanding share capital of USD 3.4 million, fully paid, consists of 43,443,911 common shares, excluding 430,625 non-vested shares and 1,602,601 treasury shares. As at December 31, 2017, the total outstanding share capital of USD 2.9 million, fully paid, consisted of 36,342,945 common shares, excluding 778,134 non-vested shares and 10,183 treasury shares. All shares have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date.

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

On October 13, 2017, the Company completed a private placement with institutional investors and issued 7,500,000 common shares at a subscription price of USD 8.00 per share and a par value of 1/13 of a Swiss franc per share. The gross proceeds of USD 60.0 million have been recorded in equity net of directly related share issuance costs of USD 3.7 million. On March 16, 2018, the Company issued 3,499,990 common shares at par value of 1/13 of a Swiss franc per share. The shares were subscribed by the Company and are held as treasury shares, hence the operation did not impact the share capital. Share issuance costs of USD 11 thousand related to the operation were recorded as a deduction in equity.

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

On June 22, 2018, the Company completed an underwritten public offering of 4,750,000 common shares at a price of USD 15.39 per share, with an option to issue to an additional 712,500 common shares (the "follow-on offering"). The gross proceeds of USD 73.1 million resulting from this transaction have been recorded in equity net of directly related share issuance costs of USD 5.3 million. Subsequent to the initial closing of the follow-on offering, on July 19, 2018, the Company sold an additional 306,721 common shares for total gross proceeds of USD 4.7 million (USD 15.39 per share). These shares were sold pursuant to the 30-day option granted in connection with the follow-on offering to purchase up to an additional 712,500 common shares. Directly related share issuance costs amounted to USD 0.3 million.

Equity incentive plans

In 2018, the Company issued 347,509 common shares (2017: 454,548) under its 2013 EIP (see note 18). All shares issued under the 2013 EIP have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date.

Authorized share capital

The authorized share capital that is not outstanding as at December 31, 2018 and December 31, 2017 is as follows:

	As at December 31,	
Number of shares	**2018**	**2017**
Authorized share capital	15,565,620	6

12. Revenue and other operating income

The Group currently derives no revenue from sales of its biopharmaceutical product candidates.
Operating income other than revenue mainly relates to compensation received from the Swiss tax authorities as the Company acts as collecting agent of the withholding tax on salaries.

13. Operating expenses by nature

	Year ended December 31,		
	2018	**2017**	**2016**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
External research and development costs	49,480	43,268	16,811
Staff costs (note 14)	19,537	17,999	7,436
Professional fees	3,871	2,862	4,016
Rents	827	592	427
Travel expenses	1,044	1,073	541
Patent registration costs	1,002	426	512
Depreciation	109	70	46
Other	1,299	1,190	374
Total operating expenses by nature	**77,169**	**67,480**	**30,163**

Due to the difficulty in assessing when research and development projects would generate revenue, the Group expenses all research and development costs on the consolidated statement of comprehensive loss. In 2018, research and development expenses amounted to USD 62.9 million (2017: USD 54.9 million, 2016: USD 23.7 million).

The depreciation expense has been allocated as follows:

	Year ended December 31,		
	2018	2017	2016
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Research and development expenses	63	44	35
General and administrative expenses	46	26	11
Total depreciation	**109**	**70**	**46**

14. Staff costs

	Year ended December 31,		
	2018	2017	2016
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Wages and salaries	9,023	7,715	4,807
Social charges	946	993	443
Post-employment benefits expense	416	435	(51)
Share-based payments	9,152	8,856	2,237
Total staff costs	**19,537**	**17,999**	**7,436**

The Group employed on average 39.6 full-time equivalents ("FTE") in 2018, compared to 32.3 FTE in 2017 and 22.4 FTE in 2016, and 43.2 FTE as at December 31, 2018 compared to 37.7 FTE as at December 31, 2017 and 25.3 FTE as at December 31, 2016.

For the year ended December 31, 2018, the post-employment benefits line includes a gain of USD 162 thousand relating to the plan amendment enacted in 2018 (2017: nil, 2016: USD 512 thousand).

15. Finance income and expense

Finance income mainly relates to foreign exchange gains and interests on bank deposits.

Finance expense mainly relates to foreign exchange losses and interest expense.

16. Income taxes and deferred taxes

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

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

The following table details the tax losses carry forwards of the Company and their respective expiring dates.

Expiring tax losses

	As at December 31,	
	2018	**2017**
	(in USD ,000)	(in USD ,000)
2020	2,896	2,925
2021	11,473	11,587
2022	16,093	16,253
2023	28,349	28,631
2024	58,019	58,596
2025	67,403	–
Total unrecorded tax losses carry forwards	**184,233**	**117,992**

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, 2018 and 2017.

The Company's U.S. subsidiary, ObsEva USA Inc., is a service organization for the Group and is therefore subject to taxes on the revenues generated from its services to the Group that are charged based upon the U.S. subsidiary's cost plus arrangement with the Group. The profits of the U.S. subsidiary for the year ended December 31, 2018 and 2017 were subject to a total U.S. income tax rate of 27.3% and 39.3%, respectively based on both the U.S. federal and Massachusetts state tax rates. The decrease in U.S. tax rate is due to the recent tax reform, effective January 1, 2018. The income tax for the year ended December 31, 2018 and 2017 were USD (45) thousand and USD 51 thousand, respectively. Additionally, since ObsEva USA Inc. is totally dependent on ObsEva SA for revenue, there is uncertainty as to whether ObsEva USA Inc. will be able to use a deferred tax asset for tax purposes in the future, therefore, no deferred taxes have been recognized on the balance sheet of the Group as of December 31, 2018 and December 31, 2017.

The following elements explain the difference between the income tax expense at the applicable Group tax rate and the effective income tax expense:

	Year ended December 31, 2018		
	ObsEva SA	**ObsEva USA**	**Total Group**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Net loss before tax	(75,616)	(1,145)	(76,761)
Statutory tax rate (blended at Group level)	7.8%	27.3%	8.1%
Income tax credit at statutory tax rates	(5,898)	(313)	(6,211)
Tax impact of permanent differences	602	76	678
Temporary differences not recognized as deferred tax assets	–	251	251
Adjustments for current tax of prior periods	–	(59)	(59)
Tax on losses not recognized as deferred tax assets	5,296	–	5,296
Effective income tax credit	**–**	**(45)**	**(45)**
Effective tax rate	0%	3.9%	0.1%

	Year ended December 31, 2017		
	ObsEva SA	**ObsEva USA**	**Total Group**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Net loss before tax	(65,397)	(1,478)	(66,875)
Statutory tax rate (blended at Group level)	7.8%	39.3%	8.5%
Income tax credit at statutory tax rates	(5,123)	(581)	(5,704)
Tax impact of permanent differences	577	225	802
Temporary differences not recognized as deferred tax assets	–	407	407
Tax on losses not recognized as deferred tax assets	4,546	–	4,546
Effective income tax expense	**–**	**51**	**51**
Effective tax rate	0%	3.5%	0.1%

17. Loss per share

As of December 31, 2018 and 2017, the Company has one category of shares, which are common shares. As of December 31, 2016, the Company's shares were comprised of ordinary shares, consisting of both common shares and non-voting shares, and series A and series B preferred shares. The Company's non-voting shares and series A and series B preferred shares were converted into common shares upon the closing of the IPO on January 25, 2017.

For the year ended December 31, 2016, as the series A and series B preferred shares participated with ordinary shares in the profit or loss on a pro-rata basis, the net loss was allocated to each class pro-rata to their weighted average number of shares outstanding during the period.

The basic loss per share is calculated by dividing the loss of the period attributable to the ordinary shares by the weighted average number of ordinary shares (common and non-voting) outstanding during the period as follows:

	Year ended December 31, 2018
	Common shares
Net loss attributable to shareholders (in USD ,000)	(76,716)
Weighted average number of shares outstanding	40,172,498
Basic and diluted loss per share (in USD)	**(1.91)**

	Year ended December 31, 2017
	Common shares
Net loss attributable to shareholders (in USD ,000)	(66,926)
Weighted average number of shares outstanding	29,799,047
Basic and diluted loss per share (in USD)	**(2.25)**

	Year ended December 31, 2016		
	Preferred B shares	**Preferred A shares**	**Common and non-voting shares**
Net loss attributable to shareholders (in USD ,000)	(15,516)	(10,910)	(3,776)
Weighted average number of shares outstanding	11,079,549	7,790,475	2,695,898
Basic and diluted loss per share (in USD)	**(1.40)**	**(1.40)**	**(1.40)**

For the year ended December 31, 2018, 430,625 non-vested shares and 3,028,275 shares issuable upon the exercise of stock-options, which would have an anti-dilutive impact on the calculation of the diluted earnings per share, were excluded from the calculation. For the year ended December 31, 2017, 778,134 non-vested shares and 1,866,740 shares issuable upon the exercise of stock-options were excluded. For the year ended December 31, 2016, 1,237,662 non-vested shares and no shares issuable upon the exercise of stock-options were excluded.

