Annual Report 2016

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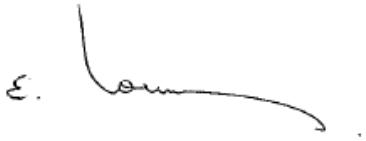
Letter to shareholders

DEAR SHAREHOLDERS,

As we look back on the year of 2016, we recognize the significant progress that was made in our development programs and implementation of our corporate strategy, ultimately culminating in our initial public offering (IPO) on the U.S. NASDAQ exchange in early 2017.

We have a rich pipeline of three New Chemical Entities with our lead asset OBE2109 pursuing two important indications in Endometriosis and Uterine Fibroids. We continue to make great progress on all of our assets as noted by the major clinical milestones we reached for all three development programs in 2016. For our lead asset OBE2109, we began a phase2b clinical trial for the treatment of endometriosis, our EDELWEISS study. Our progress in 2016 has positioned us to complete enrolment of the EDELWEISS study in late 2017. Our preliminary work supporting the Uterine Fibroid indication in 2016 has enabled us to initiate our Phase 3 program in 2017, the PRIMROSE 1 and 2 studies. Our second asset is Nolasiban (OBE001), for use in assisted reproduction during in vitro fertilization (IVF) procedures, and we completed a Phase 2 study in 2016. This led us to initiate our Phase 3 study in 2017. And finally for our third asset, OBE022 for the treatment of pre-term labor, we conducted pre-clinical work and a Phase 1 human trial in 2016, setting the foundation for initiating a phase 2 trial in 2017.

We continue to focus on 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 on achieving our clinical development milestones with judicious use of our capital. We would like to thank our shareholders, employees and partners for their unwavering support.



Frank Verwiel
Chairman

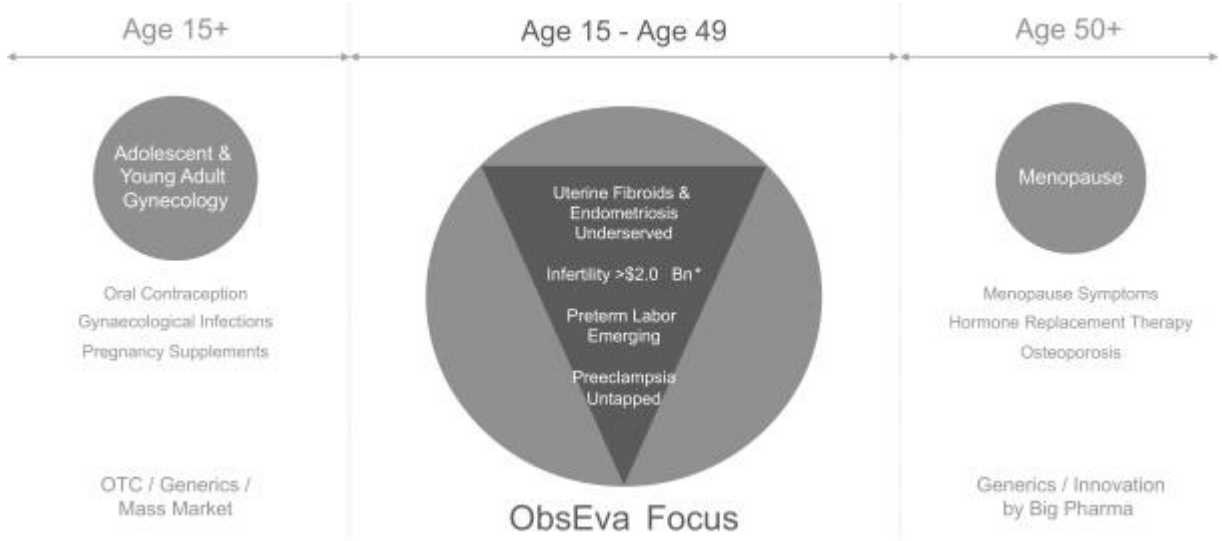
Ernest Loumaye
CEO

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 more healthy and 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 segments and associated characteristics of the therapeutic market for women's reproductive health products:



* IMS Health Incorporated estimate as of 2015.

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:

- ***OBE2109 for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids***. We are developing OBE2109 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

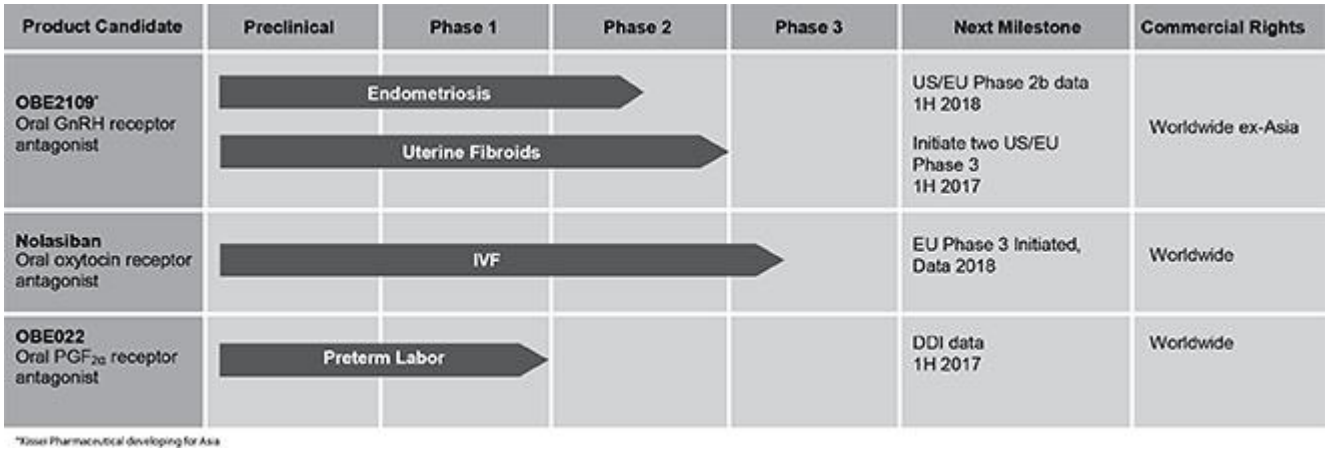
the inside of the uterus, called the endometrium, grows outside of the uterus, causing monthly bleeding and chronic inflammatory reactions inside the abdomen that may result in ovarian cyst formation, scar tissue and adhesions. The symptoms of endometriosis include significant pain during menstrual periods, chronic pelvic pain, pain during intercourse, 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 Phase 1 and Phase 2 clinical trials, OBE2109 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 OBE2109 i.e. (i) a moderate dose of OBE2109 without add-back therapy and (ii) a high dose of OBE2109 with add-back therapy. We are currently conducting a multiple-dose, placebo-controlled Phase 2b clinical trial of OBE2109 in patients with endometriosis, with a target enrollment of 330 patients, which we refer to as the EDELWEISS trial. We expect to report data from the first 24-week evaluation period of the EDELWEISS trial in the first half of 2018. For the uterine fibroids indication, we plan to perform 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 OBE2109 over six weeks. We expect that the results of this clinical trial, which we expect to receive in the first half of 2017, will confirm the selection of the add-back therapy dose or doses planned in the two randomized, placebo-controlled Phase 3 clinical trials that we intend to commence in the first half of 2017. We refer to these Phase 3 clinical trials of OBE2109 in patients with heavy menstrual bleeding associated with uterine fibroids as the PRIMROSE clinical trials. The PRIMROSE clinical trials will each have a target enrollment of approximately 500 patients. We expect to report data from the PRIMROSE clinical trials in the first half of 2020. We believe OBE2109, 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 OBE2109 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 OBE2109 has the potential to offer personalized dosing that can be tailored to a patient's individual response. Finally, we believe OBE2109 has certain advantageous characteristics including the absence of food effect, high bioavailability, low volume of distribution, 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 outcome***. 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, approximately 620,000 IVF treatments were performed in 2012, and in the United States, approximately 210,000 IVF treatments were performed in 2014. We believe that nolasiban, if approved, could represent a compelling option for increasing IVF outcomes, which, based on current treatments, only has an overall live birth rate of approximately 33% in the United States and 21% in Europe. In 2016, we completed our 247-patient Phase 2 clinical trial of nolasiban in women undergoing IVF. Nolasiban did not reach the primary endpoint of a statistically significant increase in pregnancy rate at six weeks after embryo transfer, or ET. 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 believe that high progesterone levels can lead to a premature closing of the embryo implantation window. We initiated a European Phase 3 clinical trial, which we refer as IMPLANT2, in women undergoing IVF in March 2017 and expect to report data for the primary endpoint in the second quarter of 2018.

- ***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. 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. 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. 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.

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



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 Elke Bestel M.D., our Chief Medical Officer 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.

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, 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 OBE2109 from Kissei and nolasiban and OBE022 from Merck Serono. Additionally, we have raised $93.2 million in equity financing from inception to December 31, 2016 from leading healthcare investors, including HBM Healthcare Investments, New Enterprise Associates, Novo A/S, OrbiMed, Sofinnova Partners and Sofinnova Ventures.

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;
- 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:***
  - ***OBE2109 for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids***. We are currently conducting the EDELWEISS trial, which is a multiple-dose, placebo-controlled Phase 2b clinical trial of OBE2109 in endometriosis patients in the United States and Europe, with a target enrollment of 330 patients, from which we expect to report initial data in the first half of 2018. Additionally, we intend to commence the 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 will each have a target enrollment of approximately 500 patients and will be conducted in the United States and in Europe. We expect to report data from these Phase 3 clinical trials in the first half of 2020.
  - ***Nolasiban for the improvement of IVF outcomes in women undergoing assisted reproductive technology, or ART***. We are advancing nolasiban into Phase 3 clinical development to evaluate its potential to improve clinical pregnancy and live birth rates for women undergoing IVF. We initiated our initial IMPLANT2 Phase 3 clinical trial in Europe, where we believe more IVF treatments are conducted than in the United States, in March 2017, and expect to report data for the primary endpoint in the second quarter of 2018. If this trial is successful, we plan on conducting an end-of-Phase 2

meeting with the FDA and to reactivate our investigational new drug application, or IND, before commencing any U.S. clinical trials.

- ***OBE022 for the treatment of preterm labor (GA 24-34 weeks)***. We intend to advance OBE022 into Phase 2a Proof-of-Concept clinical trial in the second half of 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.

- ***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 OBE2109. 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.
- ***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. For example, we are evaluating the relevance and the feasibility of developing OBE2109 for the treatment of symptoms associated with adenomyosis, precocious puberty, polycystic ovary syndrome and prostate cancer; nolasiban for improving clinical pregnancy and live birth rates following frozen thawed embryo transfer; and OBE022 for treatment of late-stage preterm labor in weeks 34 to 37 of pregnancy. We plan to pursue additional indications for our existing product candidates.
- ***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 and dysmenorrhea.

OBE2109: Investigational GnRH Receptor Antagonist for Symptoms Associated with Endometriosis and Uterine Fibroids

We are developing OBE2109 as an oral GnRH receptor antagonist for the treatment of pain associated with endometriosis and heavy menstrual bleeding associated with uterine fibroids. We believe OBE2109, 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 OBE2109 has the potential to offer personalized dosing that can be tailored to a patient's individual response and that it will be supported by key differentiating product characteristics, including absence of food effect, high bioavailability, low volume of distribution, 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 OBE2109 from Kissei. Kissei completed three Phase 2a clinical trials in Japan of OBE2109 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 OBE2109 i.e. (i) a moderate dose of OBE2109 without add-back therapy and (ii) a high dose of OBE2109 with add-back therapy. We are currently conducting the 330-patient multiple-dose, placebo-controlled Phase 2b EDELWEISS clinical trial of

OBE2109 in endometriosis patients across 46 sites in the United States and 15 sites in Central and Eastern Europe. We expect to report data from the first 24-week evaluation period of this trial in the first half of 2018. We intend to commence our two Phase 3 PRIMROSE clinical trials in patients with heavy menstrual bleeding associated with uterine fibroids in the first half of 2017. The PRIMROSE clinical trials will each have a target enrollment of approximately 500 patients and will be conducted in the United States and in Europe. We expect to report data from these Phase 3 clinical trials in the first half 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 in 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. 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, GnRH agonists nasal spray pumps or surgery 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 $80 billion in the United States and approximately $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 $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. However, GnRH agonists have significant drawbacks and limitations.

GnRH agonists act by overstimulating the GnRH receptors, which desensitizes 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 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, 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 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 tolerance.

OBE2109's Mechanism of Action and Solution to GnRH Agonist Drawbacks and Limitations

OBE2109 has been designed to be a GnRH receptor antagonist with oral administration and low PK and PD variability. OBE2109 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 reduction of estrogen levels.

At selected doses, OBE2109 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.

We believe OBE2109 has the potential to overcome certain drawbacks and limitations of GnRH agonists. The potential advantages of OBE2109 compared to GnRH agonists include:

- ***Fast onset of therapeutic effect***. By blocking, as opposed to stimulating, the GnRH receptor, OBE2109 has the potential to suppress LH and FSH within hours, lowering estradiol levels and reducing pain within days while potentially mitigating the initial worsening of symptoms which is often associated with GnRH agonist treatments.
- ***Ease of administration***. OBE2109 has the potential to be administered orally once daily due to its observed half-life of approximately 15 hours. 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 add-back therapy may be recommended when treatment exceeds three months and is required when treatment exceeds six months, we believe that at the 50 to 200 mg doses being tested in our Phase 2b trial, OBE2109 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, without the need for add-back therapy to counteract the side effects associated with severe suppression of estradiol. For the treatment of heavy menstrual bleeding associated with uterine fibroids, we believe that based on our proposed dosing (100-200 mg) some patients may not require add-back therapy, while others may require add-back therapy, depending on the treatment dosage. Others patients may require add-back therapy, depending on the treatment dosage required to control symptoms.

- ***Quick reversibility of effect***. As a result of OBE2109's observed half-life of approximately 15 hours, we believe OBE2109 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.

OBE2109's Potential Advantages to Other GnRH Receptor Antagonists in Development

There are currently no GnRH receptor antagonists approved for the treatment of symptoms associated with endometriosis or uterine fibroids. We are aware that AbbVie Inc., Myovant Sciences, Inc. and Astellas Pharma Inc. are developing GnRH receptor antagonists for the treatment of symptoms associated with endometriosis or uterine fibroids.

Based on publicly available information and data for these other product candidates in development, we believe the potential advantages of OBE2109 compared to other GnRH receptor antagonists being developed include:

- ***Favorable and consistent PK profile***. OBE2109 has been observed to have a consistent PK profile and low variability, due to high bioavailability and low volume of distribution. We believe some of the competitive product candidates have low bioavailability and high volume of distribution due to drug accumulation in fat, which we believe may translate into variable efficacy and safety. In addition, OBE2109's half-life allows for once daily dosing for across indications, while one of the competitive product candidates is being developed for twice daily dosing.
- ***Personalized dosing***. Based on OBE2109's consistent PK and PD profile observed in preclinical studies and clinical trials, we are currently evaluating personalized dosing that can be tailored to a patient's individual response. We believe this may allow us to pursue a label for varied dosing based on a patient's estradiol levels and symptoms. We believe other products in clinical development are currently only being evaluated for one or two dosing options, which do not appear to account for patient characteristics, individual response or patient preference.
- ***No systematic need for add-back therapy***. For symptoms associated with both endometriosis and uterine fibroids, we are developing OBE2109 as a stand-alone treatment (without need for add-back therapy) and in association with add-back therapy (e.g. fixed-dose combination therapy) to fulfill the needs of a broad patient population with endometriosis or uterine fibroids. We believe at least one other product in clinical development is only being evaluated as a fixed-dose combination therapy that includes add-back therapy, which we believe may not be suitable for treatment of women with poor tolerance or contraindications to add-back therapy. We also believe that at least one of the other products in clinical development has demonstrated, at the dose being developed in the clinical trials, a bone mineral density loss at 24 weeks of treatment comparable to Lupron, a GnRH agonist used for the treatment of endometriosis and uterine fibroids.
- ***Compliance benefit***. OBE2109 may have an advantage in patient compliance due to the lack of observed food effect and the ability to be taken once anytime throughout the day, as compared to certain of the competitive product candidates, which we believe need to be taken on an empty stomach.

OBE2109 Preclinical and Clinical Development for Pain Associated with Endometriosis

Prior to in-licensing OBE2109, 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, OBE2109 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 OBE2109 from Kissei, we submitted an IND for OBE2109 in May 2016, which was accepted by the FDA. We are currently conducting the multiple-dose, placebo-controlled Phase 2b EDELWEISS clinical trial of OBE2109 in 330 endometriosis patients in the United States and Europe. We expect to report initial data for this trial in the first half of 2018.

Preclinical Studies and Phase 1 Clinical Trial

In preclinical studies, OBE2109 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, OBE2109 was observed to have a favorable safety profile and to be well-tolerated up to 400 mg once daily for seven days. Additionally, OBE2109 had a linear PK profile, a half-life of approximately 15 hours and no significant differences between women of Japanese and European descent. Moreover, OBE2109 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. OBE2109 was observed to induce a dose-dependent decrease in LH and FSH over time, which we believe correlates with the ability of OBE2109 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 OBE2109. In addition, in 2016 we completed a Phase 1 trial to assess the impact of OBE2109 on the potential induction of a liver enzyme known as cytochrome P450 3A4 (CYP3A4), which is believed to be responsible for the metabolism of add-back therapy. In this trial, we observed no relevant CYP3A4 induction, which we believe suggests that OBE2109 will not interfere with add-back therapy.

Figure 1: Mean OBE2109 Concentration Over Time

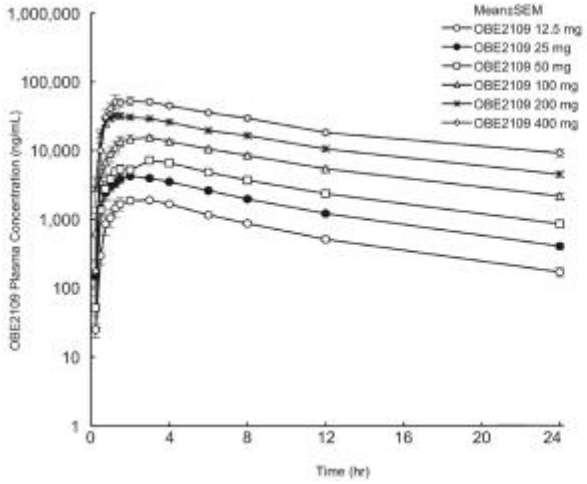
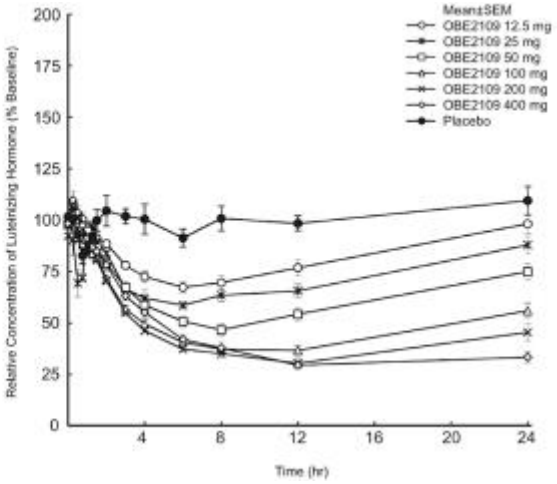


Figure 2: LH Reduction from Baseline Over Time



Completed Phase 2a Clinical Trials

Kissei completed three Phase 2a clinical trials of OBE2109 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 (including 57 patients that also had uterine fibroids)	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.