18. Share-based compensation

The total expenses arising from share-based payment transactions recognized during the period as part of staff costs were as follows:

	Year ended December 31,		
	2018	**2017**	**2016**
	(in USD ,000)	(in USD ,000)	(in USD ,000)
Employee 2013 EIP	2,242	5,497	2,237
Employee 2017 EIP	6,910	3,359	–
Total share-based compensation	**9,152**	**8,856**	**2,237**

Employee equity incentive plan 2013

The Company established the 2013 EIP for employees, executives, directors and consultants (the "Beneficiaries") of the Group.

Upon enrollment in the 2013 EIP, Beneficiaries were granted a certain number of shares which they were entitled to acquire at a pre-determined price of 1/13 of a Swiss franc. The pre-determined price was generally paid by the Beneficiaries at the grant date and recognized as a pre-payment until the vesting period elapses resulting in the shares issuance being accounted for.

The shares generally fully vest over a four-year vesting period, with 25% of the shares underlying the grant vesting after one year, and 1/48th of the shares underlying the grant vesting each month over a further period of three years.

The Group has no present obligation to repurchase or settle the shares in cash.

	2018	**2017**	**2016**
Number of shares issued under the 2013 EIP	347,509	454,548	264,524
Average grant date fair value (in USD)	–	–	11.37
Expense arising from the 2013 EIP (in USD ,000)	2,242	5,497	2,237

The fair value of the shares was calculated using a combination of the discounted cash flow method, under the income approach, and the backsolve method. The income approach estimates value based on the expectation of future cash flows that the Company will generate, such as cash earnings, costs savings, tax deduction and the proceeds from disposition. These future cash flows were discounted to their present values using a discount rate derived based on an analysis of the cost of capital of comparable publicly traded companies in similar lines of business, as of each valuation date, and was adjusted to reflect the risks inherent in the Company's cash flows. The backsolve method, a form of the market approach to valuation, derives the implied enterprise equity value and the fair value of the non-voting share from a recent and contemporaneous transaction involving the Company's own securities, using the following assumptions: rights and preferences of the different categories of shares, probability of various liquidity event scenarios, expected timing of a liquidity event, volatility and expected value in a liquidity event.

The Group has stopped granting equity instruments under the 2013 EIP in 2016.

Employee equity incentive plan 2017

The Company established in 2017 the 2017 EIP for Beneficiaries of the Group, under which 1,317,420 and 1,866,740 stock-options were granted during the year ended December 31, 2018 and 2017, respectively. The stock-options 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.

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

	Average exercise price	Number of options	Average exercise price	Number of options
	(USD)		(USD)	
At January 1,	9.19	1,866,740	–	–
Granted	13.98	1,317,420	9.19	1,866,740
Forfeited	6.98	(60,000)	–	–
Exercised	7.01	(95,885)	–	–
At December 31,	**11.39**	**3,028,275**	**9.19**	**1,866,740**

The weighted average share price at the date of exercise of options exercised during the year ended December 31, 2018 was USD 13.04.

The outstanding stock-options have the following range of exercise prices and remaining contractual life:

	As at December 31,	
Range of exercise prices	**2018**	**2017**
USD 15.00 to USD 17.99	361,500	136,500
USD 12.00 to USD 14.99	1,109,370	31,950
USD 9.00 to USD 11.99	1,185,905	1,173,290
USD 6.00 to USD 8.99	371,500	525,000
Total outstanding options	**3,028,275**	**1,866,740**
out of which are exercisable	447,538	46,708
Weighted-average remaining contractual life (in years)	9.2	9.7

The weighted average fair value of the stock-options granted during the years ended December 31, 2018 and 2017, determined using a Black-Scholes model was USD 13.98 and USD 6.98, respectively. The significant inputs to the model were:

	2018	2017
Weighted average share price at grant date	USD 13.98	USD 9.19
Weighted average exercise price	USD 13.98	USD 9.19
Weighted average 10-year volatility	65%	58%
Dividend yield	0%	0%
Weighted average 10-year risk free rate	3.06%	2.35%

Since the Company has a short track record as a public company, expected volatility has been determined based on the his-

torical trend of an appropriate sample of public companies operating in the biotech and pharmaceutical industry.

19. Commitments and contingencies

Operating lease commitments

	As at December 31,	
	2018	**2017**
	(in USD ,000)	(in USD ,000)
Within 1 year	705	535
Later than 1 year and no later than 5 years	2,369	2,145
Later than 5 years	–	144
Total	**3,074**	**2,824**

Operating lease commitments relate to the Group's lease for its headquarters in Geneva, Switzerland and its subsidiary's lease in Boston, Massachusetts, USA.

Contingencies

As a result of the licenses granted to the Group, the following contingencies are to be noted:

Kissei license

Under the terms of the license and supply agreement, the Group would be obligated to make milestone payments upon the achievement of specified regulatory milestones with respect to linzagolix. The total of all potential undiscounted future payments that the Group could be required to make under this arrangement ranges between USD 0 and USD 188 million, of which USD 5 million have already been paid.

Pursuant to the Kissei license and supply agreement, the Group has agreed to exclusively purchase the active pharmaceutical ingredient for linzagolix from Kissei. During the development stage, the Group is obligated to pay Kissei a specified supply price. Following the first commercial sale of licensed product, the Group is obligated to pay Kissei a royalty payment in the low twenty percent range as a percentage of net sales, which includes payment for Kissei's supply of the active pharmaceutical ingredient until the latest of the date that the valid claim of a patent for the product has expired, the expiration of our regulatory exclusivity period or 15 years from the first commercial sale of such product on a country-by-country and product-by-product basis.

Merck Serono licenses

Under the terms of the two license agreements with Merck Serono for nolasiban and OBE022, the Group would be obligated to pay Merck Serono a high-single digit and a mid-single digit royalty, respectively, of net sales generated by the Group, its affiliates or sub-licensees of any product containing the in-licensed compounds.

20. Related parties transactions

As of December 31, 2018, the Group's related parties include key management (Board of Directors and Executive Committee) and members of their immediate families. The following transactions were carried out with related parties:

Key management remuneration

The Board of Directors is composed of 8 members, whereas the Executive Committee is composed of 7 members. The following table sets forth the total remuneration recorded for members of the Board of Directors and Executive Committee:

	Year ended December 31,	
	2018	**2017**
	(in USD ,000)	(in USD ,000)
Short-term employee benefits (including base and variable cash remuneration)	4,150	3,403
Post-employment benefits	117	135
Share-based payments	6,125	6,451
Total	**10,392**	**9,989**

Other transactions with related parties

There were no other significant transactions with related parties during the years presented.

21. Going concern

The Group fulfills its obligations by the use of its cash reserves. The Board of Directors believes the Group will be able to meet all of its obligations for a further 12 months as they fall due and, hence, the consolidated financial statements have been prepared on a going concern basis.

22. Events after the reporting period

There were no material events after the balance sheet date.

Report from the Auditor on the Consolidated IFRS Financial Statements

Report of the statutory auditor
to the General Meeting of ObsEva SA
Plan-les-Ouates

Report on the audit of the consolidated financial statements

Opinion

We have audited the consolidated financial statements of ObsEva SA and its subsidiaries (the Group), which comprise the consolidated balance sheet as at 31 December 2018 and the consolidated statement of comprehensive loss, consolidated statement of cash flows and consolidated statement of changes in equity for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying consolidated financial statements give a true and fair view of the consolidated financial position of the Group as at 31 December 2018 and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with the International Financial Reporting Standards (IFRS) and comply with Swiss law.

Basis for opinion

We conducted our audit in accordance with Swiss law, International Standards on Auditing (ISAs) and Swiss Auditing Standards. Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the consolidated financial statements" section of our report.

We are independent of the Group in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession, as well as the IESBA Code of Ethics for Professional Accountants, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our audit approach

Overview

Overall Group materiality: USD 772,000

We performed full scope audit work at the Group's Swiss entity, and specified procedures at the Group's entity in the Unites States of America. Our audit scope addressed 100% of the Group's total operating expenses and total assets.

As a key audit matter the following area of focus has been identified:

Carrying value of intangible assets

Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the consolidated financial statements. In particular, we considered where subjective judgements were made; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the consolidated financial statements as a whole, taking into account the structure of the Group, the accounting processes and controls, and the industry in which the Group operates.

The Group is comprised of three entities located in three different countries, namely Switzerland, the United States of America (US) and Ireland (inactive). The Group financial statements are a consolidation of these three entities, comprising the Group's operating business and centralised functions. Based on the client's operations we have performed full scope audit work on the Swiss entity, and specified procedures on the US entity.

Materiality

The scope of our audit was influenced by our application of materiality. Our audit opinion aims to provide reasonable assurance that the consolidated financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the consolidated financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall Group materiality for the consolidated financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate, on the consolidated financial statements as a whole.

Overall Group materiality	USD 772,000
How we determined it	1% of total expenses
Rationale for the materiality benchmark applied	Profit before tax is not considered an appropriate benchmark as the Group is a start-up still in the developmental phase, and has no recurring revenue. Based on the nature of the Group we determined total expenses as the most appropriate benchmark, applying a 1% rule of thumb.

We agreed with the Audit Committee that we would report to them misstatements above USD 77,000 identified during our audit as well as any misstatements below that amount which, in our view, warranted reporting for qualitative reasons.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Carrying value of intangible assets

Key audit matter	How our audit addressed the key audit matter
The Group has intangible assets totaling USD 21.6 million at December 31, 2018 comprised of licenses to operate several biopharmaceutical product candidates. The Group is required to review its intangibles for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable, and at least annually. As part of such review, the Group did not identify any impairment. We focused on the carrying value of intangible assets as these assets are significant to the Group and relate to licenses that haven't yet received regulatory and marketing approvals. The assessment of the carrying value of intangible assets is dependent on future cash flows expected to be derived from the successful development and commercialization of the various biopharmaceutical product candidates. The assessment performed by the Group contains a number of significant judgments and estimates such as determining the probabilities of achieving development milestones based on industry standards, expected market share, life of the assets, and the discount rate, and contains risk of management bias. Refer to Note 2 Accounting principles applied in the preparation of the consolidated financial statements (page 101) and Note 8 Intangible assets (page 110).	We assessed factors that could trigger indications that a potential impairment may exist by performing a review of the minutes of Management, Board of Directors and Board Committee meetings, inquiry with Management concerning the ongoing results of clinical trials, external communications, including press releases and other public filings, public communications coming from direct competitors, and consideration of the results of subsequent event procedures performed. We assessed the reasonableness of the valuation model used by management to determine the recoverable amounts of the intangible assets, and reviewed the consistency of the current-year's significant assumptions with prior periods. We assessed management's sensitivity analysis around key estimates to quantify the changes in assumptions that could result in an impairment and the disclosures included in Note 8 Intangible assets (page 110) of the annual report. We reviewed management's assessment on each of the qualitative factors, including those associated with timely and successful completion of clinical trials and subsequent approval, and corroborated management's explanation to the underlying documentation and market information. On the basis of the above procedures performed we did not identify any triggering event that would potentially challenge the Group's carrying value of intangible assets, nor did we identify any factors that would indicate any management bias existed in the significant assumptions used. As such, we found the assessment made by the Group, in its determination that no impairment existed in the carrying value of intangible assets, was based upon reasonable assumptions, consistently applied.

Other information in the annual report

The Board of Directors is responsible for the other information in the annual report. The other information comprises all information included in the annual report, but does not include the consolidated financial statements, the stand-alone financial statements and the remuneration report of ObsEva SA and our auditor's reports thereon.

Our opinion on the consolidated financial statements does not cover the other information in the annual report and we do not express any form of assurance conclusion thereon.

In connection with our audit of the consolidated financial statements, our responsibility is to read the other information in the annual report and, in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Directors for the consolidated financial statements

The Board of Directors is responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with IFRS and the provisions of Swiss law, and for such internal control as the Board of Directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the Board of Directors is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the consolidated financial statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Swiss law, ISAs and Swiss Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with Swiss law, ISAs and Swiss Auditing Standards, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Board of Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the Group audit. We remain solely responsible for our audit opinion.

We communicate with the Board of Directors or its relevant committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board of Directors or its relevant committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors or its relevant committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on other legal and regulatory requirements

In accordance with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists which has been designed for the preparation of consolidated financial statements according to the instructions of the Board of Directors.

We recommend that the consolidated financial statements submitted to you be approved.

PricewaterhouseCoopers SA

Michael Foley
Audit expert
Auditor in charge

Filippos Mintiloglitis
Audit expert

Genève, 5 March 2019

Enclosure:

- Consolidated financial statements (consolidated balance sheet, consolidated statement of comprehensive loss, consolidated statement of cash flows, consolidated statement of changes in equity and notes to the consolidated financial statements)

Statutory Financial Statements of ObsEva SA

Statutory Financial Statements of ObsEva SA for the year ended December 31, 2018

Balance Sheet as at December 31,

	Notes	2018 (in USD)	2017 (in USD)	2018 (in CHF)	2017 (in CHF)
ASSETS					
Current assets					
Cash and cash equivalents		138,237,935	110,389,709	136,164,366	107,663,084
Other current receivables		879,225	782,795	866,038	763,460
Other current receivables – Group Comp.		–	4,657	–	4,542
Deferred costs and prepaid expenses		5,672,840	1,480,917	5,587,747	1,444,338
Total current assets		**144,790,000**	**112,658,078**	**142,618,151**	**109,875,424**
Non-current assets					
Financial assets	4	191,692	109,168	188,816	106,472
Investments	5	3	3	3	3
Property, plant and equipment	6	154,246	114,927	151,932	112,088
Intangible assets	7	19,503,378	19,503,378	19,210,827	19,021,644
Total non-current assets		**19,849,319**	**19,727,476**	**19,551,578**	**19,240,207**
Total assets		**164,639,319**	**132,385,554**	**162,169,729**	**129,115,631**
LIABILITIES & SHAREHOLDERS' EQUITY					
Current liabilities					
Trade payables		2,350,655	2,380,361	2,315,395	2,321,566
Other current liabilities		266,358	266,358	262,363	259,779
Other current liabilities - Group Comp.		235,370	–	231,839	–
Accrued expenses		13,725,727	6,128,585	13,519,841	5,977,209
Total current liabilities		**16,578,110**	**8,775,304**	**16,329,438**	**8,558,554**
Shareholders' equity					
Share capital		3,586,269	2,927,319	3,498,373	2,856,251
Treasury shares		(130,584)	(967)	(123,408)	(783)
Legal reserve from capital contribution		300,586,132	208,769,597	296,136,491	205,865,074
Accumulated deficit		(155,980,608)	(88,085,699)	(153,671,165)	(88,163,465)
Total shareholders' equity	10	**148,061,209**	**123,610,250**	**145,840,291**	**120,557,077**
Total liabilities & shareholders' equity		**164,639,319**	**132,385,554**	**162,169,729**	**129,115,631**

Plan les Ouates, March 5, 2019

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

Statement of Loss for the year ended December 31,

	2018 (in USD)	2017 (in USD)	2018 (in CHF)	2017 (in CHF)
INCOME				
Other income	15,198	15,978	14,862	15,733
Total income	**15,198**	**15,978**	**14,862**	**15,733**
OPERATING EXPENSES				
Staff costs	(8,705,747)	(7,787,412)	(8,513,278)	(7,668,202)
External research and development costs	(49,480,468)	(43,267,909)	(48,386,537)	(42,605,563)
Patent costs	(1,002,140)	(426,432)	(979,984)	(419,904)
Professional fees	(3,442,277)	(2,682,615)	(3,366,174)	(2,641,550)
Professional fees – Group Companies	(2,973,751)	(2,045,379)	(2,908,007)	(2,014,068)
Facilities	(567,361)	(476,960)	(554,817)	(469,659)
Other operating expenses	(2,036,147)	(2,023,048)	(1,991,131)	(1,992,080)
Depreciation	(60,725)	(51,219)	(59,382)	(50,435)
Total operating expenses	**(68,268,616)**	**(58,760,974)**	**(66,759,311)**	**(57,861,461)**
OPERATING LOSS	**(68,253,418)**	**(58,744,996)**	**(66,744,449)**	**(57,845,728)**
Finance income	358,509	708,869	350,583	698,017
Finance expense	–	(893)	–	(879)
NET LOSS BEFORE TAX	**(67,894,909)**	**(58,037,020)**	**(66,393,865)**	**(57,148,590)**
Income tax expense	–	–	–	–
NET LOSS FOR THE PERIOD	**(67,894,909)**	**(58,037,020)**	**(66,393,865)**	**(57,148,590)**

Plan les Ouates, March 5, 2019

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

Notes to the Financial Statements 2018

1. General information

ObsEva Ltd was founded on November 14, 2012 in Geneva, Switzerland, and is domiciled 12 chemin des Aulx, 1228 Plan-les-Ouates. The purpose of the Company is all activities and services in the domains of research, development, fabrication, registration, promotion and commercialization of biotechnological and pharmaceutical products.

2. Accounting principles applied in the preparation of the financial statements

These financial statements have been prepared in accordance with the provisions of commercial accounting as set out in the Swiss Code of Obligations (Art. 957 to 963b CO, effective since January 1, 2013). Significant balance sheet items are accounted for as follows:

- Current assets
  Other current receivables are carried at their nominal value. Impairment charges are calculated for these assets on an individual basis.

- Non-current assets
  Property, plant and equipment is carried at cost less depreciation. Depreciation is calculated using the straight-line method, on the basis of the following useful lives:
  - furniture 5 years
  - hardware 3 years
  - leasehold improvement duration of lease

  Property, plant and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable, on an individual basis. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount.

- Recognition of income
  Income is recognised if its amount can be reliably measured and it is sufficiently probable that the economic benefits will flow to the company.

- Foreign currencies
  Monetary and non-monetary items in foreign currency are translated into the company functional currency as follows:
  - the exchange rates used for balance sheet items are the rates prevailing on 31 December;
  - the exchange rates used for transactions conducted during the course of the year and for items in the profit and loss statement are the exchange rates prevailing at the dates of the transactions or valuations where items are re-measured.