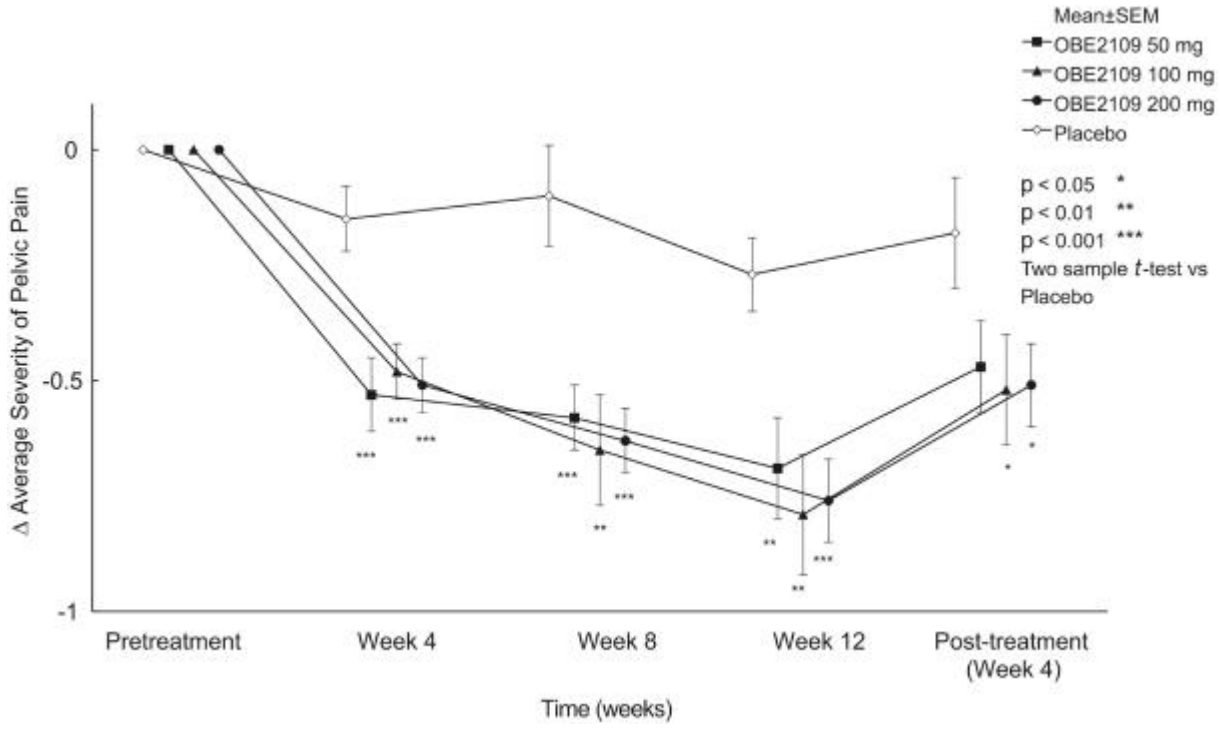
Improvement rate of pelvic pain severity was assessed using the proportion of pain free days during the evaluation period. Pain free is defined as the absence of pain or slight pain during menstruation and the absence of pain during non-menstruation. Across all three studies, OBE2109 was observed to 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.

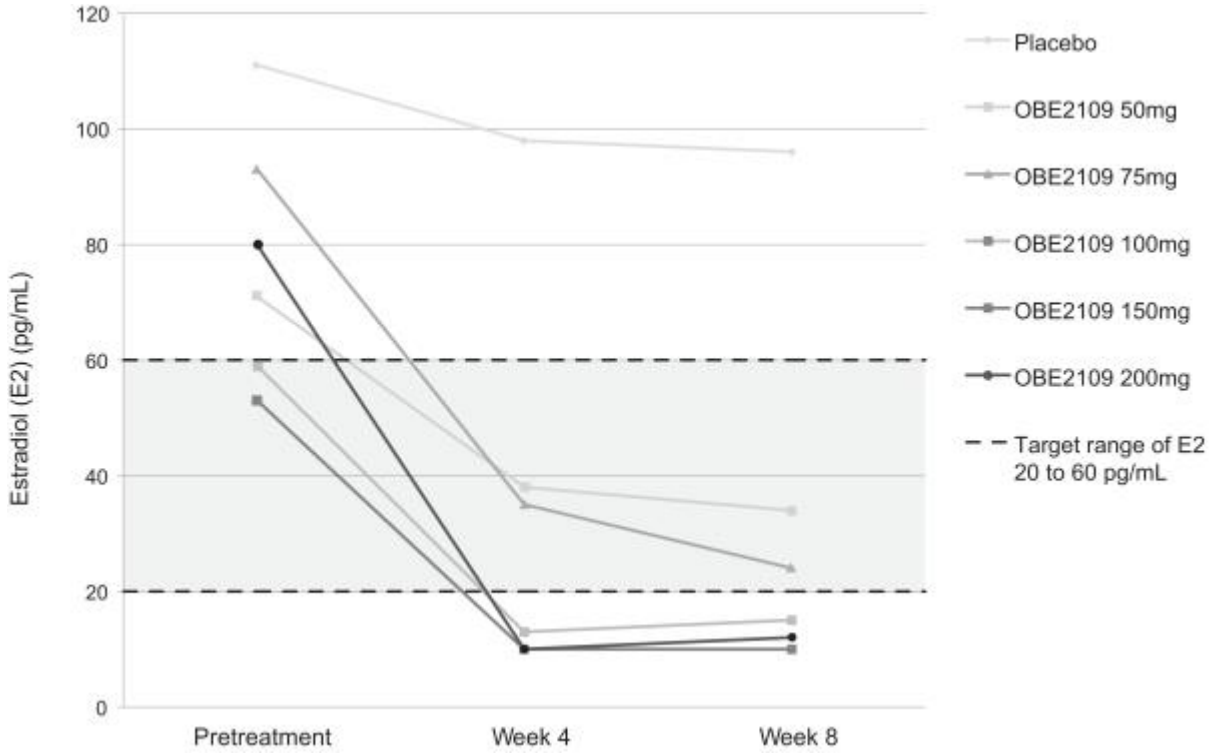
Figure 3: Average Change in Severity of Pelvic Pain Over Time (Menstrual and Non-menstrual Pain Combined)



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

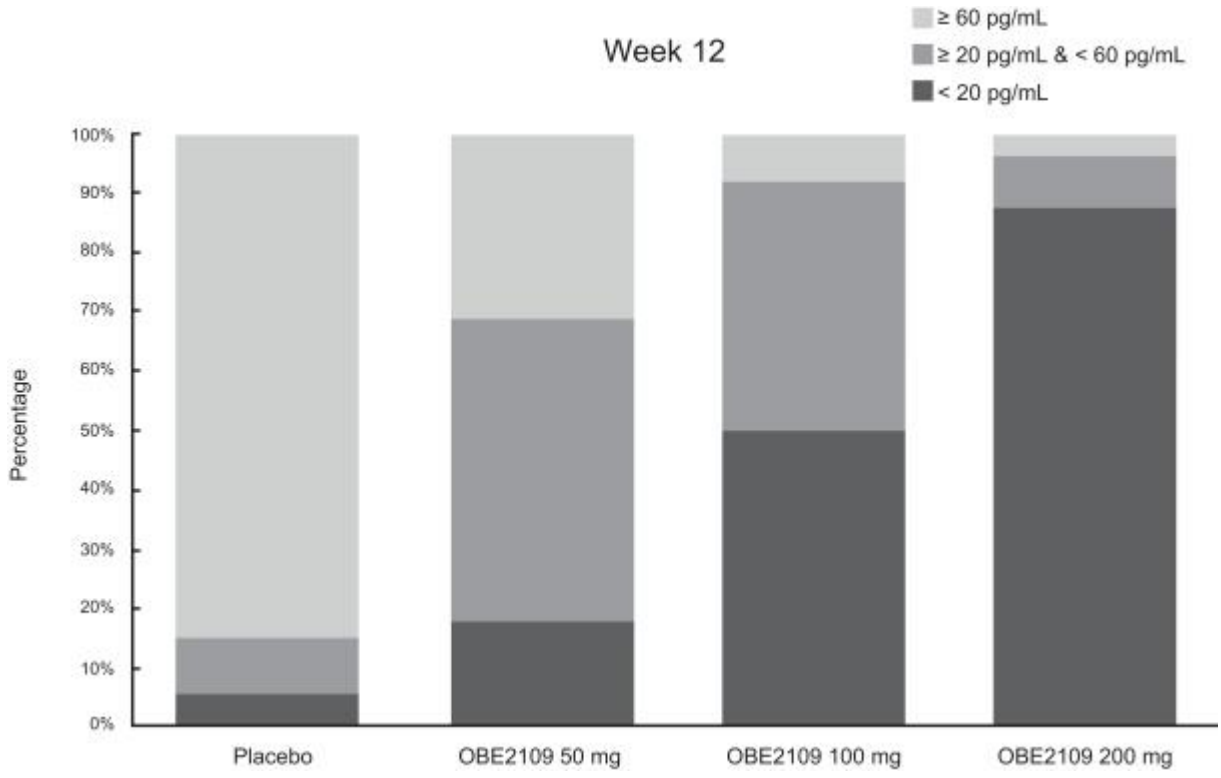
2a trials, which we believe resulted in the reduction of pelvic pain, analgesic use and bleeding days. Doses of 50 mg and 75 mg were observed to result in median serum estradiol levels in the target range of 20 to 60 pg/ml. Doses of 100 mg, 150 mg and 200 mg were observed to reduce median estradiol serum levels below 20 pg/ml.

Figure 4: Median Estradiol Levels Over Time



In addition, as shown in Figure 5 below, approximately 40% of the patients receiving 50 mg and 100 mg doses of OBE2109 were observed to have estradiol levels between 20 to 60 pg/ml at week 12.

Figure 5: Percent of Patients at Various Estradiol Levels in KLH1202 Trial at Week 12



Safety Results of Phase 1 and Phase 2a Clinical Trials

The safety and tolerability of OBE2109 was evaluated in a total of 128 patients with endometriosis and 77 healthy female volunteers across the four clinical trials, with doses up to 400 mg for seven days and up to 200 mg for 12 weeks.

In the Phase 1 clinical trial, adverse events were reported with similar frequency in all groups, including the placebo group. No serious adverse events were reported.

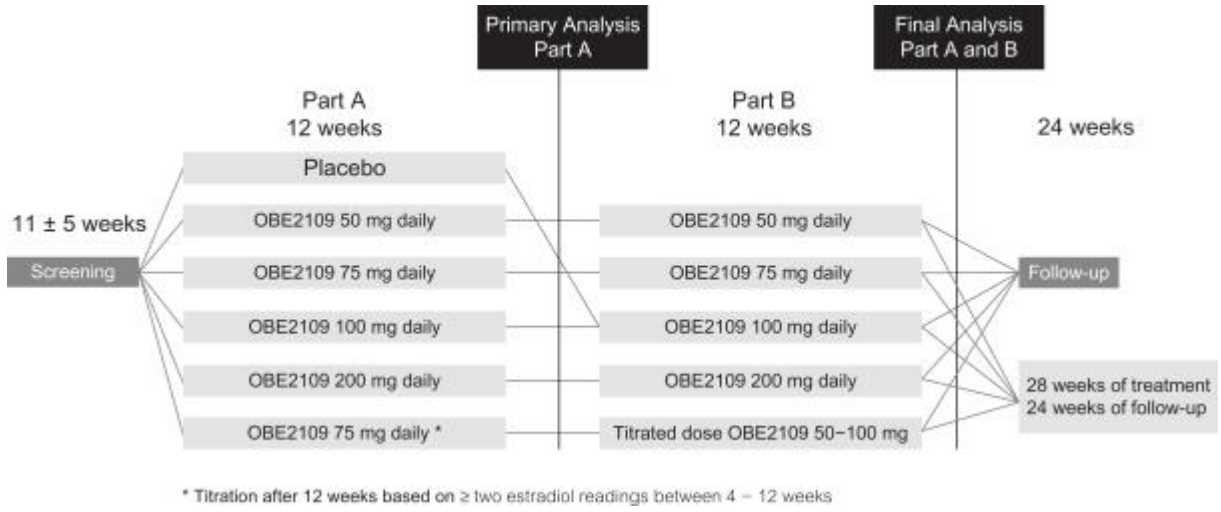
In the three Phase 2a clinical trials, almost all of the adverse events were mild across all treatment groups. The most common adverse events were abnormal bleeding from the uterus, contracting a cold, headaches and hot flashes. Most hot flashes were mild, three were moderate in severity and none were 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 OBE2109.

Clinical Development Plan—Phase 2b EDELWEISS Clinical Trial in Pain Associated with Endometriosis

We are currently conducting the Phase 2b EDELWEISS clinical trial in patients with endometriosis. We expect to enroll approximately 330 patients across 46 sites in the United States and 15 sites in Central and Eastern Europe. In this double-blind, placebo-controlled trial, we are evaluating four doses of OBE2109: 50 mg, 75 mg, 100 mg and 200 mg, each with no add-back therapy. Patients will report their pain on a daily basis with an electronic diary and we will analyze data at 12 weeks and 24 weeks after initial treatment. After the initial 12-week evaluation period, we plan on exploring a dose titration regimen in an additional trial arm, in which some patients initially dosed with 75 mg will receive an increased dose of 100 mg, a decreased dose of 50 mg or the same dose of 75 mg for the second 12-week evaluation period, depending on their respective estradiol levels at 4 and 8 weeks after initial treatment. In addition, after the first 12 weeks, patients receiving placebo will switch to a 100 mg daily dose.

Figure 6 below depicts the trial design of the EDELWEISS trial:

Figure 6: Design of Phase 2b EDELWEISS Clinical Trial



We believe our current data in endometriosis patients of Japanese descent supports a daily dose of 50 mg or 75 mg of OBE2109. We believe this daily dose will suppress estradiol within the target range and not result in bone mineral density loss that requires add-back therapy. We expect slightly higher doses will be required to achieve estradiol suppression within the target range in patients of American and European descent given a higher average body weight. We plan to confirm this following the review of the results from the Phase 2b EDELWEISS clinical trial.

Menstrual and non-menstrual pelvic pain will be assessed with a 4-point Verbal Rating Scale, or VRS, and an 11-point Numeric Rating Scale, or NRS. The primary endpoint of this trial will be the reduction from baseline at week 12 in the mean overall pelvic VRS pain score. The key secondary endpoint is the bone mineral density after 24 weeks of treatment assessed with a dual-energy x-ray absorptiometry scan.

After 24 weeks of treatment, patients may choose to continue in an extension trial. In the extension trial, patients will continue treatment for another 28 weeks at the same dose, with the exception of patients receiving a 200 mg dose, who will be switched to a 100 mg daily dose. After treatment, all patients will be followed for an additional, 24-week period that will be treatment free.

We expect to receive the primary efficacy results for the 24-week evaluation period in the first half of 2018, which will allow us to assess the efficacy of OBE2109 in patients with endometriosis. We expect to receive the final results for the 28-week extension by the fourth quarter of 2018 and the 24-week follow-up period in the first half of 2019. Upon completion of the initial 24-week period and assuming the results of the trial are favorable, we will request an end-of-Phase 2 meeting with the FDA to determine the design of our Phase 3 program for pain associated with endometriosis.

OBE2109 Clinical Development for Heavy Menstrual Bleeding Associated with Uterine Fibroids

We are developing OBE2109 for reduction of heavy menstrual bleeding associated with uterine fibroids in adult women of reproductive age. We believe OBE2109 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.

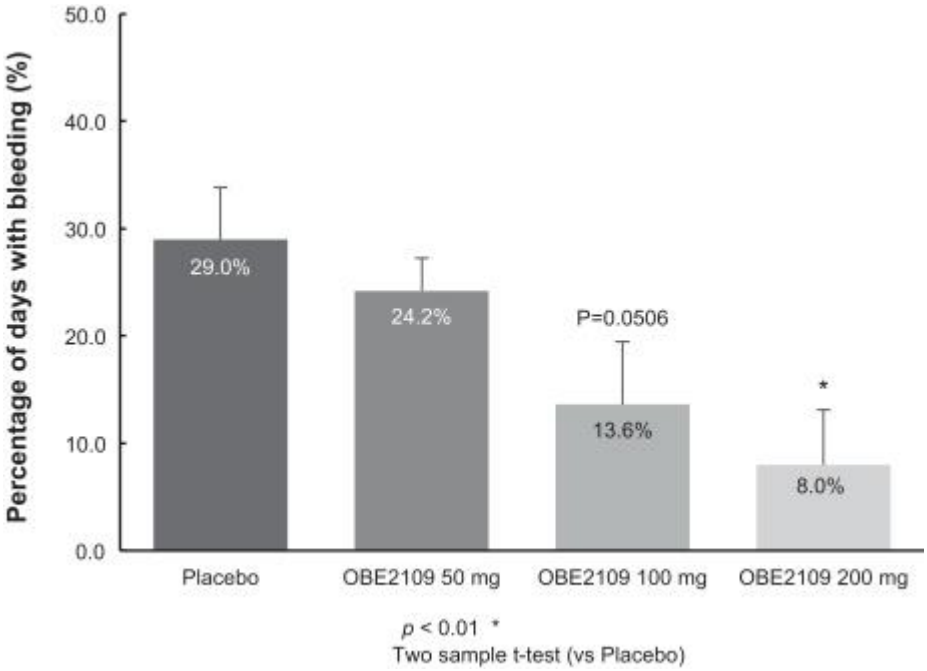
Completed Phase 2a Clinical Trial

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

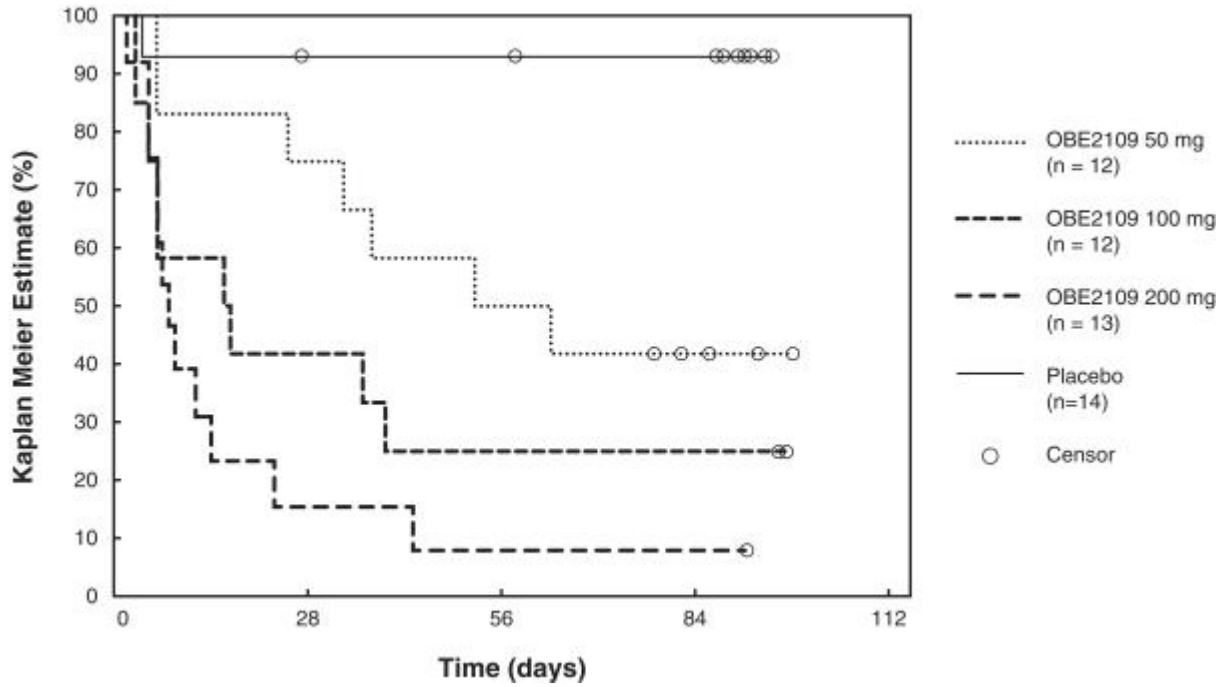
As shown in Figure 7 below, we observed a dose-dependent reduction in the percentage of days in which bleeding occurred during the 12-week treatment period in patients treated with OBE2109.

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



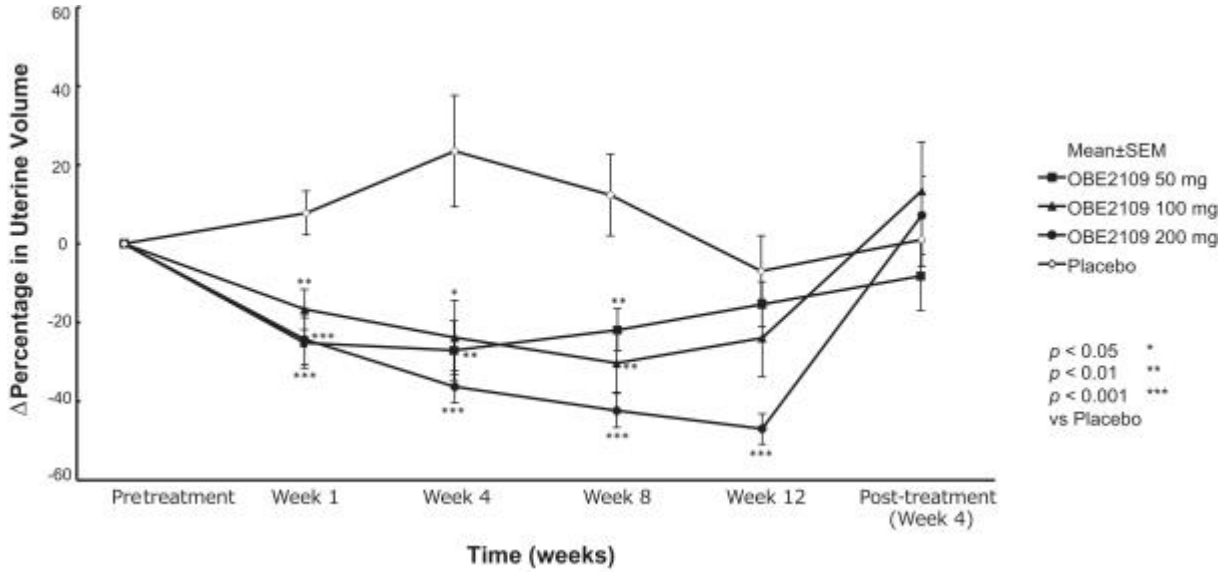
Further, in these patients with uterine fibroids, the 50 mg dose of OBE2109 suppressed bleeding in approximately 55% of patients, whereas the 200 mg daily dose of OBE2109 suppressed bleeding in approximately 95% of patients as shown in Figure 8 below. In addition, most patients stopped bleeding within 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 important for the treatment of uterine fibroid patients, as patients with lower uterine volume are eligible for less invasive surgical procedures, such as a hysterectomy by vaginal route rather than abdominal route. In addition, uterine volume is correlated with several symptoms of uterine fibroids, such as urinary incontinence and frequency.

Figure 9: Change in Uterine Volume over Time



Safety Results

The safety results on the subgroup of patients with uterine fibroids did not differ from the safety in endometriosis patients. The adverse events were generally mild across all treatment groups. The most common adverse events were those

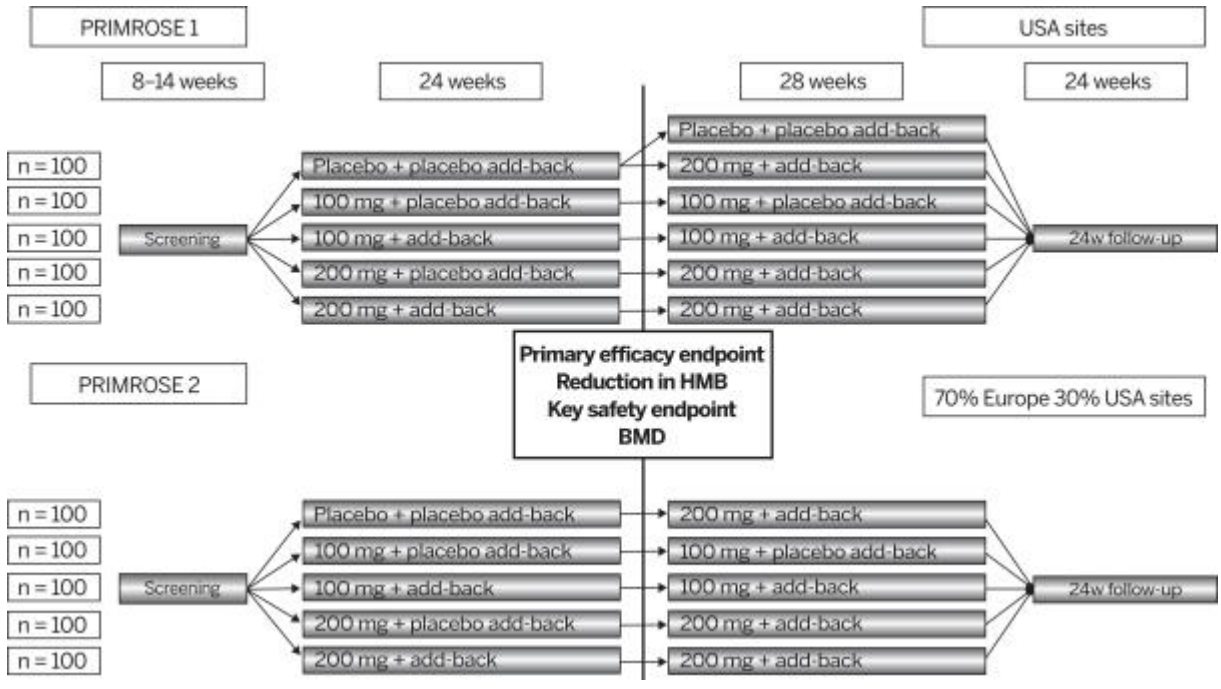
associated with suppression of estradiol, including abnormal bleeding from the uterus during the first weeks of treatment and hot flashes. Abnormal bleeding from the uterus was not more frequent in uterine fibroid patients than in endometriosis only patients.

Clinical Development Plan—Heavy Menstrual Bleeding Associated with Uterine Fibroids

Based on feedback we received from the FDA in November 2016, we intend to commence 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 will each have a target enrollment of approximately 500 patients. One of the trials will be conducted in the United States and the other trial will be conducted in the United States and in Europe. We expect to report data from these PRIMROSE Phase 3 clinical trials in the first half of 2020. We are currently conducting 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 OBE2109 over six weeks. We expect that the results of this clinical trial, which we expect to receive in the first half of 2017, will confirm the selection of the add-back therapy dose or doses planned in the PRIMROSE clinical trials. We believe that a 100 mg dose of OBE2109 could control symptoms in a significant proportion of patients without requiring add-back therapy. We also intend to further assess the efficacy of a 200 mg dose of OBE2109 both with and without add-back therapy. We believe that the 200 mg dose will require add-back therapy to prevent excessive bone mineral density loss. In addition, in 2016 we completed a Phase 1 trial to assess the impact of OBE2109 on the potential induction of a liver enzyme known as cytochrome P450 3A4 (CYP3A4), which is believed to be responsible for the metabolism of add-back back therapy. In this trial, we observed no relevant CYP3A4 induction, which we believe suggests that OBE2109 will not interfere with add-back therapy.

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 us to be analyzed. 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 data from the PRIMROSE Phase 3 clinical trials in the first half of 2020, and, if the results are favorable, we intend to submit an NDA in the second half of 2020.

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 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 trial. In the IMPLANT trial, nolasiban did not reach the primary endpoint of demonstrating a statistically significant increase in pregnancy rate at six weeks after ET. 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, which, based on current treatments, only has an overall live birth rate of approximately 33% in the United States and 21% in Europe. We initiated our 760 patient, IMPLANT2 European Phase 3 clinical trial in women undergoing IVF in March 2017 and expect to report data for the primary endpoint in the second quarter of 2018.

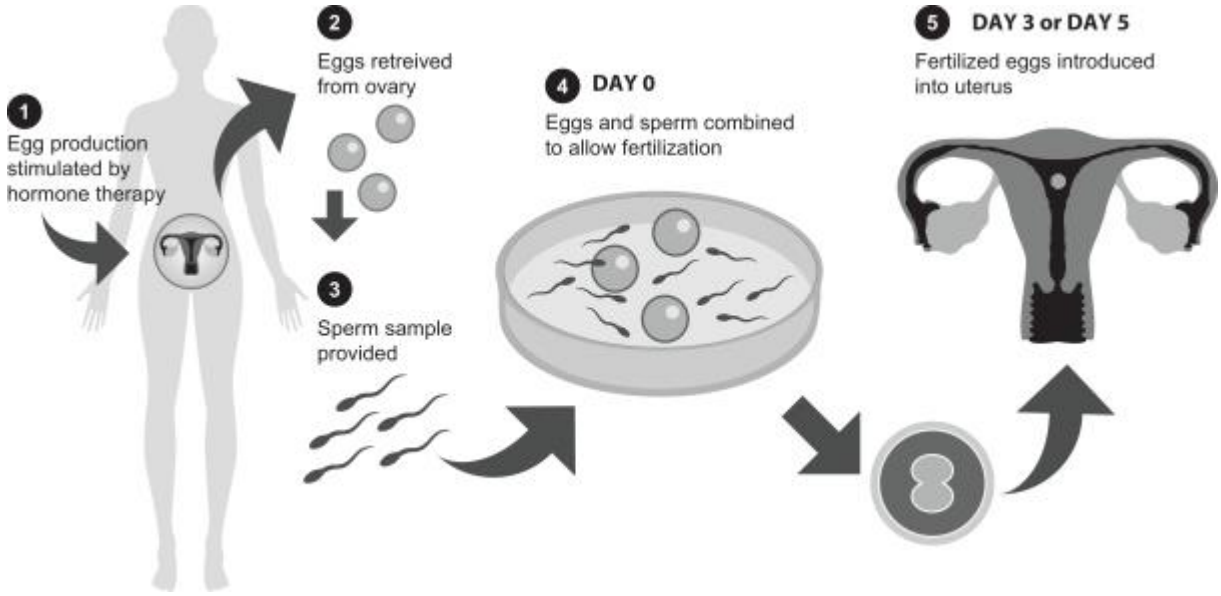
Background on Assisted Reproductive Technology (IVF/ICSI)

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, every year about 1.6 million ART treatments are performed worldwide. In Europe, ART treatments doubled from 2000 to 2010, and approximately 620,000 IVF treatments were performed in 2012. In the United States, IVF treatments increased by 41.7% from 2010 to 2014, with approximately 210,000 treatments performed in 2014. In Japan, approximately 325,000 IVF treatments were performed in 2012.

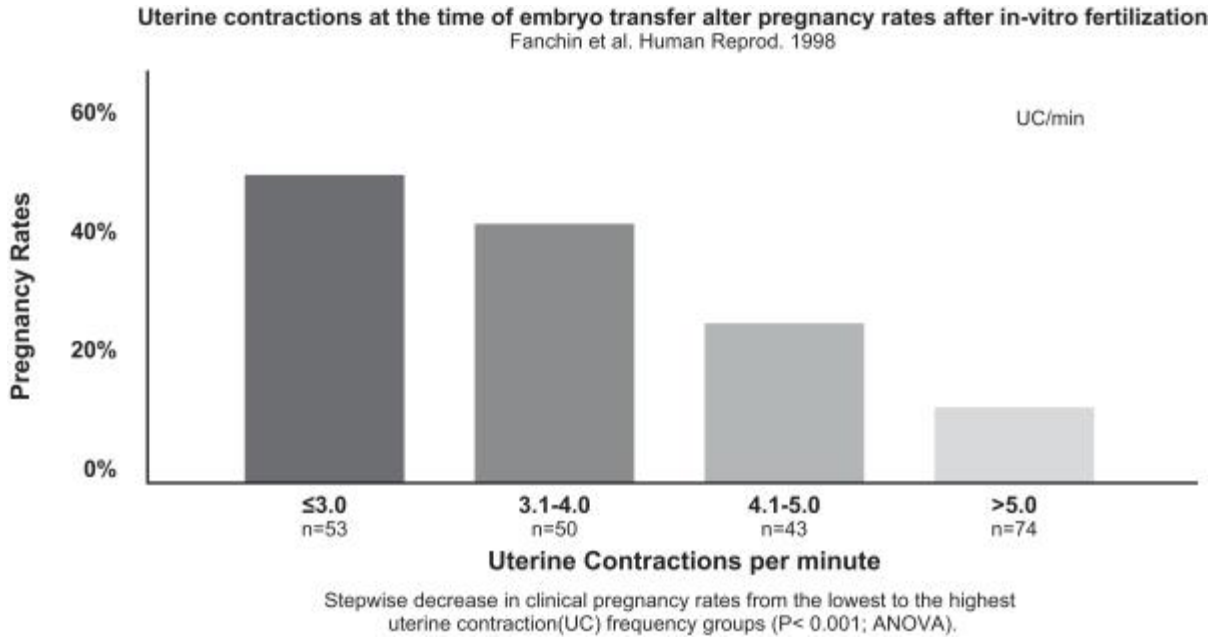
The first step in IVF is stimulation of egg production. Approximately ten days later, the eggs are harvested from the ovaries, otherwise known as ovum pick-up, or OPU, and co-incubated with sperm cells, with this day being referred to as Day 0. The resulting embryos are either used for fresh transfer to the uterus over the next three to five days or frozen for

future use. In Europe, approximately 50% of all embryo transfers occur three days after Day 0 and an additional 25% occur five days after Day 0, with the remaining 25% frozen for future transfer. The figure below depicts the IVF procedure:



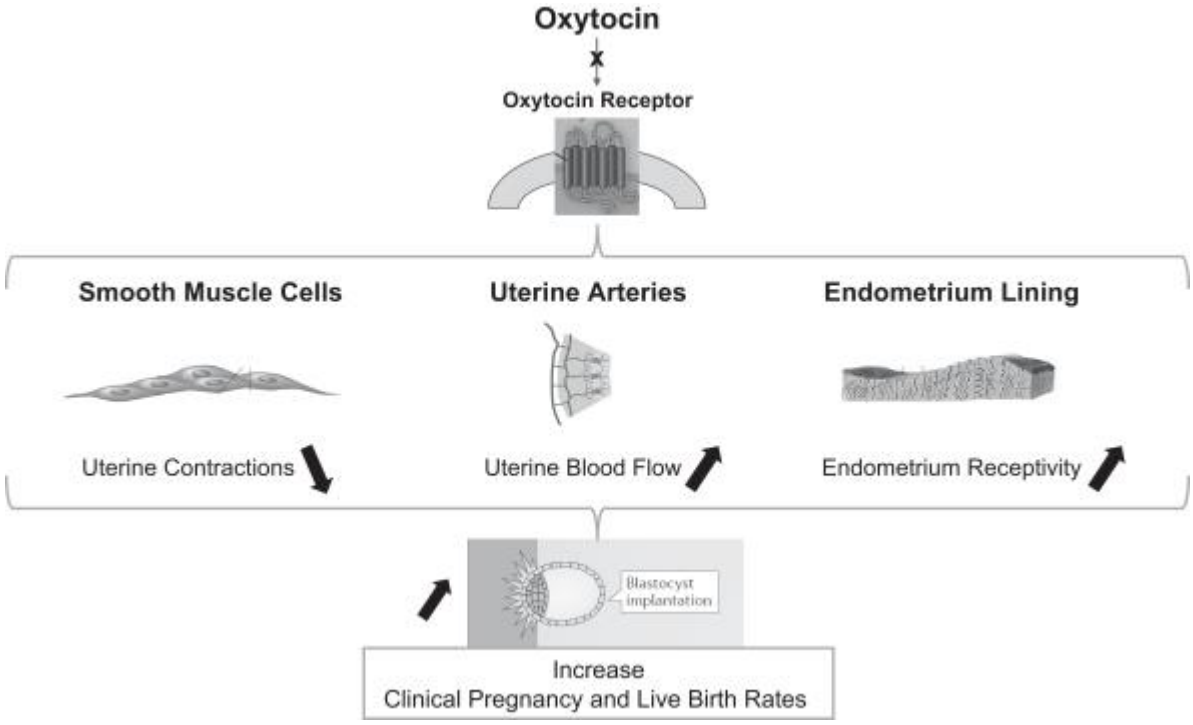
The cost of one IVF cycle varies between $8,000 to $15,000 in the United States, EUR 2,000 to EUR 10,000 in Europe and $3,000 to $6,000 in Japan. As of 2006, fertility drugs account for more than $2,000 of the cost of a treatment cycle. Most patients require multiple fertility treatment cycles. IMS Health Incorporated estimates that global sales of fertility drugs exceeded $2 billion in 2014.

The IVF process has an overall live birth rate of approximately 33% in the United States and 21% in Europe. 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. Uterine contractions occur throughout the course of a woman's menstrual cycle and the frequency and intensity of the contractions depend on the phase of the cycle. In a study published in Human Reproduction in 1998, after IVF, the rate of uterine contractions assessed at the time of embryo transfer was observed to be negatively correlated with pregnancy rates as shown in the figure below.



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. 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 live birth rate***. Though nolasiban did not reach the primary endpoint of a statistically significant increase in pregnancy rate at six weeks after ET, we conducted a post-hoc analysis of the IMPLANT clinical trial, which excluded patients with progesterone levels in the top quartile of the patient pool. In this post-hoc analysis, we identified a dose-proportional increase in ongoing pregnancy rate at week 10 and live birth rate from 30.6% for placebo to 51.0% for 900 mg nolasiban, representing a 67% increase relative to placebo.
- ***Convenience of administration***. We are designing nolasiban to be an oral oxytocin receptor antagonist, which could be easily incorporated into IVF procedures.
- ***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.

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 based on our post-hoc analysis of the Phase 2 data excluding patients with progesterone levels in the top quartile of the patient pool, we identified a statistically significant dose-proportional increase in ongoing pregnancy rate at week 10 and live birth rate, with both having an absolute increase of up to 20%, equivalent to a 67% relative increase to the placebo. In March 2017, we initiated a European Phase 3 clinical trial in women undergoing IVF to further evaluate the efficacy and safety of nolasiban. Our IND for nolasiban is currently inactive following the Phase 2 clinical trial, but we intend to reactivate the IND after discussions with the FDA if the planned European Phase 3 clinical trial is successful.

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.

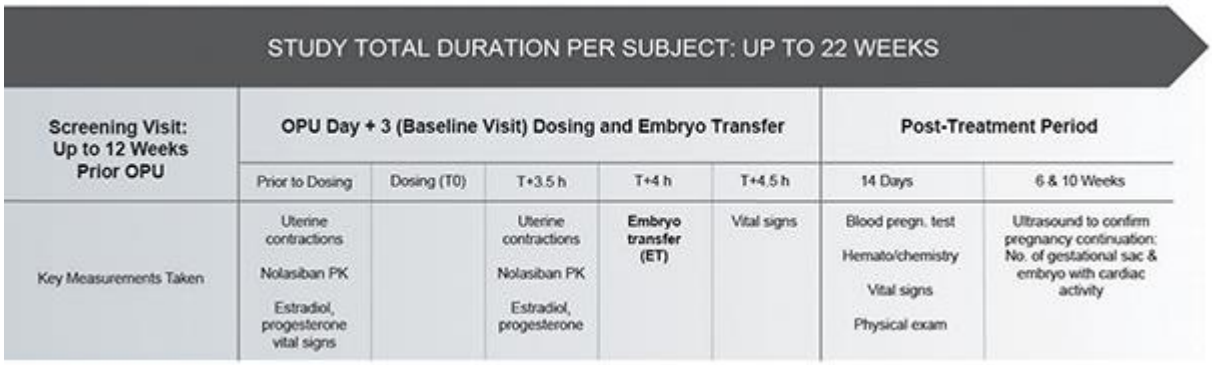
In single and multiple ascending dose Phase 1 clinical trials conducted in the United Kingdom by Merck Serono, nolasiban was tested in 103 healthy female volunteers with single doses up to 1,500 mg and multiple doses up to 900 mg for seven

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.