The functional currency of ObsEva SA is the US dollar (USD). Values in Swiss franc presented in accordance with Art. 958d of the Swiss code of Obligations were converted from the functional currency as follows:

	USD/CHF prevailing rate	USD/CHF rate used for year ended December 31, 2018	USD/CHF rate used for year ended December 31, 2017
Statement of loss	BNS average rate for the period	0.977892	0.984692
Shareholders' equity	Historical rates	–	–
Balance sheet, other line items	BNS rate as of December 31	0.985000	0.975300

All resulting exchange differences were reported as currency translation differences in equity.

3. Full-time positions

The company employed on average 33.3 full-time equivalents (FTE) in 2018 (2017: 28.7 FTE) and 37.2 FTE as at December 31, 2018 (December 31, 2017: 31.7 FTE).

4. Pledges on assets to secure own liabilities

	2018	December 31, 2017	2018	December 31, 2017
	(in USD)	(in USD)	(in CHF)	(in CHF)
Escrow accounts	191,692	109,168	188,816	106,472
Total	**191,692**	**109,168**	**188,816**	**106,472**

As at December 31, 2018, USD 191,692 (CHF 188,816) were held on escrow accounts as security rental deposits (December 31, 2017: USD 109,168 (CHF 106,472)).

5. Investments

ObsEva SA owned as at December 31, 2018:

Company	Business	Capital	Interest in capital	Voting rights
ObsEva Ireland Ltd, Cork, Ireland	Research and development	EUR 2.00	100%	100%
ObsEva USA Inc., New York, USA	Research and development	USD 0.50	100%	100%

Recognized in the balance sheet as follows:

	December 31, 2018	December 31, 2017	2018	December 31, 2017
	(in USD)	(in USD)	(in CHF)	(in CHF)
Shareholding ObsEva Ireland Ltd	2	2	2	2
Shareholding ObsEva USA Inc	1	1	1	1
Total	**3**	**3**	**3**	**3**

6. Property, plant and equipment

	Furniture	Hardware	Leasehold improvement	Total
	(in USD)	(in USD)	(in USD)	(in USD)
Net book value as at 1st Jan. 18	45,183	29,806	39,938	114,927
Additions	26,828	51,714	21,502	100,044
Depreciation charge	(16,052)	(23,909)	(20,764)	(60,725)
Net book value as at 31 Dec. 18	**55,959**	**57,611**	**40,676**	**154,246**
Total cost	104,121	141,368	122,402	367,891
Accumulated depreciation	(48,162)	(83,757)	(81,726)	(213,645)

	Furniture	Hardware	Leasehold improvement	Total
	(in USD)	(in USD)	(in USD)	(in USD)
Net book value as at 1st Jan. 17	43,802	29,080	48,285	121,167
Additions	15,256	18,175	11,548	44,979
Depreciation charge	(13,875)	(17,449)	(19,895)	(51,219)
Net book value as at 31 Dec. 17	**45,183**	**29,806**	**39,938**	**114,927**
Total cost	77,293	89,654	100,900	267,848
Accumulated depreciation	(32,110)	(59,848)	(60,962)	(152,921)

	Furniture	Hardware	Leasehold improvement	Total
	(in CHF)	(in CHF)	(in CHF)	(in CHF)
Net book value as at 1st Jan. 18	44,066	29,070	38,952	112,088
Additions	26,235	50,571	21,026	97,832
Currency translation difference	515	486	393	1,394
Depreciation charge	(15,697)	(23,380)	(20,305)	(59,382)
Net book value as at 31 Dec. 18	**55,119**	**56,747**	**40,066**	**151,932**
Total cost	102,559	139,247	120,566	362,372
Accumulated depreciation	(47,440)	(82,500)	(80,500)	(210,440)

	Furniture	Hardware	Leasehold improvement	Total
	(in CHF)	(in CHF)	(in CHF)	(in CHF)
Net book value as at 1st Jan. 17	44,503	29,545	49,058	123,106
Additions	15,022	17,897	11,371	44,290
Currency translation difference	(1,796)	(1,190)	(1,887)	(4,873)
Depreciation charge	(13,663)	(17,182)	(19,590)	(50,435)
Net book value as at 31 Dec. 17	**44,066**	**29,070**	**38,952**	**112,088**
Total cost	75,383	87,440	98,408	261,231
Accumulated depreciation	(31,317)	(58,370)	(59,456)	(149,143)

7. Intangible assets

As at December 31, 2018 the company holds a number of licenses to operate several pharmaceutical compounds, which were acquired for USD 19,503,378 (CHF 19,210,827) (31 December 2017: USD 19,503,378 (CHF 19,021,645)).

On April 25, 2017, the company announced the initiation of a Phase 3 clinical trial for one of its development program, triggering, as part of its contractual obligations under the terms of a license agreement, the recognition and payment of a USD 5.0 million milestone to its licensor.

8. Amounts due to pension funds

As at December 31, 2018, amounts due to pension funds amounted to USD 256,944 (CHF 253,090) (December 31, 2017: USD 217,497 (CHF 212,125)).

9. Lease commitments not reported in the balance sheet

Operating lease commitments (including rent costs)

	December 31, 2018	December 31, 2017	2018	December 31, 2017
	(in USD)	(in USD)	(in CHF)	(in CHF)
Within 1 year	458,762	292,730	451,881	285,499
Later than 1 year and no later than 5 years	1,605,697	1,169,205	1,581,611	1,140,325
Later than 5 years	–	144,053	–	140,495
Total	**2,064,459**	**1,605,988**	**2,033,492**	**1,566,319**

10. Shareholders' equity

	Share capital	Legal reserve from capital cont.	Accumulated deficit	Shareholders' equity
	(in USD)	(in USD)	(in USD)	(in USD)
January 1, 2018	2,926,352	208,769,597	(88,085,699)	123,610,250
Issuance of shares – Follow-on offering (incl. Green-shoe)	391,601	77,431,335	–	77,822,936
Issuance of shares – ATM offering	130,303	19,880,675	–	20,010,978
Costs of share issuance – Follow-on	–	(5,552,419)	–	(5,552,419)
Costs of share issuance – ATM	–	(608,170)	–	(608,170)
Stock-option exercise	7,429	665,114	–	672,543
Net loss for the year	–	–	(67,894,909)	(67,894,909)
December 31, 2018	**3,455,685**	**300,586,132**	**(155,980,608)**	**148,061,209**

	Share capital	Non-voting share capital	Legal reserve from capital cont.	Accumulated deficit	Shareholders' equity
	(in USD)	(in USD)	(in USD)	(in USD)	(in USD)
January 1, 2017	1,690,810	147,739	65,071,469	(30,048,679)	36,861,339
Issuance of shares – IPO	496,193	–	96,253,807	–	96,750,000
Issuance of shares – PIPE	592,010	–	59,407,990	–	60,000,000
Costs of share issuance – IPO	–	–	(8,221,149)	–	(8,221,149)
Costs of share issuance – PIPE	–	–	(3,742,520)	–	(3,742,520)
Repurchase of non-voting shares	–	(400)	–	–	(400)
Conversion of non-voting shares	147,339	(147,339)	–	–	–
Net loss for the year	–	–	–	(58,037,020)	(58,037,020)
December 31, 2017	**2,926,352**	**–**	**208,769,597**	**(88,085,699)**	**123,610,250**

	Share capital	Legal reserve from capital cont.	Accumulated deficit	Shareholders' equity
	(in CHF)	(in CHF)	(in CHF)	(in CHF)
January 1, 2018	2,855,468	205,865,074	(88,163,465)	120,557,077
Issuance of shares – Follow-on offering (incl. Green-shoe)	388,979	76,912,867	–	77,301,846
Issuance of shares – ATM offering	123,143	18,788,232	–	18,911,375
Costs of share issuance – Follow-on	–	(5,515,241)	–	(5,515,241)
Costs of share issuance – ATM	–	(574,751)	–	(574,751)
Stock-option exercise	7,375	660,310	–	667,685
Currency translation differences	–	–	886,165	886,165
Net loss for the year	–	–	(66,393,865)	(66,393,865)
December 31, 2018	**3,374,965**	**296,136,491**	**(153,671,165)**	**145,840,291**

	Share capital	Non-voting share capital	Legal reserve from capital cont.	Accumulated deficit	Shareholders' equity
	(in CHF)	(in CHF)	(in CHF)	(in CHF)	(in CHF)
January 1, 2017	1,640,520	142,254	63,592,444	(27,924,098)	37,451,120
Issuance of shares – IPO	496,154	–	96,246,242	–	96,742,396
Issuance of shares – PIPE	576,923	–	57,894,037	–	58,470,960
Costs of share issuance – IPO	–	–	(8,220,503)	–	(8,220,503)
Costs of share issuance – PIPE	–	–	(3,647,146)	–	(3,647,146)
Repurchase of non-voting shares	–	(383)	–	–	(383)
Currency translation differences	–	–	–	(3,090,777)	(3,090,777)
Conversion of non-voting shares	141,871	(141,871)	–	–	–
Net loss for the year	–	–	–	(57,148,590)	(57,148,590)
December 31, 2017	**2,855,468**	**–**	**205,865,074**	**(88,163,465)**	**120,557,077**

Outstanding Share Capital and Non-Voting Share Capital

As at December 31, 2018, the total outstanding share capital of USD 3,455,685 (CHF 3,374,965), fully paid, consists of 45,477,137 common shares, less 1,602,601 shares held by the company as treasury shares. All shares have a nominal value of 1/13 of a Swiss franc.