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:



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 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

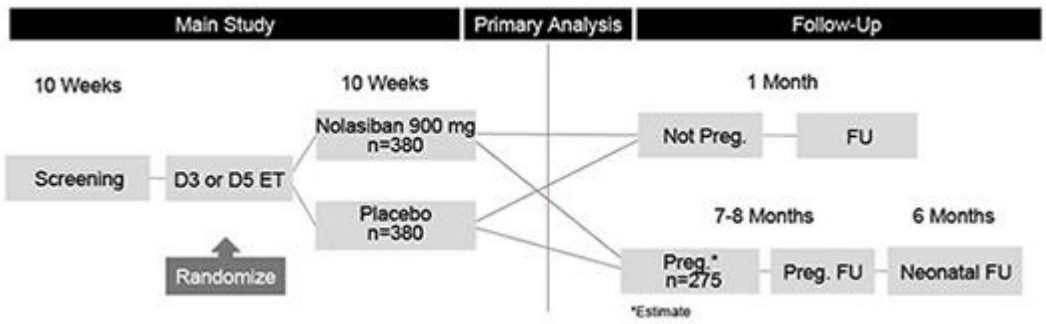
Parameters	Placebo n=65	Nolasiban 100 mg n=62	Nolasiban300 mg n=60	Nolasiban 900 mg n=60
Ectopic Pregnancy	1	1	0	1
Congenital Malformation	2*	4°	0	1§
Intra-uterine Growth Retardation	0	0	2	0

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

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 IMPLANT2, where we believe more IVF treatments are conducted. The IMPLANT2 European Phase 3 clinical trial is designed to test the effect of a single oral dose of 900 mg of nolasiban administered four hours before embryo transfer, compared to placebo. The primary endpoint is the ongoing pregnancy rate at ten weeks after the OPU day. 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 IMPLANT2 European Phase 3 clinical trial is shown in Figure 14 below.

Figure 14



We initiated this IMPLANT2 European Phase 3 clinical trial in March 2017, and expect to report data for the primary endpoint in the second quarter of 2018. If this trial is successful, we plan on holding an end-of-Phase 2 meeting with the FDA and to reactivate our IND before commencing any U.S. clinical trials.

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 $PGF_{2\alpha}$, receptor antagonist for the treatment of preterm labor in weeks 24 to 34 of pregnancy. $PGF_{2\alpha}$ is a naturally occurring prostaglandin that acts to induce labor in pregnant women. Through specific antagonism of the $PGF_{2\alpha}$ receptor, 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 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.

Background and Impact of Preterm Labor

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

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

Role of Prostaglandins in Preterm Labor

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

Limitations of Current Treatment Options

Various classes of pharmaceutical agents that decrease uterine contractions, also known as tocolytics, are used to 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 used off-label in the United States. These different classes include nifedipine, a calcium channel blocker, magnesium sulfate and glyceryl trinitrate, each of which have been observed to have limited efficacy. Beta-adrenergic agonists have been largely discontinued because of severe maternal cardiovascular side effects. Atosiban, an oxytocin receptor antagonist, is approved in Europe and 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, also known 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 a steroid 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 15: 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 (90–95) [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 through the inhibition of PGE2, NSAIDs are no longer recommended for pregnant women 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.

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 intend to advanceOBE022 into Phase 2a Proof-of-Concept clinical trial in the second half of 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

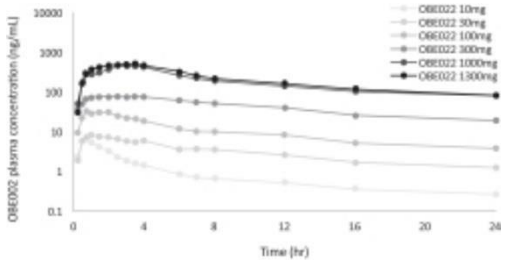
In the preclinical pharmacology, PK and toxicology studies conducted by Merck Serono, OBE022 was observed to be a highly selective, competitive and reversible $PGF_{2\alpha}$ receptor antagonist with over 100 times the affinity for it compared to other prostaglandin receptor subtypes. OBE022 has been 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 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 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.

Clinical Development Plan

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, OBE022 was observed to be readily absorbed and converted into the active stable metabolite OBE002. Exposure to OBE002 increased with dose of OBE022 and reached clinically meaningful exposure levels within an hour after administration which is an important feature for orally administered preterm labor treatments. Median OBE002 half-lives have been observed to be between 7 and 15 hours, which we believe is an adequate half-life for OBE022 to have once daily or twice daily dosing. Preliminary plasma concentration-time data is presented in Figure 16 below. Concomitant administration with food resulted in decreased peak exposures, but we believe this effect was not clinically significant and believe that OBE022 can be taken with or without food. 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 16:



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. OBE022 in combination with those drugs was observed to have a favorable safety profile and to be well-tolerated up 1,100 mg per day, which was the highest tested dose.

Based on these Phase 1 clinical trial results, we intend to advance OBE022 in the second half of 2017 into a Phase 2a proof-of-concept clinical trial. The trial objectives will be to assess the safety and efficacy of OBE022 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 and less than 34 weeks pregnant, with intact membranes, presenting with spontaneous preterm labor and no contraindications to a prolongation of pregnancy. Giving birth between 34 weeks and 37 weeks is generally not viewed as high risk to the baby and therefore using pharmaceutical agents to delay child birth is controversial during this period.

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 OBE2109, 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 OBE2109 from Kissei. The CMO that Kissei is using to supply the active pharmaceutical ingredient for OBE2019 received a warning letter from the FDA in November 2016 citing deviations from cGMP requirements with respect to its drug manufacturing facility. Kissei is working with the CMO to completely correct all deviations cited in the warning letter and Kissei is currently qualifying alternate OBE2109 cGMP API suppliers. For nolasiban and OBE022, we obtain supply on a purchase order basis from a single source. However, we believe that there are multiple potential sources for our contract manufacturing for nolasiban and OBE022. We have not engaged alternate suppliers in the event that our current CMO for nolasiban and OBE022 is unable to scale production or suffer disruption to their supply. 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 (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 OBE2109, there are no GnRH antagonists currently approved for the treatment of pain associated with endometriosis or heavy menstrual bleeding associated with uterine fibroids. However, we are aware that AbbVie Inc., Myovant Sciences, Inc. and Astellas Pharma Inc. are developing GnRH antagonist product candidates for treatment of symptoms associated with endometriosis or uterine fibroids. We also anticipate competing with GnRH agonists, including

Lupron (leuprolide acetate), marketed by AbbVie Inc. and Takeda Pharmaceuticals, Visanne, which is approved for the treatment of endometriosis outside the United States and marketed by Bayer, ulipristal acetate, which is approved for the treatment of moderate-to-severe symptoms of uterine fibroids outside the United States and marketed by Gedeon Richter in Europe and other regions, and by Actavis (Allergan) in Canada. Actavis (Allergan) has stated that it expects to submit an NDA for ulipristal acetate with the FDA in 2017. In addition, oral contraceptives and NSAIDs are routinely used as a first-line therapy for 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 oxytocin receptor antagonists approved for use in connection with IVF. However, we are aware that Ferring Pharmaceuticals Inc. has been developing barusiban, an oxytocin receptor antagonist, to be administered subcutaneously, for use in connection with IVF. Ferring Pharmaceuticals' atosiban, an oxytocin receptor antagonist, has been used in investigator initiated trials in connection with IVF outside the United States.

With respect to OBE022, we anticipate competing with atosiban, which has been approved to delay preterm birth outside of the United States, as well as currently available calcium channel blockers, such as nifedipine or prostaglandin inhibitors, such as NSAIDs. We are also aware that GlaxoSmithKline is developing retosiban, an oxytocin receptor antagonist, to delay preterm birth.

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 OBE2109, 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 OBE2109, 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 March 31, 2017, our patent portfolio as it pertains to certain of our product candidates included:

- six U.S. patent applications, projected to expire between 2034 and 2037, as well as corresponding patent applications internationally, directed to nolasiban compositions of matter and uses of nolasiban in artificial reproductive technology and for the treatment of preterm labor; and
- one international (PCT) application, which, if granted in the United States, projects to expire in 2037, directed to OBE022 compositions of matter and uses of OBE022 for the treatment of preterm labor.

As of March 31, 2017, 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 compositions of matter and uses of nolasiban for the treatment of preterm labor;
- two U.S. patents, projected to expire between 2024 and 2036, as well as corresponding patents and patent applications internationally, one U.S. patent application, projected to expire in 2036, and one PCT application, which, if granted in the U.S., projects to expire in 2037, directed to OBE022 compositions of matter and uses of OBE022 for the treatment of preterm labor; and
- two U.S. patents, projected to expire between 2030 and 2032, as well as corresponding patents and patent applications internationally outside of specified Asian countries, as well as one U.S. patent application, projected to expire in 2031, directed to OBE2109 compositions of matter and uses of OBE2109 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 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.

2013 License Agreement with Merck Serono

In August 2013, we entered into a license agreement, or the 2013 license agreement, with Merck Serono, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including nolasiban, which we are developing for the treatment of conditions associated with ART. In consideration for the license, we issued 914,069 Series A preferred shares to Merck Serono at the time of our Series A financing, which had a fair-value of $4.9 million. With respect to any products we commercialize under the 2013 license

agreement, we have agreed to pay Merck Serono quarterly royalties based on our annual net sales of each product at a high-single-digit percentage of annual net sales, subject to specified reductions, until the later of the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis, or ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

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

2015 License Agreement with Merck Serono

In June 2015, we entered into a second license agreement with Merck Serono, or the 2015 license agreement, which we amended in July 2016, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including 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 OBE2109. Under the Kissei license and supply agreement, we are developing OBE2109 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 $10.0 million upfront payment. In addition, we have agreed to make aggregate milestone payments of up to $63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. With respect to any Product we commercialize under the Kissei license and supply agreement, we have agreed to make additional aggregate milestone payments of up to $125.0 million to Kissei upon the achievement of specified commercial milestones.

Pursuant to the Kissei license and supply agreement, we have agreed to exclusively purchase the active pharmaceutical ingredient for OBE2109 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 a second source of the supply of OBE2109 upon Kissei failing to deliver a substantial percentage of the requested supply, delivering the supply late or delivering the supply of OBE2019 in nonconforming manner; provided that Kissei has a specified period of time to cure any of these defects. 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, who 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 manufacturer or sponsor under an approved NDA are also subject to annual drug and establishment 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 agree to offer 50% 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;
- creation of the Independent Payment Advisory Board, which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law unless overruled by a supermajority vote of Congress; and
- establishment of a Center for Medicare and Medicaid Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. The current administration and Congress will likely continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the ACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, which, if enacted, would have amended or repealed significant portions of the ACA. However, consensus over the scope of the American Health Care Act could not be reached by its proponents in the U.S. House of Representatives. Thus, the proposed legislation has been withdrawn and the prospects for legislative action on this bill are uncertain. Congress could consider other legislation to repeal or replace certain elements of the ACA. At this time, the full effect that the ACA would have on our business remains unclear.

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 through 2025 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 bills 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.

Individual states in the United States have also become increasingly aggressive in passing legislation and implementing 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. This measure could reduce the ultimate demand for our products or put pressure on our product pricing.

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 set a goal of moving 30% of Medicare payments to alternative payment models tied to the quality or value of services by 2016 and 50% of Medicare payments into these alternative payment models by the end of 2018. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for our products.

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 adequate coverage and 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, other divisions of the HHS, the U.S. Department of Justice, and similar foreign, state, and local government authorities, regulate sales, promotion and other activities following product approval. 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, make 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 anti-kickback or similar laws. Moreover, recent healthcare reform legislation has strengthened these laws. For example, the ACA, among other things, amends 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, private individuals 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 HIPAA. Violations of fraud and abuse laws may be punishable by criminal and civil 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 HITECH, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; analogous state laws governing the privacy and security of health information, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, and the federal Physician Payments Sunshine Act, which requires certain manufacturers of products, devices, biologics, and medical supplies to report annually to HHS 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 states require manufacturers to make reports to states on pricing and marketing information. 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 expiry 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

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 OBE2109 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. We are currently conducting a multiple-dose, placebo-controlled Phase 2b clinical trial of OBE2109 in patients with endometriosis, with a target enrollment of 330 patients. We expect to report data from the first 24-week evaluation period of this trial in the first half of 2018. For the uterine fibroids indication, we intend to commence a Phase 3 clinical development program with two Phase 3 clinical trials in the first half of 2017. We expect to report data from these Phase 3 clinical trials in the first half of 2020. We are also developing nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing IVF. We initiated a European Phase 3 clinical trial in women undergoing IVF in the first half of 2017 and expect to report data for the primary endpoint in the second quarter of 2018. In addition, we are developing OBE022 an oral and selective prostaglandin $F_{2\alpha}$ receptor antagonist, as a once daily treatment for preterm labor in weeks 24 to 34 of pregnancy. Based on results of Phase 1 clinical trials conducted in February and March 2017, we intend to advance OBE022 into Phase 2a Proof-of-Concept clinical trial in the second half of 2017 to assess its safety and efficacy to delay birth in women 24 to 34 weeks pregnant who face preterm labor and potentially preterm delivery.

We were founded in November 2012 and our operations to date have included organizing and staffing our company, raising capital, in-licensing rights to OBE2109, nolasiban and OBE022 and conducting preclinical 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 $180.0 million of gross proceeds, including the proceeds from our initial public offering, and also acquired license rights on product candidates from the sale of preferred shares.

We have never been profitable and have incurred significant net losses in each period since our inception. Our net losses were $30.2 million, $19.9 million and $12.8 million for years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had accumulated losses of $70.2 million, out of which $30.6 million were offset with share premium. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will 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 Phase 2b clinical trial of OBE2109 for the treatment of endometriosis, our planned Phase 3 clinical trials of OBE2109 for the treatment of uterine fibroids, our European Phase 3 clinical trial for nolasiban, our planned Phase 2a Proof-of-Concept clinical trial for OBE022 and any additional clinical trials and nonclinical studies 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 if any of our product candidates are approved, proceed to commercialization. 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. Additionally, we currently utilize third-party CROs, to carry out our clinical development and trials. We do not yet have a sales organization.

Strategic Licensing Agreements

OBE2109

In November 2015, we entered into the Kissei license and supply agreement with Kissei. Pursuant to the Kissei license and supply agreement we received an exclusive license to develop, manufacture and commercialize products, or the Product, containing the compounds which is a specified GnRH antagonist and covered by certain licensed patent rights, or the Compound, throughout the world except for specified Asian countries and we arranged to exclusively acquire from Kissei the material necessary to produce OBE2109.

In consideration for the license, we made an initial $10.0 million upfront payment. In addition, we have agreed to make aggregate milestone payments of up to $63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. With respect to any Product we commercialize under the Kissei license and supply agreement, we have agreed to make additional aggregate milestone payments of up to $125.0 million to Kissei upon the achievement of specified commercial milestones.

Pursuant to the Kissei license and supply agreement, we have agreed to exclusively purchase the active pharmaceutical ingredient for OBE2109 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.

Nolasiban

In August 2013, we entered into 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. In consideration for the license, we issued 914,069 Series A preferred shares to Merck Serono at the time of our Series A financing, which had a fair-value of $4.9 million based on an exchange rate of $1.00 for CHF 0.9244 as of the date of the transaction. With respect to any products we commercialize under the 2013 license agreement, we agreed to pay Merck Serono quarterly royalties based on a high-single-digit percentage of annual net sales of each product, 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.

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 quarterly royalties based on a mid-single-digit percentage of annual net sales of each product, 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.

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 for the foreseeable future.

Other Operating Income

Other operating income mainly relates to consulting services rendered to a third party in 2015 and re-invoicing costs associated with both our Merck Serono and Kissei Pharmaceutical license agreements in 2016.

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 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 preclinical 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 preclinical 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.

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

From inception through December 31, 2016, we have incurred $54.8 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, 2016, 2015 and 2014, respectively.

	Year Ended December 31,		
	2016	2015	2014
OBE2109	$ (9,689)	$ (188)	$ —
Nolasiban	(2,873)	(9,252)	(6,983)
OBE022	(4,103)	(1,275)	(833)
Total outsourced research and development expenses	$ (16,665)	$ (10,715)	$ (7,816)

We expect our research and development expense will increase for the foreseeable future as we seek to advance the development of our product candidates. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of our product 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; and
- the results of our clinical trials.

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, for personnel in executive, finance, accounting, business development, legal and human resource functions. General and administrative expense also includes corporate facility costs not otherwise included in research and development expenses, legal fees related to corporate matters and fees for accounting and consulting services.

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, compliance and director and officer insurance 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 on our cash and cash equivalents and foreign exchange gains and losses.

Taxation

We are subject to corporate taxation in Switzerland. 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 the compliance with certain reporting provisions.

We are also entitled under Swiss laws to carry forward any losses incurred for a period of seven years and can offset our losses carried forward against future taxes. As of December 31, 2016, we had tax loss carryforwards totaling $57.0 million. We do not believe it is probable that we will generate sufficient profits to avail ourselves of these tax loss carryforwards.

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,		
	2016	2015	2014
		(in thousands)	
Consolidated Statement of Operations Data:			
Other operating income	$ 22	$ 17	$ 45
Operating expenses:			
Research and development expenses	(23,711)	(16,892)	(11,402)
General and administrative expenses	(6,452)	(2,954)	(1,560)
Total operating expenses	(30,163)	(19,846)	(12,962)
Finance result, net	(61)	(38)	109
Net loss	$ (30,202)	$ (19,867)	$ (12,808)

Years Ended December 31, 2016 and 2015

Operating Expenses

Research and Development Expenses

	Year Ended December 31,	
	2016	2015
	(in thousands) (unaudited)	
Research and development expenses by product candidate		
OBE2109	$ (9,689)	$ (188)
Nolasiban	(2,873)	(9,252)
OBE022	(4,103)	(1,275)
Unallocated expenses		
Staff costs	(5,520)	(5,367)
Other research and development costs	(1,526)	(810)
Total research and development expenses	$ (23,711)	$ (16,892)

Research and development expenses increased by $6.8 million in 2016 compared to 2015 primarily due to the increased costs of $9.7 million resulting from the initiation of the clinical activities for OBE2109, including primarily the Phase 2b clinical trial in endometriosis, and increased costs of $2.8 million resulting from the initiation of our Phase 1 clinical trials with OBE022, which were partially offset by decreased costs of $6.4 million resulting from the completion of the Phase 2 clinical trials of nolasiban.

General and Administrative Expenses

	Year Ended December 31,	
	2016	2015
	(in thousands) (unaudited)	
Staff costs	$ (1,916)	$ (1,946)
Professional fees	(3,959)	(690)
Other general and administrative costs	(577)	(318)
Total general and administrative expenses	$ (6,452)	$ (2,954)

General and administrative expenses increased by $3.5 million in 2016 compared to 2015 primarily due to an increase of $3.3 million in professional fees mainly due to legal, audit, accounting and printing fees associated with our initial public offering.