As at December 31, 2017, the total outstanding share capital of USD 2,926,352 (CHF 2,855,468), fully paid, consists of 37,131,262 common shares, less 10,183 shares held by the company as treasury shares. All shares have a nominal value of 1/13 of a Swiss franc.

All company's non-voting shares, series A preferred shares and series B preferred shares were converted into common shares upon the closing of the company's initial public offering (IPO) in January 2017.

Significant Changes in Shareholders' Equity

On January 30, 2017, the Company completed an IPO and issued 6,450,000 common shares at a subscription price of USD 15.00 per share and a par value of 1/13 of a Swiss franc per share. The gross proceeds of USD 96,750,000 (CHF 96,742,396) have been recorded in equity net of directly related share issuance costs of USD 8,221,149 (CHF 8,220,503).

On October 13, 2017, the Company completed a private placement with institutional investors and issued 7,500,000 common shares at a subscription price of USD 8.00 per share and a par value of 1/13 of a Swiss franc per share. The gross proceeds of USD 60,000,000 (CHF 58,470,960) have been recorded in equity net of directly related share issuance costs of USD 3,742,520 (CHF 3,647,146).

On March 16, 2018, the Company issued 3,499,990 common shares at par value of 1/13 of a Swiss franc per share. The shares were subscribed by the Company and are held as treasury shares, hence the operation did not impact the share capital.

On May 17 and 25, 2018, the Company sold 1,000,851 and 600,000 treasury shares, respectively, at a price of USD 12.50 per share, from its "at the market" (ATM) program, generating gross proceeds of USD 20,010,978 (CHF 18,911,375). Directly related share issuance costs of USD 608,170 (CHF 574,751) were recorded as a deduction in equity.

On June 22, 2018, the Company completed an underwritten public offering of 4,750,000 common shares at a price of USD 15.39 per share, with an option to issue to an additional 712,500 common shares (the "follow-on offering"). The gross proceeds resulting from this transaction amounted to USD 73,102,500 (CHF 72,613,017). Subsequent to the initial closing of the follow-on offering, on July 19, 2018, the Company sold an additional 306,721 common shares for total gross proceeds of USD 4,720,436 (CHF 4,688,829). These shares were sold pursuant to the 30-day option granted in connection with the follow-on offering to purchase up to an additional 712,500 common shares ("green-shoe"). Directly related share issuance costs for the overall transaction (follow-on and green-shoe) amounted to USD 5,552,419 (CHF 5,515,241) and have been recorded as a deduction in equity

Treasury shares

The changes in the number of treasury shares owned by the company in 2018 and 2017 are as follows:

(number of treasury shares)	2018	2017
At January 1,	10,183	5,200
Sale of treasury shares	(1,907,572)	–
Purchase of treasury shares	3,499,990	4,983
At December 31,	**1,602,601**	**10,183**

11. Authorized capital and conditional capital

The authorized share capital and conditional share capital as at December 31, 2018 and December 31, 2017 are as follows:

	December 31, 2018	December 31, 2017
	(CHF)	(CHF)
Authorized share capital	1,197,355	–
Conditional share capital	1,562,740	710,097

12. Major shareholders

A list of our major shareholders is disclosed in the Corporate Governance section of this Annual Report (page 77).

13. Going concern

The company fulfills its obligations by the use of its cash reserves. The Board of Directors believes the company will be able to meet all of its obligations for a further 12 months as they fall due and, hence, the financial statements have been prepared on a going concern basis.

14. Events after the balance sheet date

There were no material events after the balance sheet date.

Report from the Auditor on the Statutory Financial Statements of ObsEva SA

Report of the statutory auditor
to the General Meeting of ObsEva SA
Plan-les-Ouates

Report on the audit of the financial statements

Opinion

We have audited the financial statements of ObsEva SA, which comprise the balance sheet as at 31 December 2018, statement of loss and notes for the year then ended, including a summary of significant accounting policies.

In our opinion, the accompanying financial statements as at 31 December 2018 comply with Swiss law and the company's articles of incorporation.

Basis for opinion

We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report.

We are independent of the entity in accordance with the provisions of Swiss law and the requirements of the Swiss audit profession and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our audit approach

Overview

Overall materiality: USD 683,000

We tailored the scope of our audit in order to perform sufficient work to enable us to provide an opinion on the financial statements as a whole, taking into account the structure of the entity, the accounting processes and controls, and the industry in which the entity operates.

As a key audit matter the following area of focus has been identified:

Carrying value of intangible assets

Audit scope

We designed our audit by determining materiality and assessing the risks of material misstatement in the financial statements. In particular, we considered where subjective judgements were made; for example, in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits, we also addressed the risk of management override of internal controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud.

Materiality

The scope of our audit was influenced by our application of materiality. Our audit opinion aims to provide reasonable assurance that the financial statements are free from material misstatement. Misstatements may arise due to fraud or error. They are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.

Based on our professional judgement, we determined certain quantitative thresholds for materiality, including the overall materiality for the financial statements as a whole as set out in the table below. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures and to evaluate the effect of misstatements, both individually and in aggregate, on the financial statements as a whole.

Overall materiality	USD 683,000
How we determined it	1% of total expenses
Rationale for the materiality benchmark applied	Profit before tax is not considered an appropriate benchmark as the entity is a start-up, still in the developmental phase, and has no recurring revenue. Based on the nature of the entity we determined total expenses as the most appropriate benchmark, applying a 1% rule of thumb.

We agreed with the Audit Committee that we would report to them misstatements above USD 68,000 identified during our audit as well as any misstatements below that amount which, in our view, warranted reporting for qualitative reasons.

Report on key audit matters based on the circular 1/2015 of the Federal Audit Oversight Authority

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Carrying value of intangible assets

Key audit matter	How our audit addressed the key audit matter
The entity has intangible assets totaling USD 21.6 million at December 31, 2018 comprised of licenses to operate several biopharmaceutical product candidates. The entity is required to review its intangibles for impairment whenever events or changes in circumstances indicate that their carrying amounts may not be recoverable, and at least annually. As part of such review, the entity did not identify any impairment. We focused on the carrying value of intangible assets as these assets are significant to the entity and relate to licenses that haven't yet received regulatory and marketing approvals. The assessment of the carrying value of intangible assets is dependent on future cash flows expected to be derived from the successful development and commercialization of the various biopharmaceutical product candidates. The assessment performed by the entity contains a number of significant judgments and estimates such as determining the probabilities of achieving development milestones based on industry standards, expected market share, life of the assets, and the discount rate, and contains risk of management bias. Refer to Note 2 Accounting principles applied in the preparation of the financial statements (page 135) and Note 7 Intangible assets (page 138).	We assessed factors that could trigger indications that a potential impairment may exist by performing a review of the minutes of Management, Board of Directors and Board Committee meetings, inquiry with Management concerning the ongoing results of clinical trials, external communications, including press releases and other public filings, public communications coming from direct competitors, and consideration of the results of subsequent event procedures performed. We assessed the reasonableness of the valuation model used by management to determine the recoverable amounts of the intangible assets, and reviewed the consistency of the current-year's significant assumptions with prior periods. We assessed management's sensitivity analysis around key estimates, to quantify the downside changes in assumptions that could result in an impairment. We reviewed management's assessment on each of the qualitative factors, including those associated with timely and successful completion of clinical trials and subsequent approval, and corroborated management's explanation to the underlying documentation and market information. On the basis of the above procedures performed we did not identify any triggering event that would potentially challenge the entity's carrying value of intangible assets, nor did we identify any factors that would indicate any management bias existed in the significant assumptions used. As such, we found the assessment made by the entity, in its determination that no impairment existed in the carrying value of intangible assets, was based upon reasonable assumptions, consistently applied.

Responsibilities of the Board of Directors for the financial statements

The Board of Directors is responsible for the preparation of the financial statements in accordance with the provisions of Swiss law and the company's articles of incorporation, and for such internal control as the Board of Directors determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Board of Directors is responsible for assessing the entity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the entity or to cease operations, or has no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Swiss law and Swiss Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with Swiss law and Swiss Auditing Standards, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made.
- Conclude on the appropriateness of the Board of Directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the entity to cease to continue as a going concern.

We communicate with the Board of Directors or its relevant committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the Board of Directors or its relevant committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Board of Directors or its relevant committee, we determine those matters that were of most significance in the audit of the financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, we determine that a matter should not be communicated in our report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on other legal and regulatory requirements

In accordance with article 728a paragraph 1 item 3 CO and Swiss Auditing Standard 890, we confirm that an internal control system exists which has been designed for the preparation of financial statements according to the instructions of the Board of Directors.

Furthermore, we draw attention to the fact that half of the share capital and legal reserves is no longer covered (article 725 para. 1 CO).

We recommend that the financial statements submitted to you be approved.

PricewaterhouseCoopers SA

Michael Foley
Audit expert
Auditor in charge

Filippos Mintiloglitis
Audit expert

Genève, 5 March 2019

Enclosure:

- Financial statements (balance sheet, statement of loss and notes)

Compensation Report of ObsEva SA

Compensation Report of ObsEva SA for the year ended December 31, 2018

A – GUIDING PRINCIPLES

The Company's articles of association (the "Articles"), organizational regulations and policies provide the basis for the principles of compensation (the "Compensation Policy"). The Board of Directors (the "Board") is responsible for establishing the Compensation Policy guidelines within the group.

The term "compensation" has the meaning set forth in Article 14 of the Ordinance, or any successor legislation, and includes, without limitation, salary, long-term incentives, bonuses, perquisites, equity incentives, severance arrangements (to the extent permitted by applicable law), retirement benefits and other related benefits and benefit plans.

The Company's Compensation Policy is designed to attract, motivate, and retain well-qualified employees and gain new, highly skilled staff, in order to support the achievement of the Company's strategic objectives. The compensation package must be fair and competitive, and the Company uses the services of a reputable, independent expert firm to assess the appropriateness of its compensation level and structure for the members of its Board (the "Board Members") and the members of its Executive Committee (the "Executive Officers"). The individual overall compensation takes into account the individual's professional skills, engagement and personal performance. It is made up of short-term compensation components, which are generally paid in cash, and long-term compensation components, generally in the form of a participation to an equity incentive plan.

B – ORGANISATION AND COMPETENCIES

Subject to the powers of the general meeting of shareholders, the Board determines the compensation of its members and of the Executive Officers in accordance with the Company's Compensation Policy, on the recommendation of the Compensation, Nominating and Corporate Governance Committee (the "Committee"). The Committee is composed of two or more members of the Board who have been individually elected by the general meeting of shareholders, for a term of one year, until the end of the next annual general meeting. If the Committee is not complete, the Board nominates the missing members for the remaining period of office. The Board elects the chair from the members of the Committee. Members of the Committee are eligible for re-election indefinitely.

The Committee supports the Board in establishing and reviewing the Company's compensation strategy, guidelines and the performance targets. The Committee may also submit proposals to the Board in other compensation-related issues. For a more detailed description of the Committee, please refer to section 3 of the Corporate Governance Report on page 88.

The Committee meets as often as necessary to fulfil its role, and at least once:

a) during the first semester of each business year, to review and make recommendations to the Board regarding the proposals to be made to the Annual General Meeting of Shareholders ("AGM") of such year, as required under Swiss law, regarding the maximum aggregate compensation, on a prospective basis, for (i) the Board Members for the period from the AGM of such year until the AGM of the following year and (ii) the Executive Officers for the following business year; and

b) during the fourth quarter of each business year, to review and make recommendations to the Board, based on the maximum aggregate compensation approved by the shareholders, regarding (i) the fixed cash compensation to be paid to the Board Members for the period from the AGM of the following business year until the following AGM; (ii) the variable cash compensation to be paid to the Executive Officers for the current business year; (iii) the fixed cash compensation to be paid to the Executive Officers for the following business year; (iv) the grant of equity instruments to the Board Members for the current business year as part of their fixed non-cash compensation; and (v) the grant of equity instruments to the Executive Officers for the current business year as part of their variable non-cash compensation.

The Board generally resolves on the recommendations of the Committee during the meeting of the Board which immediately follows the meeting of the Committee during which a recommendations was made.

As a principle, the Chief Executive Officer ("CEO") attends the meetings of the Committee and, as a Board Member, attends and votes during the meetings of the Board where the compensation of the Board Members and the compensation of the Executive Officers are discussed. However, discussions and decisions of the Board and of the Committee regarding the compensation of the CEO are resolved in his absence. The other Executive Officers do not attend the meetings of the Committee nor the parts of the meetings of the Board, where the compensation of the Board Members or the compensation of the Executive Officers are discussed.

Board Members, who are not members of the Committee, do not attend the meetings of the Committee, but take part to the meetings of the Board during which are discussed the compensation of the Board Members and the compensation of the Executive Officers as well as the vote relating thereto.

Maximum Aggregate Compensation subject to Shareholders' Approval

Based on the Committee's recommendations, the Board submits two proposals for approval at the shareholders meeting: (i) the maximum aggregate compensation for the Board Members until the next annual general meeting; and (ii) the maximum aggregate compensation for the Executive Officers for the following business year. The approval of these proposals requires an absolute majority (50% plus one) of the vote cast at the shareholders meeting. Specific procedures in case a proposal is not approved or for new hires to the executive committee are described in the Articles and are set forth under the "Rules in the Articles regarding Compensation of the Board Members and of the Executive Officers" section of this Compensation Report**.**

C – COMPENSATION COMPONENTS

Compensation Review Process of the Committee and General Philosophy
In its review process, the Committee considers compensation packages of other companies in the biotech and pharmaceutical industry that are comparable to ObsEva, with respect to size, listing place or business model, the professional experience and areas of responsibility of the respective members. Such benchmark is conducted by a reputable, independent expert firm which has not been awarded additional mandates by the Company, and is used to assess the appropriateness of the Company's compensation level and structure.

For the business year 2018, the peer groups used for benchmark purposes were composed of:

- 20 US public biotech or pharmaceutical companies: Acceleron Pharma, Aimmune Therapeutics, Alder Biopharmaceuticals, Ardelyx, Cara Therapeutics, Clearside Biomedical, Concert Pharmaceuticals, Corbus Pharmaceuticals, Epizyme, Global Blood Therapeutics, Intra-Cellular Therapies, Minerva Neurosciences, Myovant Sciences, Reata Pharmaceuticals, Revance Therapeutics, Savara, TG Therapeutics, Vital Therapies, XBiotech and Xencor; and
- 18 European public biotech or pharmaceutical companies: AC Immune, Adaptimmune Therapeutics, Argenx, Ascendis Pharma, Basilea Pharmaceutica, Cassiopea, CRISPR Therapeutics, DBV Technologies, Innate Pharma, Merus, Mithra Pharmaceuticals, Molecular Partners, Newron Pharmaceuticals, Nightstar Therapeutics, Nordic Nanovector, NuCana, UniQure and Zealand Pharma.

The Company is a leading biotech operating and listed in both Europe and the US and needs to attract and retain the best talents in order to ensure its strategic objectives. In this regard, the compensation philosophy is to target rewards approaching the 75th European market percentile for the annual cash compensation of the Executive Officers based in Switzerland, and the 75th US market percentile for the annual cash compensation of the Executive Officers based in the US, the annual cash compensation of the Board Members and the value of equity instruments granted to the Board Members and the Executive Officers.

Board of Directors Members Annual Cash Compensation
Each member of the Board who is not also serving as an employee of the Company or/and of its affiliates, receives an annual fixed cash compensation, payable in quarterly installments, as determined under the review process of the Committee and approved by the Board, as set forth below:

1 - Annual Board service retainer:
   a) Chairman of the Board USD 70,000
   b) All other eligible members of the Board USD 40,000
2 - Annual committee member service retainer:
   a) Member of the Audit Committee USD 7,500
   b) Member of the Compensation, Nominating and Corporate Governance Committee USD 7,500
3 - Annual committee chair service retainer (in addition to committee member service retainer)
   a) Chair of the Audit Committee USD 7,500
   b) Chair of the Compensation, Nominating and Corporate Governance Committee USD 7,500

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

In addition, the Company reimburses Board Members for out-of-pocket expenses incurred in relation to their services on an on-going basis upon presentation of the corresponding receipts. Expenses reimbursements are not part of the compensation.

Pursuant to organizational regulations of the Board, Board Members who are also serving as an employee of the Company or/and of its affiliates only receive compensation in their capacity as employees and do not receive additional compensation for their activities as members of the Board.

Executive Committee Members Annual Cash Compensation
The annual cash compensation of the Executive Officers consists of fixed and variable compensation elements.

Fixed compensation comprises the base salary and other compensation elements, as determined under the review process of the Committee and approved by the Board, and based on the position and level of responsibility of the recipient.

Variable compensation comprises performance-related cash bonuses that are based on target bonuses which could be of 30%, 35%, 40% or 50% of the base salary depending on the Executive Officer's position and level of responsibility, and as determined under the review process of the Committee and approved by the Board. Actual amount of cash bonus awarded for a specific year to an Executive Officer ranges from 50% to 150% of the target bonus for such Executive Officer. Adjustment rate applied to target bonus of an Executive Officer is determined at the end of every year based on the Company's general performance and the Executive Officer individual performance for the such business year, which performance is being assessed based on annual corporate and individual objectives. The Company doesn't use specific metrics to calculate the adjustment rates, which are determined at the sole and full discretion of the Committee and subject to Board approval. The average adjustment rate to target bonuses of Executive Officers was of 110% for the business year 2018 and of 112.5% for the business year 2017.

For both 2018 and 2017, on average, variable cash compensation represented 31% of the total cash compensation of the Executive Officers, or 45% of their fixed cash compensation.

Social contributions, to the extent required by Swiss law, are accrued on the annual cash compensation of the Executive Officers.

In addition, the Company reimburses the Executive Officers for out-of-pocket expenses incurred in relation to their services on an on-going basis upon presentation of the corresponding receipts. Expenses reimbursements are not part of the compensation.

Equity incentive plans
The Company has established two equity incentive plans, in 2013 (the "2013 EIP") and 2017 (the "2017 EIP").