Finance Result, Net

	Year Ended December 31,	
	2016	2015
	(in thousands)	
Finance result, net	$ (61)	$ (38)

Finance result, net, in 2016 and 2015 primarily consisted of foreign exchange losses.

Years Ended December 31, 2015 and 2014

Operating Expenses

Research and Development Expenses

	Year Ended December 31,	
	2015	2014
	(in thousands) (unaudited)	
Research and development expenses by product candidate		
OBE2109	$ (188)	$ —
Nolasiban	(9,252)	(6,983)
OBE022	(1,275)	(833)
Unallocated expenses		
Staff costs	(5,367)	(2,989)
Other research and development costs	(810)	(597)
Total research and development expenses	$ (16,892)	$ (11,402)

Research and development expenses increased by $5.5 million in 2015 compared to 2014 primarily due to a $2.3 million increase in the costs of outsourced research and development activities primarily attributable to the two Phase 2 clinical trials for nolasiban and a $2.4 million increase in employee salaries, related benefits and share-based compensation costs associated with an increased headcount.

General and Administrative Expenses

	Year Ended December 31,	
	2015	2014
	(in thousands) (unaudited)	
Staff costs	$ (1,946)	$ (933)
Professional fees	(690)	(367)
Other general and administrative costs	(318)	(260)
Total general and administrative expenses	$ (2,954)	$ (1,560)

General and administrative expenses increased by $1.4 million in 2015 compared to 2014 primarily due to costs associated with an increase in employee salaries, related benefits and share-based compensation costs associated with an increased headcount, as well as our Series B financing and the Kissei license and supply agreement.

Finance Result, Net

	Year Ended December 31,	
	2015	2014
	(in thousands)	
Finance result, net	$ (38)	$ 109

Finance result, net decreased by $0.1 million in 2015 compared to 2014 primarily due to foreign exchange losses realized on our cash and cash equivalents.

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, 2016, we have raised an aggregate of $93.2 million of gross proceeds from the sale of preferred shares. As of December 31, 2016, we had $25.5 million in cash and cash equivalents. In January 2017, we completed our initial public offering of

6,450,000 common shares at a public offering price of $15.00 per share. We received $90.0 million in net proceeds after deducting $6.8 million of underwriting discounts and commissions, excluding approximately $3.2 million in offering expenses. As a result, our cash on hand increased by approximately $86.8 million, resulting in a total liquidity position of $112.3 million following the completion of our initial public offering.

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 would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2019. We have based this estimate on assumptions that may prove to be wrong, and we could utilize 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 preclinical studies and clinical trials for OBE2109, 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 associated with building out our U.S. operations;
- 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 preclinical 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, if ever, as we can generate substantial product revenue, 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, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder. 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,		
	2016	2015	2014
Cash and cash equivalents at beginning of period	$ 54,275	$ 4,008	$ 16,293
Net cash used in operating activities	(28,589)	(13,911)	(12,124)
Net cash used in investing activities	(45)	(10,050)	(101)
Net cash (used in) / from financing activities	(167)	74,404	427
Effect of exchange rates	34	(176)	(487)
Cash and cash equivalents at end of period	$ 25,508	$ 54,275	$ 4,008

Operating Activities

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

During the year ended December 31, 2016, operating activities used $28.6 million of cash, primarily as the result of our net loss before tax of $30.2 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to $2.0 million and mainly consisted of share-based payments. Changes in the net working capital included primarily a $2.0 million increase in prepaid expenses, mainly due to upfront payments made in relation with our Phase 3 clinical trials in uterine fibroids, as well as a $1.8 million increase in other payables and current liabilities mainly due to our ongoing Phase 2 clinical trial of OBE2109 in endometriosis and Phase 1 clinical trials of OBE022 as of December 31, 2016.

During the year ended December 31, 2015, operating activities used $13.9 million of cash, primarily as the result of our net loss before tax of $19.9 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to $3.4 million and primarily consisted of share-based payments and the issuance of anti-dilution common shares during our Series B financing in November 2015. Changes in the net working capital included a $2.1 million increase in accrued expenses, primarily due to the stamp duty due on the proceeds from the Series B financing, as well as to accrued staff costs, including annual bonuses, and our ongoing clinical trials as of December 31, 2015.

During the year ended December 31, 2014, operating activities used $12.1 million of cash, primarily as the result of our net loss before tax of $12.8 million, as adjusted for non-cash items and changes in the net working capital. Non-cash items amounted to $0.4 million and mainly consisted of share-based payments. Changes in the net working capital included mainly a $1.1 million increase in accrued expenses, mainly due to staff costs accrued, including annual bonuses, and our ongoing clinical trials as of December 31, 2014.

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.

Net cash used in investing activities in the years ended December 31, 2016 and December 31, 2014, were primarily used to purchase furniture and fixtures for our offices in Switzerland. Net cash used in investing activities in 2015 mainly consisted of the upfront payment made to Kissei under the Kissei license and supply agreement.

Financing Activities

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

Cash flows used in financing activities in 2016 mainly consisted of payments of costs incurred in connection with our initial public offering and related issuance of new shares. Cash flows from financing activities in 2015 and 2014 mainly consisted of the proceeds from the Series B financing and payments received for the second tranche of the Series A financing.

C. Research and Development

For a discussion of our research and development activities, see the Business Overview section and the item "A. Operating Results" of this Financial Review section.

D. Trend Information

For a discussion of trends, see item "A. Operating Results" and "B. Liquidity and Capital Resources" of this Financial Review section.

E. Off-Balance Sheet Arrangements

During the periods presented, we did not have, and we do not currently have, any off-balance sheet arrangements.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2016:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
			(in thousands)		
Operating leases	$ 243	$ 121	$ —	$ —	$ 364
Total	$ 243	$ 121	$ —	$ —	$ 364

Under our license agreements with Kissei and Merck Serono, we may be required to pay royalties in the future. In addition, pursuant to the Kissei license and supply agreement, we have agreed to make aggregate milestone payments of up to $63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. With respect to any product we commercialize under the Kissei license and supply agreement, we have agreed to make additional aggregate milestone payments of up to $125.0 million to Kissei upon the achievement of specified commercial milestones. We have not included any contingent payment obligations, 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, preclinical 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.

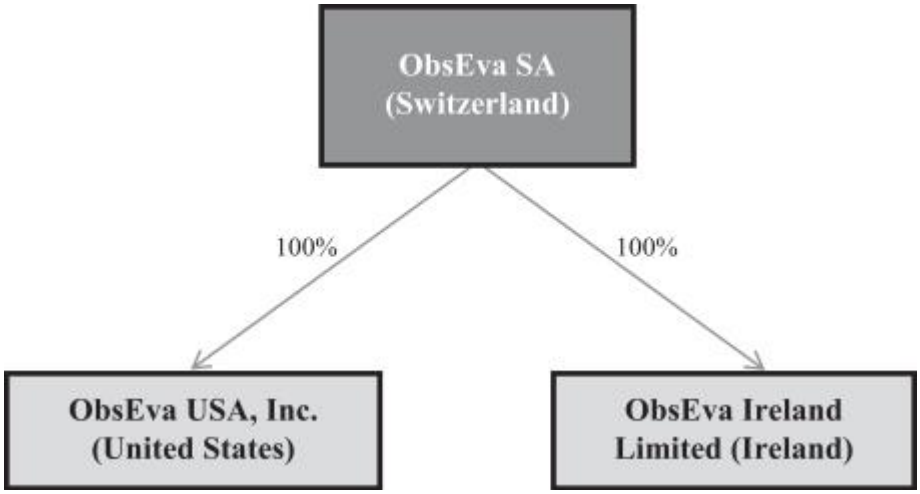
Corporate Governance

1 - Information on the Company.

Our legal and commercial name is ObsEva SA. We are a Swiss stock corporation (*société anonyme*) organized under the laws of Switzerland. We were formed in 2012 with an indefinite duration. We are currently registered in Plan-les-Ouates, Geneva, Switzerland. Our principal executive offices are located at Chemin des Aulx, 12, 1228 Plan-les-Ouates, Geneva, Switzerland. Our telephone number is +41 22 552 38 40. Investors should contact us for any inquiries through the address and telephone number of our principal executive office. We maintain a web site at *www.obseva.com*. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our web site is not a part of this Annual Report.

2 - Organizational Structure.

The following diagram illustrates our corporate structure:



3 - Directors, Senior Management and Employees.

A. Directors and Senior Management.

The following table sets forth information regarding our executive officers and directors, including their ages, as of December 31, 2016. Our directors are appointed for one-year terms, which expire on the occasion of each annual general meeting. Accordingly, the terms of the directors set forth below will expire on our first annual general meeting as a public company in 2017.

Name	Age	Position(s)
Executive Officers:		
Ernest Loumaye	64	Chief Executive Officer and Director
Jean-Pierre Gotteland	52	Chief Scientific Officer
Elke Bestel	50	Chief Medical Officer and Head of Pharmacovigilance
Timothy Adams	57	Chief Financial Officer
Fabien Lefebvre de Ladonchamps	38	Vice President of Finance
Ben T.G. Tan	57	Vice President of Commercial & Business Development
Non-Employee Directors:		
Frank Verwiel	54	Chairperson of the Board of Directors
Annette Clancy	62	Director
Barbara Duncan	52	Director
James I. Healy	51	Director
Ed Mathers	56	Director
Rafaèle Tordjman	47	Director
Jacky Vonderscher	62	Director

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

Executive Officers

Ernest Loumaye is a co-founder of our company and has served as our Chief Executive Officer since our 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 until October 2012. Dr. Loumaye currently serves as the chairman of the board of directors of GenKyoTex S.A., a private Swiss pharmaceutical company. Dr. Loumaye holds a M.D. and a Ph.D. from Louvain University, with a specialization in Obstetrics and Gynaecology. Our board of directors believes that Dr. Loumaye's leadership of our company since its inception and experience with biopharmaceutical companies prior to founding our company provide him with the qualifications and skills to serve as a director.

Jean-Pierre Gotteland has served as our 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 Pabre Meclicament. Dr. Gotteland holds a Ph.D. in Organic Chemistry from the University Claude Bernard and an Engineering Diploma from Ecole Superieure de Chimie Industrielle.

Elke Bestel has served as our Chief Medical Officer and Head of Pharmacovigilance since September 2015. Prior to joining our 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.

Timothy Adams has served as our 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 served as a member of the board of directors of ABILITY Network, a private healthcare technology company, since November 2014. Mr. Adams has served as a member of the board of directors of Model N, a public revenue management solutions company, since December 2016. Mr. Adams obtained a B.S. from Murray State University and an M.B.A. from Boston University.

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

Ben T.G. Tan has served as our Vice President of Commercial & Business Development since September 2014. Prior to joining our 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.

Non-Employee Directors

Frank Verwiel has served as a member of our board of directors since March 2016 and has served as the chairperson of the board since December 2016. 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 currently serves as a member of the board of directors of the public companies Achillion Pharmaceuticals, Inc., a pharmaceutical company, Avexis, Inc., a biotechnology company, and Bavarian Nordic A/S, a biotechnology company. Dr. Verwiel previously served on the board of directors of InterMune, Inc. from 2012 to 2014. Dr. Verwiel was also a director of the Biotechnology Industry Organisation. Dr. Verwiel received his M.D. from Erasmus University, Rotterdam, The Netherlands, and his M.B.A. from INSEAD in Fontainebleau, France. Our board of directors believes that Dr. Verwiel's scientific acumen and his over 25 years of strategic, operational and international experience in the pharmaceutical industry provide him with the qualifications and skills to serve as a director.

Annette Clancy has served as a member of our board of directors since November 2013 and served as our chairperson from November 2013 to December 2016. Since 2009, 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 positions at GlaxoSmithKline, a global healthcare company. Ms. Clancy is currently on the board of directors of Swedish Orphan Biovitrum AB, a public biopharmaceutical company, as well as several private companies. Ms. Clancy holds a B.Sc. in Pharmacology from Bath University and a series of American Management Association diplomas in finance and marketing. Our board of directors believes that Ms. Clancy's over 30 years of experience in the pharmaceutical and biopharmaceutical industries provide her with the qualifications and skills to serve as a director.

Barbara Duncan has served as a member of our board of directors since December 2016. 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 Medicines, Inc., a biopharmaceutical company, and Adaptimmune Therapeutics plc, a biopharmaceutical company, and Innoviva, Inc., a biopharmaceutical company, as well as two private companies. 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. Our board of directors believes that Ms. Duncan's expertise with public and financial accounting matters, as well as her experience in the pharmaceutical industry, provide her with the qualifications and skills to serve as a director.

James I. Healy has served as a member of our board of directors since August 2013. Dr. Healy has been a General Partner of Sofinnova Ventures, a venture capital firm, since June 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals (as successor to Miles Laboratories) and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of the public companies Ascendis Pharma A/S, a clinical-stage pharmaceutical company, Auris Medical Holding AG, a biopharmaceutical company, Coherus BioSciences, Inc., a biologics platform company, Amarin Corporation PLC, a biopharmaceutical company, Edge Therapeutics, Inc., a biotechnology company, and Natera, Inc., a genetic testing company, as well as several private companies. Previously, he served as a board member of InterMune, Inc., Anthera Pharmaceuticals, Inc., Durata Therapeutics, Inc., CoTherix, Inc., Hyperion Therapeutics, Inc. and KaloBios Pharmaceuticals, Inc. Dr. Healy was nominated to our board of directors by Sofinnova Ventures. Dr. Healy holds an M.D. and a Ph.D. in Immunology from the Stanford School of Medicine and holds a B.A. in Molecular Biology and a B.A. in Scandinavian Studies from the University of California at Berkeley. Our board of directors believes that Dr. Healy's experience in the pharmaceutical industry and investing in life sciences companies, as well as his medical and scientific background, provide him with the qualifications and skills to serve as a director.

Ed Mathers has served as a member of our board of directors since February 2016. Since August 2008, Mr. Mathers has been a Partner at New Enterprise Associates, Inc., or NEA, a private venture capital firm focusing on technology and healthcare investments. Mr. Mathers serves on the board of directors of Envisia Therapeutics, Inc., a biopharmaceutical company, Liquidia Technologies, a biotechnology company, Ra Pharmaceuticals, Inc., a pharmaceutical company, Rhythm Pharmaceuticals, a pharmaceutical company, Lumos Pharma, a biotechnology company, Mirna Therapeutics, Inc., a pharmaceutical company, as well as several private companies. From 2002 to 2008, Mr. Mathers served as Executive Vice President, Corporate Development and Venture at MedImmune, Inc., or MedImmune, and led its venture capital subsidiary, MedImmune Ventures, Inc. Before joining MedImmune in 2002, he was Vice President, Marketing and Corporate Licensing and Acquisitions at Inhale Therapeutic Systems. Previously, Mr. Mathers spent 15 years at Glaxo Wellcome, Inc.

where he held various sales and marketing positions. Mr. Mathers was nominated to our board of directors by NEA. Mr. Mathers holds a B.S. in Chemistry from North Carolina State University. Our board of directors believes that Mr. Mathers's experience with the healthcare and pharmaceutical industries and his broad management experience provide him with the qualifications and skills to serve as a director.

Rafaèle Tordjman has served as a member of our board of directors since August 2013. Dr. Tordjman joined the French venture capital firm Sofinnova Partners in 2001 and is a Managing Partner specializing in life sciences investments. Dr. Tordjman serves on the board of directors of the public company Ascendis Pharma A/S, a clinical-stage pharmaceutical company. Dr. Tordjman has also served on the boards of directors at several life sciences companies including, DBV Technologies SA, a French publicly traded company specializing in allergy therapies, Flexion Therapeutics, Inc., a publicly traded company specializing in clinical-stage pharmaceuticals, as well as a private company, and Preglem, 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 was nominated to our board of directors by Sofinnova Partners. 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. Our board of directors believes that Dr. Tordjman's experience in the pharmaceutical industry and investing in life sciences companies, as well as her medical and scientific background, provide her with the qualifications and skills to serve as a director.

Jacky Vonderscher has served as a member of our board of directors since October 2013. Since September 2013, Dr. Vonderscher has served as the Chief Executive Officer of Vonderscher & Co GmbH, a consultancy company, and since January 2014, Dr. Vonderscher has served 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 several private companies. 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. Our board of directors believes that Dr. Vonderscher's experience in the pharmaceutical industry, as well as his scientific background, provide him with the qualifications and skills to serve as a director.

Family Relationships

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

B. Compensation.

Compensation of Executive Officers and Directors

For the year ended December 31, 2016, the aggregate compensation paid to the members of our board of directors and our executive officers for services in all capacities was $9.0 million.

During the year ended December 31, 2016, other than the non-voting share incentive plan outline below, we had no performance based compensation programs.

The amount set aside by us to provide pension, retirement or similar benefits to members of our board of directors or executive officers amounted to a total of $0.1 million in the year ended December 31, 2016.

Non-Voting Share Incentive Plan

On November 26, 2013, we adopted an incentive plan, or the Plan, under which, subject to the approval of our board of directors, we may grant awards of restricted non-voting shares to eligible participants. The material terms of our Plan are set forth below.

All of our employees, advisors, including scientific consultants, agents and members of our board of directors are eligible to participate in our Plan. As of December 31, 2016, there were 1,854,502 issued and outstanding non-voting shares

awarded under our Plan. All outstanding non-voting shares were converted into common shares immediately prior to the closing of our initial public offering. Under our Plan, non-voting shares are issued to participants and registered in their name. Each non-voting share has a par value of CHF 0.0769 per share, which the participant must pay, in respect of the aggregate number of shares underlying the non-voting share award. Non-voting shares held by participants are subject to a four-year vesting period, or as otherwise set out in the participant's issuance agreement. Under the Plan, one-fourth of the non-voting shares would vest upon the first anniversary of the issuance date, and one-36th of the remaining non-voting shares would vest, starting from the first anniversary of the issuance date, over a total period of three years. Upon a termination of employment, certain forfeiture provisions may apply to a participant's vested or unvested non-voting shares.

2017 Equity Incentive Plan

Following the completion of our initial public offering, we ceased issuing any new grants under our Plan and plan to issue any new awards under our 2017 equity incentive plan, or our 2017 Plan. No awards have been granted under our 2017 Plan. Our 2017 Plan provides for the grant of incentive stock options within the meaning of Section 422 of the U.S. Internal Revenue Code, or the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. Our 2017 Plan also provides for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares

The maximum number of our common shares that may be issued under our 2017 Plan is 4,172,623 shares. The maximum number of common shares that may be issued pursuant to the exercise of incentive stock options under our 2017 Plan is 8,300,000 shares.

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

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

Administration

Our board of directors, or a duly authorized committee thereof, has the authority to administer our 2017 Plan. Our board of directors has delegated its authority to administer our 2017 Plan to our compensation, nominating and corporate governance committee under the terms of the compensation, nominating and corporate governance committee's charter. Subject to the terms of our 2017 Plan, our board of directors may also delegate to one or more of our officers the authority to (1) designate employees other than officers to receive specified stock awards and (2) determine the number of common shares to be subject to such stock awards. Subject to the terms of our 2017 Plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of one common share, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2017 Plan.

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

Section 162(m) Limits

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

Performance Awards

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

Corporate Transactions

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

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

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

Change in Control

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

Plan Amendment or Termination

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

C. Board Practices.

Our board of directors is composed of eight members. Each director is elected for a one-year term. The current members of our board of directors were appointed at an extraordinary shareholders' meeting held on December 6, 2016 to serve until our first annual general meeting as a public company in 2017.