The purpose of the Company's 2013 EIP and 2017 EIP is to provide Board Members, Executive Officers, employees and certain consultants (the "Beneficiaries") with an opportunity to benefit from the potential appreciation in the value of the Company's shares, thus providing an increased incentive for participants to contribute to the future success and prosperity of the Company, enhancing the value of the shares for the benefit of the shareholders of the Company and increasing the ability of the Company to attract and retain individuals of exceptional skill. In addition, these plans provide the Company with a mechanism to engage services for non-cash consideration.

Under 2013 EIP, the Company has granted the Beneficiaries non-voting shares that were converted into common shares upon completion of the Company's IPO in January 2017. The Company has stopped granting equity instruments under the 2013 EIP in 2016. Under 2017 EIP, the Company has been granting stock-options to the Beneficiaries.

The grant of equity instruments under 2013 EIP or 2017 EIP is at the discretion of the Board, which has delegated authority to the Committee and, collectively, the CEO and Chief Financial Officer ("CFO") to grant equity instruments under certain circumstances to new joiners that are not Board Members or Executive Officers, and subject to semi-annual reporting to the Committee when grants are approved by the CEO and CFO. The Board, the Committee or the CEO and CFO, depending on the delegation of competences, determine grant, vesting, exercise and forfeiture conditions. In particular, they may provide for continuation, acceleration or removal of vesting and exercise conditions, for payment or grant of compensation based upon assumed target achievement, or for forfeiture, in each case in the event of pre-determined events such as a change-of-control or termination of an employment or mandate agreement. Key factors considered by the Board when approving grants of equity instruments include the amount of outstanding authorized or conditional share capital approved by shareholders. The Company may procure the required shares through purchases in the market, either directly or through companies controlled by it, or by issuing new shares. The Board has the authority to amend 2013 EIP and 2017 EIP.

Annual grants of equity instruments to Board Members represent a fixed part of their compensation, whose value is determined under the review process of the Committee, based on peers group benchmark, and approved by the Board.

Annual grants of equity instruments to Executive Officers represent a variable part of their compensation, whose value is based on peers group benchmark as part of the review process of the Committee, subject to further adjustments based on individual performance of each Executive Officer. The Company doesn't use specific metrics to calculate such adjustments, which are determined at the sole and full discretion of the Committee and subject to Board approval. Equity instruments granted to Executive Officers under 2017 EIP include accelerated vesting conditions for the full unvested portion of such instruments in case of change of control.

Value of equity instruments granted in 2018 and 2017 represented approximately 75% and 80%, respectively, of the total compensation of the Board Members and 67% and 62%, respectively, of the total compensation of the Executive Officers.

Indirect benefits

The Company contributes to pension contributions and maintains certain insurance for death and invalidity for its Executive Officers in accordance with the regulations applicable to the pension schemes in which the Company or any of its subsidiary participate.

Loans, credits and guarantees

Subject to vote of the general meeting of shareholders on compensation proposals, which is binding, the Company does not grant loans or credit facilities to Board Members or Executive Officers.

Rules in the Articles regarding Compensation of the Board Members and of the Executive Officers

The Articles set forth the following rules regarding the Compensation of the Board Members and of the Executive Officers.

Article 32: Compensation Principles

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.

The Compensation of the Executive Officers consists of fixed and variable compensation elements. Fixed compensation comprises the base salary. Variable compensation may comprise short-term and long-term compensation elements. Short-term variable compensation elements shall be governed by performance metrics that take into account the performance of the Company and some or all of its subsidiaries, market performance, other companies or comparable benchmarks and/or individual quantitative and qualitative performance targets. Long-term variable compensation elements shall be governed by performance metrics that take into account strategic and/or financial objectives, as well as retention elements.

The determination of such performance metrics, the target levels as well as of their achievement is the responsibility of the Board or the Committee, to the extent delegated to it. The total compensation takes into account the position and level of responsibility of the Executive Officer.

Compensation may be paid in the form of cash or in the form of other types of benefits, including the grant of shares, stock options or other financial instruments. The Board or, to the extent delegated to it, the Committee have authority to determine grant, vesting, exercise and forfeiture conditions. In particular, they may provide for continuation, acceleration or removal of vesting and exercise conditions, for payment or grant of compensation based upon assumed target achievement, or for forfeiture, in each case in the event of pre-determined events such as a change-of-control or termination of an employment or mandate agreement. The Company may procure the required shares through purchases in the market, either directly or through companies controlled by it, or by issuing new shares.

Board Members and/or Executive Officers may participate in share purchase plans established by the Company or companies controlled by it, under the terms of which eligible employees may allocate a portion of their compensation to the purchase of shares of the Company at a discount to market price.

Compensation may be paid by the Company or companies controlled by it.

Reimbursement of expenses incurred by the Board Members and Executive Officers in their functions are not part of their compensation.

Article 33: Loans, credits and retirement benefits
Subject to other decision from the general meeting of shareholders, the Company is not allowed to grant loans or credit facilities to Board Members or Executive Officers.

Pension contributions and retirement benefits are made or provided in accordance with the regulations applicable to the pension schemes in which any Group company participates.

Article 34: Vote of the general meeting of shareholders on the compensation of the members of the Board and of the 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.

If the general meeting of shareholders does not approve a compensation proposal made by the Board, the Board has to convene an extraordinary general meeting of shareholders. Compensation may be paid out prior to their approval by the general meeting of shareholders, subject to their subsequent approval by the general meeting of shareholders and, in the absence of such subsequent approval, to restitution to the Company.

If the maximum aggregate amount of compensation already approved by the general meeting of shareholders is not sufficient to also cover the compensation of one or more persons who became members of the Executive Committee during a compensation period for which the general meeting of shareholders has already approved the compensation of the Executive Officers (new hire), the Company is authorized to pay an additional amount with respect to the compensation period already approved. Such additional amount cannot exceed (i) for the head of the Executive Committee (CEO), 140% of the total annual compensation of the former CEO and (ii) for any new hire other than the CEO, 140% of the highest total annual compensation of any member of the Executive Committee in office other than the CEO.

D – COMPENSATION FOR PERIODS UNDER REVIEW (audited)

The measurement basis for each component of compensation is as follows:

- Cash based-compensation: accrual basis;
- Social charges: accrual basis except for social charges on equity incentives which are estimated based on fair value at grant date;
- Indirect benefits: accrual basis;
- Equity incentives: total fair value at grant date as determined under IFRS 2.

Compensation of the Board Members for the financial years 2018 and 2017

The following table sets forth the name, year joined the Board, position and directorship term, as well as committee memberships, of each member of the Board:

Name	First Appointment	Elected until	Board	AC [1]	CNCGC [2]
Frank Verwiel	2016	2019	Chair	Member	–
Ernest Loumaye	2012	2019	Member, CEO	–	–
Annette Clancy	2013	2019	Member	–	Chair
Barbara Duncan	2016	2019	Member	Chair	–
Ed Mathers	2016	2019	Member	Member	–
Jim Healy	2013	2019	Member	–	Member
Rafaèle Tordjman	2013	2019	Vice-Chair	–	Member
Jacky Vonderscher	2013	2019	Member	–	–

[1] Audit Committee

[2] Compensation, Nominating and Corporate Governance Committee

The compensation received by the Board Members for the financial year 2018 in US dollars, and as converted in Swiss francs, was as follows:

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)
Frank Verwiel	76	27	–	240	343
Annette Clancy	54	22	–	240	316
Barbara Duncan	54	25	–	240	319
Ed Mathers	47	25	–	240	312
Jim Healy	47	25	–	240	312
Rafaèle Tordjman	47	25	–	240	312
Jacky Vonderscher	39	24	–	240	303
Total	**364**	**173**	**–**	**1,680**	**2,217**

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)
Frank Verwiel	78	28	–	245	351
Annette Clancy	55	22	–	245	322
Barbara Duncan	55	26	–	245	326
Ed Mathers	48	26	–	245	319
Jim Healy	48	26	–	245	319
Rafaèle Tordjman	48	26	–	245	319
Jacky Vonderscher	40	25	–	245	310
Total	**372**	**179**	**–**	**1,715**	**2,266**

[1] Include social charges on cash-based compensation and fair value of equity instruments granted
[2] Fair value of equity instruments granted during the period, as determined under IFRS2

The compensation received by the Board Members for the financial year 2017 in Swiss francs, and as converted in US dollars, was as follows:

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)
Frank Verwiel	76	34	–	296	406
Annette Clancy	54	26	–	235	315
Barbara Duncan	54	48	–	480	582
Ed Mathers	47	43	–	433	523
Jim Healy	47	43	–	433	523
Rafaèle Tordjman	26	29	–	301	356
Jacky Vonderscher	39	32	–	310	381
Total	**343**	**255**	**–**	**2,488**	**3,086**

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)
Frank Verwiel	78	35	–	301	414
Annette Clancy	55	26	–	239	320
Barbara Duncan	55	49	–	487	591
Ed Mathers	48	44	–	440	532
Jim Healy	48	44	–	440	532
Rafaèle Tordjman	26	29	–	306	361
Jacky Vonderscher	40	32	–	315	387
Total	**350**	**259**	**–**	**2,528**	**3,137**

[1] Include social charges on cash-based compensation and fair value of equity instruments granted
[2] Fair value of equity instruments granted during the period, as determined under IFRS2

Ernest Loumaye, who serves as Chief Executive Officer, was employee during the financial years 2017 and 2018 and received no additional compensation for his services as member of the Board.