We are a foreign private issuer. As a result, in accordance with the NASDAQ listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than relying on the stock exchange corporate governance requirements. However, our board of directors has undertaken a review of the independence of the directors and determined that, under current NASDAQ listing requirements, Frank Verwiel, Annette Clancy, Barbara Duncan, James I. Healy, Ed Mathers, Rafaèle Tordjman and Jacky Vonderscher, representing seven of our eight directors, are "independent directors." In making such determination, our board of directors considered whether any director has a material relationship with us that could compromise their ability to exercise independent judgment in carrying out their responsibilities. For an overview of our corporate governance principles, see "Item 10.B—Memorandum and Articles of Association."

Board Committees

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

Audit Committee

The audit committee, which consists of Barbara Duncan, Ed Mathers and Frank Verwiel, assists our board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee is directly responsible for the compensation, retention and oversight of the work of our independent registered public accounting firm and statutory auditors who are appointed by the shareholders pursuant to Swiss corporation law. Ms. Duncan serves as chairman of the committee. The audit committee consists exclusively of members of our board of directors who are financially literate, and Ms. Duncan is considered an "audit committee financial expert" as defined by the U.S. Securities and Exchange Commission, or SEC. Our board of directors has determined that Ms. Duncan, Mr. Mathers and Dr. Verwiel satisfy the "independence" requirements set forth in Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act.

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

- recommending an auditor for submission to the shareholders;
- the compensation, retention and oversight of any auditor or accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- reviewing and discussing with the independent auditor its responsibilities under generally accepted auditing standards, the planned scope and timing of the independent auditor's annual audit plan(s) and significant findings from the audit;
- obtaining and reviewing a report from the independent auditor describing all relationships between the independent auditor and us consistent with the applicable Public Company Accounting Oversight Board requirements regarding the independent auditor's communications with the audit committee concerning independence;

- confirming and evaluating the rotation of the audit partners on the audit engagement team as required by law;
- reviewing with management and the independent auditor, in separate meetings whenever the audit committee deems appropriate, any analyses or other written communications prepared by the management or the independent auditor setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative IFRS methods on the financial statements, and our other critical accounting policies and practices;
- reviewing, in conjunction with our chief executive officer and chief financial officer, our disclosure controls and procedures;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters; and
- approving or ratifying any related party transaction (as defined in our related party transaction policy) in accordance with our related party transaction policy.

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

Compensation, Nominating and Corporate Governance Committee

Our compensation, nominating and corporate governance committee consists of three members, Annette Clancy, Rafaèle Tordjman and James I. Healy. Our board of directors has determined that each of Ms. Clancy and Drs. Tordjman and Healy are independent under the NASDAQ listing standards, are "non-employee directors" as defined in Rule 16b-3 promulgated under the Exchange Act and are "outside directors" as that term is defined in Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended, or Section 162(m). The chair of our compensation, nominating and corporate governance committee is Ms. Clancy. The primary purpose of our compensation, nominating and corporate governance committee is to discharge our board of directors' responsibilities to oversee our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. We are subject to the Swiss Ordinance against excessive compensation in listed stock corporations, known as the "Minder" rules. As a result of the Minder rules, the members of the compensation, nominating and corporate governance committee must be elected by our shareholders and the aggregate compensation of our board of directors and executive officers must also be approved by our shareholders.

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

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

- review and approve, or recommend that our board of directors approve, the compensation of our executive officers based on the aggregate compensation approved by our shareholders;
- review and recommend to our board of directors the compensation of our directors based on the aggregate compensation approved by our shareholders;
- review and approve, or recommend that our board of directors approve, the terms of compensatory arrangements with our executive officers;
- administer our share and equity incentive plans;
- select independent compensation consultants and assess whether there are any conflicts of interest with any of the committees' compensation advisers;
- review and approve, or recommend that our board of directors approve, incentive compensation and equity plans, and any other compensatory arrangements for our executive officers and other senior management, as appropriate;
- review and establish general policies relating to compensation and benefits of our employees and reviewing our overall compensation philosophy;

- identify, evaluate and select, or recommend that our board of directors approve, nominees for election to our board of directors;
- evaluate the performance of our board of directors and of individual directors;
- consider and make recommendations to our board of directors regarding the composition of the committees of the board of directors;
- review developments in corporate governance practices;
- evaluate the adequacy of our corporate governance practices and reporting;
- review management succession plans;
- approve any loans by the company to executive officers (to the extent permitted by applicable law and our articles of association) and loans by the company to employees that are not executive officers, where the amount of any such loan exceeds $10,000;
- develop and make recommendations to our board of directors regarding corporate governance guidelines and matters; and
- oversee periodic evaluations of the board of directors' performance.

Other Corporate Governance Matters

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

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

D. Employees.

As of December 31, 2016, we had 27 employees. None of our employees are represented by any collective bargaining agreements. We believe that we maintain good relations with our employees. At each date shown, we had the following number of employees, broken out by department and geography.

	As of December 31,		
	2016	2015	2014
Function			
Research and preclinical development	8	6	4
Clinical, medical and regulatory affairs	11	10	7
Management and administrative	8	5	4
Total	**27**	**21**	**15**
Geography			
Switzerland	27	21	15

4 - Share Ownership.

The following table sets forth information with respect to the beneficial ownership of our common shares as of December 31, 2016 for each beneficial owner of 5% or more of our outstanding common shares; each of our directors and executive officers; and all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include common shares issuable upon the exercise of options that are immediately exercisable or exercisable within 60 days of December 31, 2016. Percentage ownership calculations are based on 23,181,262 common shares outstanding as of December 31, 2016. Such share number does not include the 6,450,000 common shares that were sold in connection with our initial public offering in January 2017. Further, the percentage ownership calculations and other information in the table does not reflect any purchases by our existing 5% shareholders and their affiliated entities in connection with our initial public offering.

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

In computing the number of common shares beneficially owned by a person and the percentage ownership of that person, we deemed outstanding common shares subject to options held by that person that are immediately exercisable or exercisable within 60 days of December 31, 2016. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

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

Name of Beneficial Owner	Number	Percentage
Principal Shareholders:		
Fund Sofinnova Capital VII[1]	3,849,274	16.6%
Sofinnova Venture Partners VIII, L.P.[2]	3,011,957	13.0
Novo A/S[3]	2,710,760	11.7
Ares Trading S.A.[4]	1,837,303	7.9
New Enterprise Associates 15, L.P.[5]	2,769,897	11.9
HBM Healthcare Investments (Cayman) Ltd[6]	1,846,598	8.0
Orbimed Private Investments V, LP[7]	1,846,598	8.0
Executive Officers and Directors:		
Ernest Loumaye[8]	3,107,299	13.4
Jean-Pierre Gotteland	*	*
Elke Bestel	*	*
Timothy Adams	—	—
Fabien Lefebvre de Ladonchamps	*	*
Ben T.G. Tan	*	*
Barbara Duncan	—	—
Annette Clancy	*	*
James I. Healy[2]	3,011,957	13.0
Ed Mathers[5]	2,769,897	11.9
Rafaèle Tordjman[1]	3,849,274	16.6
Frank Verwiel	*	*
Jacky Vonderscher	*	*
All current directors and executive officers as a group (13 persons)[9]	13,473,577	58.1%

* Represents beneficial ownership of less than 1%.

(1) Consists of 3,849,274 common shares issuable upon conversion of preferred shares held by Fund Sofinnova Capital VII. Sofinnova Partners SAS, a French corporation and the management company of Fund Sofinnova Capital VII, may be deemed to have sole voting and dispositive power over the shares held by Fund Sofinnova Capital VII. The managing partners of Sofinnova Partners SAS, Denis Lucquin, Antoine Papiernik, Rafaèle Tordjman, M.D., Ph.D. (a member of our board of directors) and Monique Saulnier, may be deemed to have shared voting and dispositive power with respect to such shares. The address of Fund Sofinnova Capital VII is Sofinnova Partners, Immeuble le Centorial, 16-18 Rue du Quatre-Septembre, 75002 Paris, France.

(2) Consists of 3,011,957 common shares issuable upon conversion of preferred shares held by Sofinnova Venture Partners VIII, L.P., or Sofinnova VIII. Sofinnova Management VIII, L.L.C. is the general partner of Sofinnova VIII, and Anand Mehra, M.D., James Healy, M.D. (a member of our board of directors) and Michael Powell, Ph.D., the managing members of Sofinnova Management VIII, L.L.C., may be deemed to have shared voting and dispositive power with respect to such shares. The address of Sofinnova VIII is c/o Sofinnova Ventures, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, California 94025.

(3) Consists of 2,710,760 common shares issuable upon conversion of preferred shares held by Novo A/S, a Danish limited liability company that manages investments and financial assets. The board of directors of Novo A/S, which is currently comprised of Sten Scheibye, Göran Ando, Jeppe Christiansen, Steen Riisgaard and Per Wold-Olsen, has shared voting and dispositive power with respect to these shares and may exercise such control only with the support of a majority of the board. As such, no individual member of the board is deemed to hold any beneficial ownership of these shares. Dr. Lüneborg, a member of our board of directors, is employed as a principal of Novo A/S and is not deemed to be a beneficial owner of these shares. The address of Novo A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.

(4) Consists of 1,837,303 common shares issuable upon conversion of preferred shares held by Ares Trading S.A. Ares Trading S.A. is the wholly owned subsidiary of Merck Serono S.A., which is the wholly owned subsidiary of Merck KGaA. By virtue of such relationships, Merck Serono S.A. and Merck KGaA may be deemed to have shared voting and dispositive power with respect to the shares held by Ares Trading S.A. The address of Ares Trading S.A. is Zone Industrielle de l'Ouriettaz, 1170 Aubonne, Switzerland.

(5) Consists of 2,769,897 common shares issuable upon conversion of preferred shares held by New Enterprise Associates 15, L.P., or NEA 15. The shares directly held by NEA 15 are indirectly held by NEA Partners 15, L.P., or NEA Partners 15, the sole general partner of NEA 15, NEA 15 GP, LLC, or NEA 15 LLC, the sole general partner of NEA Partner 15 and each of the individual Managers of NEA 15 LLC. The individual Managers of NEA 15 LLC, or collectively, the NEA 15 Managers, are Peter J. Barris, Forest Baskett, Anthony A. Florence, Jr., Kristna "Kittu " Kolluri, David M. Mott, Jon Sakoda, Scott D. Sandell, Peter Sonsini Ravi Viswanathan and Harry R. Weller. NEA 15, NEA Partners 15, NEA 15 LLC and the NEA 15 Managers share voting and dispositive power with regard to our securities directly held by NEA 15. Ed Mathers, a partner of New Enterprise Associates, Inc., is a member of our board of directors. The address of New Enterprise Associates 15, L.P. is c/o New Enterprise Associates, Inc., 1954 Greenspring Drive, Suite 600, Timonium, Maryland 21093.

(6) Consists of 1,846,598 common shares issuable upon conversion of preferred shares held by HBM Healthcare Investments (Cayman) Ltd. The board of directors of HBM Healthcare Investments (Cayman) Ltd. has sole voting and dispositive power with respect to the shares. The board of directors of HBM Healthcare Investments (Cayman) Ltd. is comprised of Jean-Marc Lesieur, Richard Coles, Sophia Harris, Dr. Andrea Wicki and Paul Woodhouse, none of whom has individual voting or dispositive power with respect to the shares. The address of HBM Healthcare Investments (Cayman) Ltd is Governor's Square, Suite 4-212-2, 23 Lime Tree Bay Avenue, West Bay, Grand Cayman, Cayman Islands.

(7) Consists of 1,846,598 common shares issuable upon conversion of preferred shares held by Orbimed Private Investments V, LP, or OPI V. OrbiMed Capital GP V LLC, or GP V, is the sole general partner of OPI V, and OrbiMed Advisors LLC, or Advisors, a registered adviser under the Investment Advisers Act of 1940, as amended, is the sole managing member of GP V. Samuel D. Isaly is the managing member of, and holder of a controlling interest in Advisors. By virtue of such relationships, GP V, Advisors and Mr. Isaly may be deemed to have voting and investment power with respect to the shares held by OPI V and as a result may be deemed to have beneficial ownership of such shares. The address of OPI V is 601 Lexington Avenue, 54th floor, New York, New York 10022.

(8) Consists of 2,085,434 common shares, 500,305 common shares issuable upon conversion of preferred shares and 521,560 common shares issuable upon conversion of non-voting shares. Of the non-voting shares, 338,299 non-voting shares were subject to a right of repurchase in our favor within 60 days of December 31, 2016 upon the occurrence of certain events.

(9) Consists of 2,085,434 common shares, 10,131,433 common shares issuable upon conversion of preferred shares and 1,256,710 common shares issuable upon conversion of non-voting shares. Of the non-voting shares, 855,218 non-

voting shares were subject to a right of repurchase in our favor within 60 days of December 31, 2016 upon the occurrence of certain events.

We have experienced significant changes in the percentage ownership held by major shareholders as a result of our initial public offering. Prior to our initial public offering in January 2017, our principal shareholders were Fund Sofinnova Capital VII (16.6%), Sofinnova Venture Partners VIII, L.P. (13.0%), Novo A/S (11.7%), Ares Trading S.A. (7.9%), New Enterprise Associates 15, L.P. (11.9%), HBM Healthcare Investments (Cayman) Ltd (8.0%) and Orbimed Private Investments V, LP (8.0%).

In January 2017, we completed our initial public offering and listed our common shares on the Nasdaq Global Select Market. In the initial public offering, we issued and sold 6,450,000 common shares. Upon the completion of our initial public offering, 29,631,262 common shares were outstanding. While none of our existing shareholders sold common shares in the initial public offering, the percentage ownership held by certain shareholders decreased as a result of the issuance of the common shares sold by us in the initial public offering.

As of December 31, 2016, we estimate that approximately 36.4% of our outstanding common shares were held in the United States by seven holders of record. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose common shares are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

5 - Controls and Procedures.

Disclosure Controls and Procedures

Our Chief Executive Officer (*principal executive officer*) and Chief Financial Officer (*principal financial officer*), after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of December 31, 2016, have concluded that, as of such date, our disclosure controls and procedures were effective and ensured that information required to be disclosed by us in reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer (*principal executive officer*) and Chief Financial Officer (*principal financial officer*), to allow timely decisions regarding required disclosure and is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

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 Chief Executive Officer, to members of the Executive Committee and to other specialized corporate functions such as Group Finance. Financial risk management is described in more details in note 3 to the Consolidated IFRS Financial Statements for the year ended December 31, 2016.

6 - Principal Accountant Fees and Services.

PricewaterhouseCoopers SA, or PWC, has served as our independent registered public accounting firm for 2016 and 2015. Our accountants billed the following fees to us for professional services in each of those fiscal years:

	December 31,	
	2016	2015
	(in thousands)	
Audit Fees	$ 1,010	$ 13
Audit-Related Fees	248	—
Tax Fees	10	—
Other Fees	186	—
Total	$ 1,454	$ 13

"Audit Fees" consist of fees billed for the annual audit of our consolidated financial statements, and the statutory audit of our consolidated and stand-alone financial statements. Audit Fees also include services that only our independent external auditor can reasonably provide, such as the review of documents filed with the U.S. stock exchange.

"Audit-Related Fees" consist of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of its financial statements or that are traditionally performed by the external auditor, and mainly include services such as comfort letters issued in connection with securities offerings, due diligence and agreed-upon or expanded audit procedures.

"Tax Fees" consist of tax consultations, such as advice in connection with employees' taxation arising from share-based compensation.

"Other Fees" consist of advisory services relating to the adoption of IFRS.

Consolidated IFRS Financial Statements for the year ended December 31, 2016

Consolidated Balance Sheet

(in USD '000)	Notes	As at December 31, 2016	2015
ASSETS			
Current assets			
Cash and cash equivalents...……..	4	25,508	54,275
Other receivables…….	5	783	69
Prepaid expenses and deferred costs……	6	2,415	174
Total current assets……...		**28,706**	**54,518**
Non-current assets			
Plant and equipment……	7	121	124
Intangible assets……..	8	16,608	16,857
Other long-term assets……	9	90	91
Total non-current assets……...		**16,819**	**17,072**
Total assets……		**45,525**	**71,590**
LIABILITIES AND EQUITY			
Current liabilities			
Other payables and current liabilities……	5	2,383	595
Accrued expenses……		4,269	3,657
Total current liabilities……		**6,652**	**4,252**
Non-current liabilities			
Post-employment obligations…..……	10	2,832	2,663
Total non-current liabilities……		**2,832**	**2,663**
Shareholders' equity			
Share capital……	11	1,740	1,694
Share premium…..……..	11	71,966	99,597
Reserves……..……	11	1,934	2,821
Accumulated losses……..	11	(39,599)	(39,437)
Total shareholders' equity……...		**36,041**	**64,675**
Total liabilities and shareholders' equity		**45,525**	**71,590**

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

Consolidated Statement of Comprehensive Loss

(in USD '000, except per share data)

	Notes	Year ended December 31, 2016	2015	2014
Other operating income…….	12	**22**	**17**	**45**
OPERATING EXPENSES				
Research and development expenses……	13	(23,711)	(16,892)	(11,402)
General and administrative expenses……	13	(6,452)	(2,954)	(1,560)
Total operating expenses…….		**(30,163)**	**(19,846)**	**(12,962)**
OPERATING LOSS……		**(30,141)**	**(19,829)**	**(12,917)**
Finance income ……..……..	15	36	-	109
Finance expense…….……....	15	(97)	(38)	-
NET LOSS BEFORE TAX…….		**(30,202)**	**(19,867)**	**(12,808)**
Income tax expense…….	16	-	-	-
NET LOSS FOR THE YEAR……..		**(30,202)**	**(19,867)**	**(12,808)**
Net loss per share				
Basic……	17	(1.40)	(1.87)	(1.41)
Diluted…….	17	(1.40)	(1.87)	(1.41)
OTHER COMPREHENSIVE LOSS				
Items that will not be reclassified to profit and loss				
Remeasurements on post-employment benefit plans……		(599)	(1,356)	(923)
Items that may be reclassified to profit or loss				
Currency translation differences……		(83)	(128)	(983)
TOTAL OTHER COMPREHENSIVE LOSS……		**(682)**	**(1,484)**	**(1,906)**
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		**(30,884)**	**(21,351)**	**(14,714)**

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

Consolidated Statement of Cash Flows

(in USD '000)	Notes	Year ended December 31, 2016	2015	2014
NET LOSS BEFORE TAX FOR THE YEAR		**(30,202)**	**(19,867)**	**(12,808)**
Adjustments for:				
Depreciation ……..……..	7	46	36	20
Post-employment cost / (benefit)……...		(384)	57	(78)
Share-based payments……	18	2,237	3,268	537
Finance expense, net……..		61	38	(109)
(Increase) / decrease in other receivables……..		(714)	4	(21)
(Increase) / decrease in prepaid expenses, deferred costs and other long term-assets……..		(2,033)	273	(443)
Increase in other payables and current liabilities……...		1,788	155	(341)
Increase in accrued expenses…….		612	2,125	1,119
NET CASH FLOWS USED IN OPERATING ACTIVITIES……		**(28,589)**	**(13,911)**	**(12,124)**
Payments for plant and equipment…….	7	(45)	(50)	(101)
Acquisition of a license...……...	8	-	(10,000)	-
NET CASH FLOWS USED IN INVESTING ACTIVITIES……		**(45)**	**(10,050)**	**(101)**
Proceeds from issues of shares and other equity securities…		46	75,836	423
Payment of share issuance costs……		(33)	(1,433)	-
Payment of deferred costs of financing activities……..		(206)	-	-
Interests paid……..		(8)	-	-
Interests received……		34	1	4
NET CASH FLOWS (USED IN) / FROM FINANCING ACTIVITIES……		**(167)**	**74,404**	**427**
Net (decrease) / increase in cash and cash equivalents.....		(28,801)	50,443	(11,798)
Cash and cash equivalents as at January 1,……...		**54,275**	**4,008**	**16,293**
Effects of exchange rate changes on cash and cash equivalents……..		34	(176)	(487)
Cash and cash equivalents as at December 31,……..		**25,508**	**54,275**	**4,008**

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

Consolidated Statement of Changes in Equity

(in USD '000)

	Notes	Share capital	Share premium	Share-based payments reserve	Foreign currency translation reserve	Total reserves	Accumulated losses	Total
December 31, 2013		**751**	**22,499**	**269**	**705**	**974**	**(4,483)**	**19,741**
Loss for the year		-	-	-	-	-	(12,808)	(12,808)
Other comprehensive loss		-	-	-	(983)	(983)	(923)	(1,906)
Total comprehensive loss		**-**	**-**	**-**	**(983)**	**(983)**	**(13,731)**	**(14,714)**
Capital contribution		-	410	-	-	-	-	410
Issuance of non-voting shares		13	346	(346)	-	(346)	-	13
Share-based remuneration		-	-	537	-	537	-	537
December 31, 2014		**764**	**23,255**	**460**	**(278)**	**182**	**(18,214)**	**5,987**
Loss for the year		-	-	-	-	-	(19,867)	(19,867)
Other comprehensive loss		-	-	-	(128)	(128)	(1,356)	(1,484)
Total comprehensive loss		**-**	**-**	**-**	**(128)**	**(128)**	**(21,223)**	**(21,351)**
Capital contribution	11	915	77,286	(2,378)	-	(2,378)	-	75,823
Share issuance costs		-	(1,433)	-	-	-	-	(1,433)
Issuance of non-voting shares		15	489	(489)	-	(489)	-	15
Acquisition of license		-	-	2,366	-	2,366	-	2,366
Share-based remuneration	18	-	-	3,268	-	3,268	-	3,268
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	11	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	11	-	(30,639)	-	-	-	30,639	-
December 31, 2016		**1,740**	**71,966**	**2,423**	**(489)**	**1,934**	**(39,599)**	**36,041**

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 (OBE2109, OBE001 ("nolasiban") and OBE022) developed in four indications. The Group has no currently marketed products.

The 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.

The consolidated financial statements were authorized for issue by the Company's Board of Directors (the "Board of Directors") on April 19, 2017.

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 published 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. Both ObsEva Ireland Ltd and ObsEva USA Inc. had no operations and no results of operations to report as of December 31, 2016.

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.

No new standards were applied to the Group's consolidated financial statements in 2016.

In 2018, the Group expects to adopt the following new relevant standards:

IFRS 9 Financial Instruments

In July 2014, the IASB issued IFRS 9 *Financial Instruments* which replaces International Accounting Standard ("IAS") 39 *Financial Instruments: Recognition and Measurement*. The new standard will change the classification and measurement requirements of financial assets and financial liabilities and the general hedge accounting rules. The Group is in the process of evaluating the impact IFRS 9 may have on its consolidated financial statements.

In 2019, the Group expects to adopt the following new relevant standards:

IFRS 16 Leases

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. The Group is in the process of evaluating the impact IFRS 16 may have on its consolidated financial statements.

Other new standards and amendments published but not yet effective will have no material impact on the consolidated financial statements of the Group.

2.4 Significant accounting policies

Current assets

Other receivables and other current receivables or prepayments 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).

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

Plant and Equipment

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

- furniture 5 years
- hardware 3 years
- leasehold improvement 5 years

Plant 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 capitalised 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 whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Intangible assets for which amortization has not commenced are subject to impairment testing at least annually.

Post-employment benefits

All employees of the Company 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.

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.

Treasury shares (equity instruments of the Company held by the Group) are accounted for as a reduction of equity at acquisition cost and are not subsequently re-measured. When shares are sold out of treasury shares, the resulting profit or loss is recognized in equity, net of tax.

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;
- 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 and its subsidiary are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). The functional currency of the Company is Swiss francs (CHF).

The consolidated financial statements are presented in USD, which is 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. 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 generally 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.

Translation into the presentation currency

The results and financial position of operations that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities are translated at the exchange rate prevailing on December 31 of each year;
- income and expenses are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transactions); and
- all resulting exchange differences are recognized in other comprehensive income.

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

	Income statement *Average rate (CHF)*			**Balance sheet** *Closing rate as of December 31, (CHF)*		
	2016	**2015**	**2014**	**2016**	**2015**	**2014**
USD	0.9850	0.9624	0.9151	1.0160	1.0010	0.9894

Share-based compensation

A share-based, equity-settled, plan (the "Plan") was formally set-up by the Group in 2013. Participants eligible for awards under the Plan are executives, directors, employees, agents and consultants. The fair value of the shares granted 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. 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, development of innovative women's reproductive, health and pregnancy therapeutics. The marketing and commercialization of such therapeutics depend on the success of the clinical development phase. The Chief Executive Officer 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.

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

The long lived assets of the Group are all held in Switzerland.

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 shares 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 (notes 8 and 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);
- Preferred shares: the classification of preferred as equity or debt is based on an assessment of the terms and conditions of such shares, involving a certain degree of judgement (note 11); and
- Going concern: the assessment of whether there is significant doubt on the Group's ability to continue as a going concern requires a certain degree of judgement (note 21).

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 U.S. dollar (USD), 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 CHF	Effect on profit before tax (in USD '000)	Effect on shareholders' equity (in USD '000)
2016	+5%	274	274
	-5%	(274)	(274)
2015	+5%	395	395
	-5%	(395)	(395)

GBP positions	Increase /decrease exchange rate vs CHF	Effect on profit before tax (in USD '000)	Effect on shareholders' equity (in USD '000)
2016	+5%	193	193
	-5%	(193)	(193)
2015	+5%	65	65
	-5%	(65)	(65)

USD positions	Increase /decrease exchange rate vs CHF	Effect on profit before tax (in USD '000)	Effect on shareholders' equity (in USD '000)
2016	+5%	349	349
	-5%	(349)	(349)
2015	+5%	22	22
	-5%	(22)	(22)

Credit risk

Cash and cash equivalents are deposited with top tier banks and institutions with a 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. Recent decisions to apply negative interests on bank deposits, especially in Switzerland, would expose the Group to certain interest risks on interest-bearing assets, which are, however, assessed as limited.

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 requirement under Swiss law. To ensure that statutory capital requirements are met, the Group monitors capital periodically. The Group may issue new shares in order to maintain sufficient cash position.

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 loans and receivables at amortized costs according to IAS 39. The Group's financial liabilities consist of other payables and accruals which are classified as other liabilities at amortized cost according to IAS 39.

4. Cash and cash equivalents

	As at December 31,	
in USD '000	**2016**	**2015**
Bank deposits……	23,292	43,801
Interest bearing deposits……	2,216	10,474
Total cash and cash equivalents as at December 31…….	**25,508**	**54,275**

Split by currency:

	2016	**2015**
CHF……..	68%	54%
USD……..	20%	21%
EUR……..	10%	20%
GBP……..	2%	5%

5. Receivables and payables

As at December 31, 2016 and December 31, 2015, 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 amortised cost.

All payables have a contract maturity within 1 year.

6. Prepaid expenses and deferred costs

Prepaid expenses and deferred costs include USD 2.1 million of prepayments and USD 0.3 million of costs which have been incurred in connection with the Group's planned Initial Public Offering ("IPO") and related issuance of new shares. These costs, which consist principally of legal fees, have been deferred and will be deducted from equity upon issuance of the new shares.

7. Plant and equipment

in USD '000	**2016**	**2015**
Net book value as at January 1……	**124**	**111**
Additions……	45	50
Depreciation charge……	(46)	(36)
Currency translation effects……	(2)	(1)
Net book value as at December 31……	**121**	**124**
Total cost……	*223*	*182*
Accumulated depreciation……	*(102)*	*(58)*

Plant and equipment assets mainly consist of office furniture and leasehold improvements.

8. Intangible assets

in USD '000	2016	2015
Net book value as at January 1……	**16,857**	**4,548**
Additions……	-	12,372
Amortization charge……	-	-
Currency translation effects……	(249)	(63)
Net book value as at December 31……	**16,608**	**16,857**
Total cost……	*16,608*	*16,857*
Accumulated amortization……	-	-

As at December 31, 2016, the Group holds a number of licenses to operate several biopharmaceutical product candidates, the value of which is recorded at USD 16.6 million (2015: USD 16.9 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 a consideration including 325,000 series A preferred shares. The consideration payment was contingent on the initiation of a Phase 1 clinical trial by the Group.

In accordance with IFRS 2 *Share Based Payments*, the in-license acquisition is measured directly, "at the fair value of the goods or services received, unless that fair value cannot be estimated reliably".

Considering the very early-stage of the product candidate, and the high uncertainty and sensitivity attached to the assumptions used in a fair valuation model of the license received, management deemed that the in-license could not be reliably measured, and measured instead the value of the in-license, indirectly, by reference to the fair value of the equity instruments granted.

As a result, the Group recognised the in-license for an amount of USD 2.4 million, based on (i) its best available estimate of the number of equity instruments expected to vest and be issued (325,000 series A preferred shares), and (ii) the fair value (CHF 6.79) of the Company's equity instruments issued at the transaction date.

Management used an income approach to determine the Company's equity value at the transaction date, from which the fair value of the series A preferred share was derived using varying allocation methodologies to each classes of shares.

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 OBE2109 for which Kissei successfully completed 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).

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

The Group's other long-term assets mainly consist of security rental deposits for the Group's offices.

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 2016, the pension fund changed the pension conversion rates, what has been considered as an amendment of the pension plan.

in USD '000	2016	2015
Change in defined benefit obligation		
Defined benefit obligation at January 1,	**(7,765)**	**(4,368)**
Current service cost	(774)	(578)
Interest cost	(70)	(66)
Net benefits paid	(643)	(1,558)
Currency translation effects	163	189
Remeasurements:		
Impact of plan amendment	512	-
Effect of changes in demographic assumptions	(316)	-
Effect of changes in financial assumptions	(203)	(411)
Effect in experience assumptions	(105)	(973)
Defined benefit obligation at December 31,	**(9,201)**	**(7,765)**

in USD '000	2016	2015
Change in plan assets		
Fair value of plan assets at January 1,	**5,102**	**3,048**
Interest income	50	52
Employer contributions	333	267
Employee contributions	333	267
Net benefits paid	643	1,559
Currency translation effects	(117)	(119)
Remeasurements: return on plan assets (excluding interest income)	25	28
Fair value of plan assets at December 31,	**6,369**	**5,102**

	Year ended December 31,	
in USD '000	2016	2015
Components of defined benefit cost		
Current service cost	774	577
Interest expense on defined benefit obligation	70	66
Interest income on plan assets	(50)	(52)
Employee contributions	(333)	(267)
Impact of plan amendment	(512)	-
Total included in staff costs (note 14)	**(51)**	**324**

	Year ended December 31,	
in USD '000	2016	2015
Remeasurements recognized in other comprehensive loss		
Effect of changes in demographic assumptions	(316)	-
Effect of changes in financial assumptions	(203)	(411)
Effect in experience assumptions	(105)	(973)
Return on plan assets (excluding interest income)	25	28
Total remeasurements recognized as other comprehensive loss	**(599)**	**(1,356)**
Cumulative amount of remeasurements immediately recognized in other comprehensive loss	(3,439)	(2,840)

in USD '000	As at December 31, 2016	2015
Amounts recognized in the statement of financial position		
Defined benefit obligation……	(9,201)	(7,765)
Fair value of plan assets……	6,369	5,102
Net liability…….	**(2,832)**	**(2,663)**

in USD '000	2016	2015
Change in defined benefit liability		
Net defined benefit liability at January 1,……	**(2,663)**	**(1,320)**
Defined benefit cost included in statement of comprehensive loss……..	51	(324)
Total remeasurements included in other comprehensive loss……..	(599)	(1,356)
Employer contributions……	333	267
Currency translation effects…….	46	70
Net defined benefit liability at December 31,……	**(2,832)**	**(2,663)**

As of the date of preparation of these consolidated financial statements, the annual report for 2016 of the pension fund has not yet been issued, and therefore the detailed structures and assets held at December 31, 2016, are not currently available for presentation. The detailed structures and assets held at December 31, 2015, are as follows:

Plan assets	**As at December 31, 2015**
Cash……..	0.3%
Bonds……	70.4%
Shares……	7.9%
Real estate……	14.0%
Mortgages…….	7.3%
Alternative investments…….	0.1%
Total	**100.0%**

To develop the expected long-term rate of return on asset assumption, the Group considered the current level of expected returns on risk free investments (high-quality corporate bonds), the historical level of the risk premium associated with the other asset classes in which the portfolio is invested, and the expectation for future returns of each asset allocation.

The principal actuarial assumptions used were as follows:

	2016	2015
Discount rate…….	0.70%	0.85%
Salary increase (including inflation)…….	1.00%	1.00%
Rate of pension increases……..	0.25%	0.25%
Post-employment mortality table……..	LPP 2015 G	LPP 2010 G

Sensitivity analysis illustrates the sensitivity of the Group defined benefit obligation at December 31, 2016 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……..	1.20%	0.20%	0.70%	0.70%	0.70%	0.70%
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…	**(8,362)**	**(10,182)**	**(9,275)**	**(9,132)**	**(9,483)**	**(8,934)**

Average duration of the defined benefit obligation	2016	2015
Duration in years……	19.8	19.1

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 360,000.

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, 2015……	1,300,000	7,706,777	-	164,684	9,171,461	764	23,255	24,019
Issuance of common shares…	915,434	-	-	-	915,434	70	2,378	2,448
Issuance of preferred B shares	-	-	11,079,549	-	11,079,549	845	58,637	59,482
Final contribution on partly paid shares……..	-	-	-	-	-	-	16,270	16,270
Transaction costs arising on share issues……..……	-	-	-	-	-	-	(1,433)	(1,433)
Issuance of non-voting shares to employees……..	-	-	-	182,429	182,429	15	490	505
December 31, 2015……	**2,215,434**	**7,706,777**	**11,079,549**	**347,113**	**21,348,873**	**1,694**	**99,597**	**101,291**

	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, 2016……	2,215,434	7,706,777	11,079,549	347,113	21,348,873	1,694	99,597	101,291
Issuance of preferred A shares	-	325,000	-	-	325,000	26	2,366	2,392
Transaction costs arising on share issues……..……	-	-	-	-	-	-	(33)	(33)
Issuance of non-voting shares to employees……..	-	-	-	264,524	264,524	20	675	695
Offset of accumulated deficit with share premium……	-	-	-	-	-	-	(30,639)	(30,639)
December 31, 2016……	**2,215,434**	**8,031,777**	**11,079,549**	**611,637**	**21,938,397**	**1,740**	**71,966**	**73,706**

Share Capital and Share Premium

As at December 31, 2016, the total outstanding share capital of USD 1.7 million, fully paid, consists of 2,215,434 common shares, 8,031,777 series A preferred shares, 11,079,549 series B preferred shares and 611,637 non-voting shares. All shares have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date. Series A preferred shares and series B preferred shares have preferential rights as to the liquidation dividends and proceeds within the terms of the articles of association, and confer the same voting rights as those attached to common shares. In case of an IPO, all series A and series B preferred shares shall automatically be converted into common shares. Based on the terms and conditions attached to the preferred shares, management concluded to a classification of those shares as equity.

On December 10, 2014, the Group called the second tranche of the subscription price of the series A preferred shares, out of which USD 16.3 million were settled and recognized in 2015.

On November 19, 2015, the Group issued 915,434 common shares at a subscription price of 1/13 of a Swiss franc per share as a result of anti-dilution provisions (note 18) and 11,079,549 series B preferred shares at a subscription price of CHF 5.42 (USD 5.37) per share, amounting to a total CHF 60.1 million (USD 59.6 million).

In August 2016, the Group's product candidate known as OBE022 entered into a Phase 1 clinical trial, triggering the obligation of payment to Merck Serono of the 325,000 series A preferred shares due upon occurrence of that event. The 325,000 shares were issued through a capital increase of the Group on September 28, 2016, and an amount of USD 2.4 million was reclassified from the share-based payment reserve to the share premium.

Non-Voting Share Capital

As at December 31, 2016, the total outstanding non-voting share capital amounting to USD 49,084, fully paid, consists of 611,637 non-voting shares issued at the end of the vesting period associated with the Plan. All non-voting shares have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date.

The non-voting shares are part of the non-voting share capital and have the same financial rights than those attached to common shares. The non-voting shares do not confer the right to vote or to participate in the ordinary and extraordinary meetings of the Group. In case of an IPO, all non-voting shares shall automatically be converted into common shares.

Authorized voting and non-voting share capital

The authorized voting share capital and authorized non-voting share capital that are not outstanding as at December 31, 2016 and December 31, 2015 are as follows:

	As at December 31,	
Number of shares	**2016**	**2015**
Authorized voting share capital……	11,590,631	-
Authorized non-voting share capital……	-	1,096,992

Offset of accumulated deficit with share premium

On February 23, 2016, the shareholders voted for statutory purposes a resolution to offset the accumulated losses with the share premium balance for an amount of USD 30.6 million. Such transaction had no impact on the overall equity position.

12. Revenue and other income

The Group currently derives no revenue from sales of its biopharmaceutical product candidates.

Other income in 2016 mainly relates to compensation received from the Swiss tax authorities as the Company acts as collecting agent of the withholding tax on salaries.

Other income in 2015 and 2014 mainly relates to consulting services rendered to third parties by the Company.

13. Operating expenses by nature

	Year ended December 31,		
in USD '000	**2016**	**2015**	**2014**
External research and development costs	16,811	10,784	7,881
Staff costs (note 14)	7,436	7,313	3,922
Professional fees	4,016	743	370
Rents	427	367	420
Travel expenses	541	313	126
Patent registration costs	512	87	46
Depreciation	46	36	20
Other	374	203	177
Total operating expenses by nature	**30,163**	**19,846**	**12,962**

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 2016, research and development expenses amounted to USD 23.7 million (2015: USD 16.9 million, 2014: USD 11.4 million).

The depreciation expense has been allocated as follows:

	Year ended December 31,		
in USD '000	**2016**	**2015**	**2014**
Research and development expenses	35	28	17
General and administrative expenses	11	8	3
Total depreciation	**46**	**36**	**20**

14. Staff costs

	Year ended December 31,		
in USD '000	**2016**	**2015**	**2014**
Wages and salaries	4,807	3,384	2,990
Social charges	443	337	256
Post-employment benefits expense	(51)	324	139
Share-based payments	2,237	3,268	537
Total staff costs	**7,436**	**7,313**	**3,922**

The Group employed on average 22.4 full-time equivalents ("FTE") in 2016, compared to 16.2 FTE in 2015 and 12.6 FTE in 2014, and 25.3 FTE as at December 31, 2016 compared to 19.9 FTE as at December 31, 2015 and 14.1 FTE as et December 31, 2014.

For the year ended December 31, 2016, the post-employment benefits line includes a gain of USD 512,000 relating to the plan amendment enacted in 2016.

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

Because the Group has incurred net losses since its inception, it has no current income tax expenses.

In 2015, the Group 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.

The following details the tax losses carry forwards and their respective expiring dates. Due to the uncertainty surrounding the future results of operations and the uncertainty as to whether the Group can use the losses carry forwards for tax purposes, no deferred taxes have been recognized on the balance sheet.