The compensation of USD 2.3 million received by the Board Members in business year 2018 was made of fixed elements, and decreased by USD 0.9 million compared to the business year 2017 mainly due to a one-off grant of stock-options made to the Board Members in January 2017 upon closing of the Company's IPO.

The total compensation received by the Board Members during the period from the AGM 2017 until the AGM 2018 amounted to CHF 1.7 million, and was within the maximum aggregate compensation of CHF 2.0 million approved for the period by the AGM 2017.

Compensation of the Executive Committee for the financial years 2018 and 2017

The following table sets forth the name, position and year of appointment, of each Executive Officer:

Name	Function	Appointment
Ernest Loumaye	Chief Executive Officer	2013
Tim Adams	Chief Financial Officer	2017
Jean-Pierre Gotteland	Chief Scientific Officer and Head of R&D	2015
Wim Souverijns	Chief Commercial Officer	2018
Elke Bestel	Chief Medical Officer	2015
Ben T.G. Tan	V.P. Commercial & B.D.	2014
Fabien de Ladonchamps	V.P. Corporate Affairs & Finance	2013

The compensation received by the Executive Officers for the financial year 2018 in US Dollars, and as converted in Swiss francs, was as follows:

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)
Ernest Loumaye	824	288	22	2,961	4,095
Other executives	2,201	640	107	5,375	8,323
Total	**3,025**	**928**	**129**	**8,336**	**12,418**

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)
Ernest Loumaye	843	295	22	3,028	4,188
Other executives	2,251	653	111	5,496	8,511
Total	**3,094**	**948**	**133**	**8,524**	**12,699**

[1] Include social charges on cash-based compensation and fair value of equity instruments granted
[2] Fair value of equity instruments granted during the period, as determined under IFRS2

The compensation received by the Executive Officers for the financial year 2017 in Swiss francs, and as converted in US Dollars, was as follows:

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)	(in CHF ,000)
Ernest Loumaye	794	221	23	1,741	2,779
Other executives	2,089	584	109	4,413	7,195
Total	**2,883**	**805**	**132**	**6,154**	**9,974**

Name	Cash-based comp.	Social charges [1]	Pension contrib.	Equity granted [2]	Total comp.
	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)	(in USD ,000)
Ernest Loumaye	806	224	23	1,768	2,821
Other executives	2,121	593	111	4,482	7,307
Total	**2,927**	**817**	**134**	**6,250**	**10,128**

[1] Include social charges on cash-based compensation and fair value of equity instruments granted
[2] Fair value of equity instruments granted during the period, as determined under IFRS2

The compensation of USD 12.7 million received by the Executive Officers in business year 2018 was made of approximately 80% of variable elements and 20% of fixed elements, and increased by USD 2.6 million compared to business year 2017 mainly due to the hiring of Wim Souverijns as new Executive Officer and the related grant of 200,000 stock-options made to him upon joining in November 2018, as well as an increased value of the equity granted based on the Committee's review process of peers group benchmark.

The total compensation received by the Executive Officers for the year ended December 31, 2018 was within the maximum aggregate compensation of USD 13.0 million approved for the year by the AGM 2018.

E – SHARE OWNERSHIP INFORMATION (audited)

Board of Directors

The Board Members held the following equity instruments as of December 31, 2018 [1]:

Name	Common Shares			Stock-options		
	Vested	Unvested	Total	Vested	Unvested	Total
Frank Verwiel	26,000	19,500	45,500	18,276	44,864	63,140
Annette Clancy	83,958	13,542	97,500	14,123	42,517	56,640
Barbara Duncan	–	–	–	30,734	51,906	82,640
Ed Mathers [2]	4,586,563	–	4,586,563	27,540	50,100	77,640
Jim Healy [2]	4,749,623	–	4,749,623	27,540	50,100	77,640
Rafaèle Tordjman	–	–	–	23,373	54,267	77,640
Jacky Vonderscher	30,442	5,958	36,400	19,234	45,406	64,640
Total	**9,476,586**	**39,000**	**9,515,586**	**160,820**	**339,160**	**499,980**

[1] excluding Ernest Loumaye, CEO, whose holdings are listed under Executive Committee
[2] includes shares held directly and indirectly through vehicles controlled by the Director

The members of the Board held the following equity instruments as of December 31, 2017 [1]:

Name	Common Shares			Stock-options		
	Vested	Unvested	Total	Vested	Unvested	Total
Frank Verwiel	14,625	30,875	45,500	4,736	33,834	38,570
Annette Clancy	67,708	29,792	97,500	2,750	29,320	32,070
Barbara Duncan	–	–	–	10,694	47,376	58,070
Ed Mathers [2]	4,586,563	–	4,586,563	9,167	43,903	53,070
Jim Healy [2]	4,749,623	–	4,749,623	9,167	43,903	53,070
Rafaèle Tordjman	–	–	–	5,000	48,070	53,070
Jacky Vonderscher	24,592	11,808	36,400	5,194	34,876	40,070
Total	**9,443,111**	**72,475**	**9,515,586**	**46,708**	**281,282**	**327,990**

[1] excluding Ernest Loumaye, CEO, whose holdings are listed under Executive Committee
[2] includes shares held directly and indirectly through vehicles controlled by the Director

Executive Committee

The Executive Officers held the following equity instruments as of December 31, 2018:

Name	Common Shares			Stock-options		
	Vested	Unvested	Total	Vested	Unvested	Total
Ernest Loumaye	2,930,703	132,395	3,063,098	66,818	504,462	571,280
Tim Adams	106,458	–	106,458	27,782	314,620	342,402
Jean-Pierre Gotteland	91,542	44,958	136,500	20,795	180,955	201,750
Wim Souverijns	1,600	–	1,600	–	200,000	200,000
Elke Bestel	88,021	41,979	130,000	13,370	71,130	84,500
Ben T.G. Tan	80,238	33,312	113,550	7,575	42,095	49,670
Fabien de Ladonchamps	105,923	30,577	136,500	13,370	75,650	89,020
Total	**3,404,485**	**283,221**	**3,687,706**	**149,710**	**1,388,912**	**1,538,622**

The members of the ExCom held the following equity instruments as of December 31, 2017:

Name	Common Shares			Stock-options		
	Vested	Unvested	Total	Vested	Unvested	Total
Ernest Loumaye	2,888,920	227,879	3,116,799	–	267,270	267,270
Tim Adams	25,000	–	25,000	–	321,960	321,960
Jean-Pierre Gotteland	57,417	79,083	136,500	–	83,180	83,180
Elke Bestel	55,521	74,479	130,000	–	53,480	53,480
Ben T.G. Tan	82,470	70,280	152,750	–	30,300	30,300
Fabien de Ladonchamps	79,924	56,576	136,500	–	53,480	53,480
Total	**3,189,252**	**508,297**	**3,697,549**	**–**	**809,670**	**809,670**

Report from the Auditor on the Compensation Report of ObsEva SA

Report of the statutory auditor
to the General Meeting of ObsEva SA
Plan-les-Ouates

We have audited the accompanying remuneration report of ObsEva SA for the year ended 31 December 2018. The audit was limited to the information according to articles 14–16 of the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance) contained in the sections labeled 'audited' on pages 156 to 161 of the remuneration report.

Board of Directors' responsibility
The Board of Directors is responsible for the preparation and overall fair presentation of the remuneration report in accordance with Swiss law and the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance). The Board of Directors is also responsible for designing the remuneration system and defining individual remuneration packages.

Auditor's responsibility
Our responsibility is to express an opinion on the accompanying remuneration report. We conducted our audit in accordance with Swiss Auditing Standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the remuneration report complies with Swiss law and articles 14–16 of the Ordinance.

An audit involves performing procedures to obtain audit evidence on the disclosures made in the remuneration report with regard to compensation, loans and credits in accordance with articles 14–16 of the Ordinance. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatements in the remuneration report, whether due to fraud or error. This audit also includes evaluating the reasonableness of the methods applied to value components of remuneration, as well as assessing the overall presentation of the remuneration report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion
In our opinion, the remuneration report of ObsEva SA for the year ended 31 December 2018 complies with Swiss law and articles 14–16 of the Ordinance.

PricewaterhouseCoopers SA

Michael Foley
Audit expert
Auditor in charge

Filippos Mintiloglitis
Audit expert

Genève, 5 March 2019

Enclosure:
- Remuneration report

Forward-Looking Statements

This Annual Report contains forward-looking statements that are based on our management's beliefs and assumptions and on information currently available to our management. All statements other than present and historical facts and conditions contained in this Annual Report, including statements regarding our future results of operations and financial positions, business strategy, plans and our objectives for future operations, are forward-looking statements. When used in this Annual Report, the words "anticipate," "believe," "continue" "could," "estimate," "expect," "intend," "may," "might," "ongoing," "objective," "plan," "potential," "predict," "should," "will" and "would," or the negative of these and similar expressions identify forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

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

We cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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

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

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