Expiring tax losses

	As at December 31,	
in USD '000	**2016**	**2015**
2020……....	2,808	2,850
2021……..	11,123	11,289
2022……..	15,602	15,836
2023……..	27,484	-
Total unrecorded tax losses carry forwards……	**57,017**	**29,975**

17. Loss per share

As of December 31, 2016, the Company's ordinary shares are comprised of common shares and non-voting shares. In addition, the Company has issued preferred A and preferred B shares. As the preferred A and preferred B shares participate with ordinary shares in the profit or loss on a pro-rata basis, the net loss is 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, 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)**

	Year ended December 31, 2015		
	Preferred B shares	**Preferred A shares**	**Common and non-voting shares**
Net loss attributable to shareholders (in USD '000)…	(2,380)	(14,384)	(3,102)
Weighted average number of shares outstanding……	1,274,910	7,706,777	1,661,231
Basic and diluted loss per share (in USD)……	**(1.87)**	**(1.87)**	**(1.87)**

	Year ended December 31, 2014		
	Preferred B shares	**Preferred A shares**	**Common and non-voting shares**
Net loss attributable to shareholders (in USD '000)…	-	(10,860)	(1,949)
Weighted average number of shares outstanding……	-	7,706,777	1,382,342
Basic and diluted loss per share (in USD)……	**-**	**(1.41)**	**(1.41)**

For the year ended December 31, 2016, 1,242,862 non-vested shares, which would have an anti-dilutive impact on the calculation of the diluted earnings per share, are excluded from the calculation (years ended December 31, 2015 and 2014: 686,647 and 602,576 non-vested shares excluded, respectively).

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,		
in USD '000	**2016**	**2015**	**2014**
Employee share plan……	2,237	890	537
Anti-dilution provisions……	-	2,378	-
Total share-based compensation……	**2,237**	**3,268**	**537**

Employee share plan

The Company has established the Plan for employees, executives, directors and consultants (the "Beneficiaries") of the Group. This equity-settled plan entitles the Beneficiaries to acquire a certain amount of the Company's non-voting shares at a pre-determined price (1/13 of a Swiss franc). The possibility to enrol in the Plan and acquire shares is generally offered at the hiring date as well as on the basis of employees' performance. The Beneficiaries may elect not to participate in the Plan.

Upon Beneficiaries' enrolment in the Plan, Beneficiaries are granted a certain number of shares which they are entitled to acquire. The pre-determined price is 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.

	2016	**2015**	**2014**
Number of shares issued under the plan……	264,524	182,429	164,684
Average grant date fair value (in USD)……..	11.37	2.48	3.95
Expense arising from the plan (in USD '000)……	2,237	890	537

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.

Anti-dilution provisions

The shareholders' agreement signed in 2013 includes specific anti-dilution clauses benefiting one of the Group's founders, Ernest Loumaye (the "Founder"). Subject to specified exceptions, per this clause, if, as a result of a share issuance, the Founder's shareholding in the Group's certain classes of shares is diluted below 10%, then the Founder is entitled to acquire at nominal value (1/13 of a Swiss franc) a number of common shares allowing him to maintain his shareholding at 10%.

In November 2015, the completion of a round of financing (note 11) triggered this clause which resulted in the issuance of 915,434 common shares to the Founder.

In accordance with IFRS 2, such transaction resulted in a share-based expense of USD 2.4 million for the year ended December 31, 2015. The fair value of the common shares delivered to the Founder was calculated using a backsolve method (USD 2.68).
The anti-dilution provisions had no impact for the year ended December 31, 2016.

19. Commitments and contingencies

Operating lease commitments

	As at December 31,	
in USD '000	**2016**	**2015**
Within 1 year……	243	246
Later than 1 year and no later than 5 years…….	121	369
Later than 5 years…….	-	-
Total……..	**364**	**615**

Operating lease commitments relate to the Group's lease for its headquarters in Geneva, Switzerland.

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 OBE2109. 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.

Pursuant to the Kissei license and supply agreement, the Group has agreed to exclusively purchase the active pharmaceutical ingredient for OBE2109 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, 2016, the Group's related parties only consist in affiliates of the Company, key management (Board of Directors and Executive Committee) and members of their immediate families. No individual shareholder is considered as a related party.

- *Key management remuneration*

The Board of Directors is composed of 9 members (with 8 directors in 2015), whereas the Executive Committee is composed of 5 members (with 8 members in 2015). The following table sets forth the total remuneration recorded for members of the Board of Directors and Executive Committee:

	Year ended December 31,	
in USD '000	**2016**	**2015**
Short-term employee benefits (including base and variable cash remuneration)…….	1,890	2,067
Post-employment benefits……	(18)	179
Share-based payments……...	1,614	3,121
Total…….	**3,486**	**5,367**

Share-based payments in 2015 mainly include the effect of the anti-dilution provisions (note 18).

- *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 and, due to its development-stage activities, has experienced cumulative losses since the inception of the Company, which raised substantial doubt as to its ability to continue as a going concern in the evaluation period, defined by the management as being one year from the balance sheet date of December 31, 2016. However, the Company has successfully completed an IPO on January 25, 2017 and as a result, the substantial doubt has been alleviated. Therefore 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

Share capital
On January 25, 2017, the Company raised gross proceeds of USD 96.8 million, or net proceeds of approximately USD 86.8 million, in an IPO on The NASDAQ Global Select Market, a U.S. market. The IPO closed on January 30, 2017 with the issuance of 6,450,000 new ordinary shares at a subscription price of USD 15.00 per share and a par value of 1/13 of a Swiss franc per share. All existing series A preferred shares, series B preferred shares and non-voting shares were immediately converted into common shares as of the IPO date. After the IPO, the Company has 29,631,262 common shares outstanding.

There were no other material events after the balance sheet date.

ObsEva SA

Plan-les-Ouates

Report of the statutory auditor to the General Meeting

on the consolidated financial statements 2016

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 statement of financial position as at 31 December 2016 and the consolidated statement of comprehensive loss, consolidated statement of changes in equity and consolidated statement of cash flows 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 2016 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 299,000

We conducted a full scope audit work at the holding and principal operating entity in Switzerland. Our audit scope addressed 100% of the Group's loss before tax.

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

- Valuation used in share-based compensation

Audit scope

We conducted our audit work for one country (Switzerland), and entity, namely ObsEva SA, covering 100% of the group due to the dormant status of the Irish subsidiary, and the lack of activity in the newly-created US subsidiary. 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, such as the defined benefit obligation, the valuation applied in the share-based compensation, and the going concern assumption. 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.

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 299,000
How we determined it	Total expenses
Rationale for the materiality benchmark applied	Profit before tax is not considered an appropriate benchmark as the Company is a start-up company still in the developmental phase, and has no recurring revenue. Based on the nature of the Company we determined total expenses as the most appropriate benchmark, applying a 1% rule of thumb.

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.

Valuation used in share-based compensation

Key audit matter	,
An equity settled share plan has been in place since 2013, under which executives, directors, employees, agents and consultants are all eligible for awards. During the period under audit non-voting shares were granted under this plan. Since the Company was a private start-up as of December 31, 2016, with no commercialized products or revenues, determining a value for the company involved a number of significant judgements. In addition the allocation of that valuation to the various categories of shares also involves elements of judgement. Since there is a risk of management bias to understate the corresponding expense, which is material to the reported results, we considered this item to be a key audit matter. The company was valued using a combination of the discounted future cash flow method and the backsolve method. The forecasting of future cashflows involved judgements around the probability of successful completion and commercialisation of the various compounds, the eventual pricing, and potential market share of each compound as well as future cost estimates. Management engaged valuation specialists to assist them in this share valuation. Refer to Note 18 for disclosure in the financial statements.	Due to the inherent complexity of the models and the very specialised nature of the underlying judgements, we involved both valuation and bio-pharma specialists in our work. With their assistance we performed the following: - We obtained an understanding of both management's forecast and the models used during the valuation exercise. - We assessed management's valuation, the key inputs, assumptions, and business forecasts. We compared these inputs, where possible, against third-party industry reports and comparable companies. - We assessed the consistency of application of the model with prior periods. - We assessed the competence, capability, objectivity, and independence of the external experts employed by management. - We compared the fair value applied in the share-based compensation expense to the post-balance sheet IPO valuation and the subsequent evolution of the share price. On the basis of the above procedures performed we determined that the valuation of the company and the allocation of the valuation to the various share categories were reasonable.

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 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.

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

Geneva, 22 May 2017

Enclosure:

- Consolidated financial statements (consolidated statement of financial position, consolidated statement of comprehensive loss, consolidated statement of changes in equity, consolidated statement of cash flows and notes)

Statutory Financial Statements of ObsEva S.A. for the year ended December 31, 2016

Balance Sheet as at 31 December

(in CHF)

	Notes	2016	2015
ASSETS			
Current assets			
Cash and cash equivalents……..		25,915,961	54,328,989
Other current receivables……	4	795,751	68,733
Deferred costs and prepaid expenses……..		2,453,351	311,044
Total current assets……...		**29,165,063**	**54,708,766**
Non-current assets			
Financial assets……...	5	90,813	90,804
Investments…….	6	3	3
Property, plant and equipment……	7	123,106	124,062
Intangible assets……..	8	14,735,432	14,735,432
Total non-current assets……...		**14,949,354**	**14,950,301**
Total assets……		**44,114,417**	**69,659,067**
LIABILITIES & SHAREHOLDERS' EQUITY			
Current liabilities			
Trade payables……	4	2,231,894	644,282
Other current liabilities……...	4	93,764	61,367
Accrued expenses……...		4,337,639	3,981,470
Total current liabilities……		**6,663,297**	**4,687,119**
Shareholders' equity			
Share capital……		1,640,520	1,615,520
Non-voting share capital…….		142,654	58,270
Treasury non-voting shares…….		(400)	(6,181)
Legal reserve from capital contribution…..		63,592,444	93,309,379
Accumulated deficit……		(27,924,098)	(30,005,040)
Total shareholders' equity……...	11	**37,451,120**	**64,971,948**
Total liabilities & shareholders' equity..		**44,114,417**	**69,659,067**

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

Statement of Income

(in CHF)

	Notes	2016	2015
INCOME			
Income from services……..		—	9,150
Other income……..		21,310	6,941
Total income……..		**21,310**	**16,091**
OPERATING EXPENSES			
Staff costs……		(5,499,947)	(3,838,157)
External research and development costs...		(16,558,718)	(10,377,520)
Patent costs…….		(504,003)	(83,884)
Professional fees…….		(3,956,266)	(715,411)
Facilities……..		(421,038)	(352,911)
Other operating expenses……		(900,349)	(496,906)
Depreciation……	7	(45,650)	(34,578)
Total operating expenses…….		**(27,885,971)**	**(15,899,367)**
OPERATING LOSS……		**(27,864,661)**	**(15,883,276)**
Finance income……...		35,688	31,686
Finance expense……..		(95,125)	—
NET LOSS BEFORE TAX…….		**(27,924,098)**	**(15,851,590)**
Income tax expense…….		—	—
NET LOSS FOR THE PERIOD…….		**(27,924,098)**	**(15,851,590)**

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

Notes to the Financial Statements 2016

1. General information

ObsEva Ltd was founded on 14 November 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.

These statutory financial statements were authorized for issue by the Company's Board of Directors (the "Board of Directors") on May 16, 2017.

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 1 January 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 5 years

  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 Swiss francs 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.

3. Full-time positions

The company employed on the average 22.3 full-time equivalents (FTE) in 2016 (2015: 16.2 FTE) and 25.3 FTE as at 31 December 2016 (31 December 2015: 19.9 FTE).

4. Receivables and payables

As at 31 December 2016 and 31 December 2015, other current receivables, trade payables and other current liabilities are all due from third parties. No receivables or payables are due from group companies or shareholders.

Notes to the Financial Statements 2016 (cont'd)

5. Pledges on assets to secure own liabilities

(CHF)	31 December 2016	31 December 2015
Escrow accounts……	90,813	90,804
Total…….	**90,813**	**90,804**

As at 31 December 2016, CHF 90,813 were held on escrow accounts as security rental deposits (31 December 2015: CHF 90,804).

6. Investments

ObsEva SA owned as at 31 December 2016:

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:

(CHF)	31 December 2016	31 December 2015
Shareholding ObsEva Ireland Ltd……..	2	3
Shareholding ObsEva USA Inc…….	1	—
Total……..	**3**	**3**

7. Property, plant and equipment

(CHF)	Furniture	Hardware	Leasehold improv.	Total
Net book value as at 1st Jan. 15….	10,500	19,207	80,544	110,251
Additions……...	31,796	16,593	—	48,389
Depreciation charge……..	(3,530)	(13,817)	(17,231)	(34,578)
Net book value as at 31 Dec. 15.	**38,766**	**21,983**	**63,313**	**124,062**
Total cost…….	*46,796*	*48,792*	*86,153*	*181,741*
Accumulated depreciation……..	*(8,030)*	*(26,809)*	*(22,840)*	*(57,679)*

(CHF)	Furniture	Hardware	Leasehold improv.	Total
Net book value as at 1st Jan. 16….	38,766	21,983	63,313	124,062
Additions……...	16,234	23,831	4,629	44,694
Depreciation charge……..	(10,497)	(16,269)	(18,884)	(45,650)
Net book value as at 31 Dec. 16.	**44,503**	**29,545**	**49,058**	**123,106**
Total cost…….	*63,030*	*72,623*	*90,782*	*226,435*
Accumulated depreciation……..	*(18,527)*	*(43,078)*	*(41,724)*	*(103,329)*

Notes to the Financial Statements 2016 (cont'd)

8. Intangible assets

As at 31 December 2016 and 31 December 2015, the company holds a number of licenses to operate several pharmaceutical compounds, which were acquired for CHF 14,735,432.

9. Amounts due to pension funds

As at 31 December 2016, amounts due to pension funds amounted to CHF 184,924 (31 Dec. 2015: CHF 145,160).

10. Lease commitments not reported in the balance sheet

Operating lease commitments (including rent costs)

(CHF)	31 December 2016	31 December 2015
Within 1 year……..	246,465	246,576
Later than 1 year and no later than 5 years.	123,357	369,462
Later than 5 years……...	—	—
Total……...	**369,822**	**616,038**

11. Shareholders' equity

	Share capital	Non-voting share capital	Legal reserve from capital cont.	Accumulated deficit	**Shareholders' equity**
1 January 2015……..	692,829	38,610	20,677,876	(14,153,450)	**7,255,865**
Issuance of ordinary shares…….	70,418	—	—	—	**70,418**
Issuance of preferred B shares…	852,273	—	59,147,746	—	**60,000,019**
Issuance of non-voting shares….	—	19,410	—	—	**19,410**
Costs of share capital issuance…	—	—	(1,766,259)	—	**(1,766,259)**
Repurchase of non-voting shares	—	(5,931)	—	—	**(5,931)**
Contrib. to the legal reserve……	—	—	15,250,016	—	**15,250,016**
Net loss for the year……	—	—	—	(15,851,590)	**(15,851,590)**
31 December 2015……	**1,615,520**	**52,089**	**93,309,379**	**(30,005,040)**	**64,971,948**

Notes to the Financial Statements 2016 (cont'd)

	Share capital	Non-voting share capital	Legal reserve from capital cont.	Accumulated deficit	**Shareholders' equity**
1 January 2016……..	1,615,520	52,089	93,309,379	(30,005,040)	**64,971,948**
Issuance of preferred A shares…	25,000	—	—	—	**25,000**
Issuance of non-voting shares….	—	84,384	—	—	**84,384**
Costs of share capital issuance…	—	—	288,105	—	**288,105**
Sale of non-voting shares……..	—	6,586	—	—	**6,586**
Repurchase of non-voting shares	—	(805)	—	—	**(805)**
Offset of accumulated loss with legal reserve from capital cont…	—	—	(30,005,040)	30,005,040	—
Net loss for the year……	—	—	—	(27,924,098)	**(27,924,098)**
31 December 2016……	**1,640,520**	**142,254**	**63,592,444**	**(27,924,098)**	**37,451,120**

Share Capital

On December 8, 2016, the Company effected a one-for-13 forward stock split of its outstanding common, preferred and non-voting shares. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes have been adjusted retroactively, where applicable, to reflect this forward stock split.

As at 31 December 2016, the total outstanding share capital of CHF 1,640,520, fully paid, consists of 2,215,434 ordinary shares, 8,031,777 preferred « A » shares and 11,079,549 preferred « B » shares. Preferred « A » and preferred « B » shares have preferential rights as to the liquidation dividends and proceeds within the terms of the articles of association. All shares have a nominal value of 1/13 of a Swiss franc.

On 19 November 2015, the company issued 915,434 ordinary shares at a subscription price of 1/13 of a Swiss franc per share and 11,079,549 preferred « B » shares at a subscription price of CHF5.42 per share.

On 28 September 2016, the company issued 325,000 preferred « A » shares at a subscription price of 1/13 of a Swiss franc per share.

Non-Voting Share Capital

As at 31 December 2016, the total outstanding non-voting share capital of CHF 142,254, fully paid, consists of 1,854,502 issued non-voting shares, less 5,200 treasury non-voting shares that are held by the company. All non-voting shares have a nominal value of 1/13 of a Swiss franc.

On 29 July 2016 and 22 November 2016, the company issued 279,500 and 817,492 non-voting shares, respectively, from its authorized non-voting share capital, to the employees and consultants of the company. The non-voting shares are part of the non-voting share capital and have the same financial rights than those attached to ordinary shares. The non-voting shares do not confer the right to vote or to participate to the ordinary and extraordinary meetings of the company. In 2016, 10,465 non-voting shares were purchased at 1/13 of a Swiss franc each to employees by the company under the claw-back provisions of the company's incentive plan, and 85,618 non-voting were sold at 1/13 of a Swiss franc each to employees as part of grants made under the company's equity incentive plan.

Offset of accumulated deficit with share premium

On February 23, 2016, the shareholders voted a resolution to offset the accumulated losses with the legal reserve from capital contribution for an amount of CHF 30,005,040.

Notes to the Financial Statements 2016 (cont'd)

The changes in the number of treasury non-voting shares owned by the company in 2016 and 2015 are as follows:

(number of treasury non-voting shares)	2016	2015
At 1 January……	80,353	3,250
Sale of non-voting shares……	(85,618)	—
Purchase of non-voting shares……	10,465	77,103
At 31 December……	**5,200**	**80,353**

12. Authorized capital and conditional capital

The authorized share capital, authorized non-voting share capital and conditional share capital as at 31 December 2016 and 31 December 2015 are as follows:

(CHF)	31 December 2016	31 December 2015
Authorized share capital…….	891,587	—
Authorized non-voting share capital……..	—	84,384
Conditional share capital……	—	—

13. Major Shareholders

A list of our major shareholders is disclosed in the Corporate Governance section of the Annual Report (page 67).

14. 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.

15. Events after the balance sheet date

On 25 January 2017, the company raised USD 96,750,000 in an Initial Public Offering (IPO) on the US Nasdaq stock exchange. The IPO was closed on 30 January 2017 with the issuance of 6,450,000 new ordinary shares at a subscription price of USD 15.00 per share and a par value of 1/13 of a Swiss franc per share. All existing preferred « A » shares, preferred « B » shares and non-voting shares were immediately converted into ordinary shares as of the IPO date.

ObsEva SA

Plan-les-Ouates

Report of the statutory auditor to the General Meeting

on the financial statements 2016

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 2016, income statement 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 2016 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

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	CHF 299,000
How we determined it	Total expenses
Rationale for the materiality benchmark applied	Profit before tax is not considered an appropriate benchmark as the Company is a start-up, in the developmental phase, and has no recurring revenue. Based on the nature of the Company we determined total expenses as the most appropriate benchmark, applying a 1% rule of thumb.

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

We have determined that there are no key audit matters to communicate in our report.

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.

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

PricewaterhouseCoopers SA

Michael Foley

Audit expert
Auditor in charge

Filippos Mintiloglitis

Audit expert

Geneva, 22 May 2017

Enclosure:

- Financial statements (balance sheet, income statement and notes)

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 OBE2109, nolasiban and OBE022;
- our ability to obtain and maintain regulatory approval of our product candidates, including OBE2109, 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 OBE2109, 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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