



Annual Report 2021

Table of Contents

Letter to Shareholders	2
Business Update	5
Financial Review	47
Corporate Governance	63
Consolidated IFRS Financial Statements for the year ended December 31, 2021	86
Report from the Auditor on the Consolidated IFRS Financial Statements	121
Statutory Financial Statements of ObsEva SA for the year ended December 31, 2021	127
Report from the Auditor on the Statutory Financial Statements of ObsEva SA	140
Compensation Report of ObsEva SA for the year ended December 31, 2021	146
Report from the Auditor on the Compensation Report of ObsEva SA	158
Forward-Looking Statements	160

Letter to shareholders

Dear Shareholders.

When ObsEva was founded, it was with a mission to address the most challenging unmet medical needs facing women. Thanks to the tireless work of our employees, significant progress on our late-stage programs in the past year, and the continued support of you, our shareholders, we are now on the cusp of realizing that vision as we pursue our first approvals in 2022.

Throughout the US, millions of women live with uterine fibroids, which can have a devastating impact on their day-to-day life. If approved, linzagolix would be the first and only approved oral gonadotropin releasing hormone (GnRH) receptor antagonist in uterine fibroids with a dosing option without additional hormonal add-back therapy, offering a more individualized treatment option to a broader range of women.

As we prepare to transition to a commercial stage company, I would like to reflect on the significant regulatory, clinical, and business development advancements made by ObsEva in 2021.

2021 Highlights:

Headlining our progress in 2021 was acceptance of the new drug application for linzagolix for uterine fibroids by the United States Food and Drug Administration (FDA). Importantly, this was our first FDA submission, and it goes without saying that the ObsEva team is incredibly excited about the potential to bring this differentiated treatment to market.

What has the potential to set linzagolix apart is a dosing option for uterine fibroids without additional hormonal add-back therapy (ABT), which would be welcomed by the significant number of women who either have contraindications to or a personal preference to avoid the use of estrogen-based therapies.

The FDA submission was based on positive data from the Phase 3 PRIMROSE studies, which were completed in May 2021, representing a major milestone for ObsEva. The studies suggest linzagolix has the potential to combine best-in-class efficacy, a favorable tolerability profile and unique, flexible dosing options for uterine fibroids.

Looking ahead to our PDUFA target action date in September 2022, we are busily advancing our commercial readiness. In October of 2021, we announced a relationship with Syneos Health to commercialize linzagolix within the United States. Syneos has a leading women's health sales force and extensive launch experience, making it the perfect fit to realize the commercial potential for linzagolix in this market.

In parallel, we also received a positive opinion for our Marketing Authorization Application for linzagolix for uterine fibroids from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in December 2021, and we are currently working with the EMA toward approval. Subsequent to 2021 year-end, we announced a strategic licensing agreement with Theramex to support the commercialization and market introduction of linzagolix across global markets outside of the United States, Canada and Asia, with EU launch preparations firmly underway. Theramex is a proven global leader in women's health and the ideal partner to maximize the opportunity for linzagolix in key international markets.

Turning to the second indication for linzagolix, endometriosis, it would be remiss of me not to mention the positive results we announced in early 2022 for the Phase 3 EDELWEISS 3 trial. Endometriosis is an emotionally and physically painful condition that affects approximately 176 million women worldwide, and there remains a critical need for therapeutic options to address this chronic disorder.

We are extremely pleased with the Phase 3 results reported in January 2022, which highlight the promising clinical profile of linzagolix 200 mg once-daily dose with ABT for women with moderate-to-severe endometriosis-associated pain and underscore the potential to be a leading GnRH option that balances safety and efficacy. What's more, by effectively addressing debilitating pain symptoms, linzagolix could improve overall quality of life and the ability to perform daily activities. While the 75 mg dose did not meet the nonmenstrual pelvic pain endpoint, the statistically significant and clinically meaningful responder rates versus placebo for dysmenorrhea at 3 months and the evidence of clinical activity and tolerability at 6 months are encouraging. Consistent with our commitment to addressing the individual treatment needs and preferences of all women, we intend to complete the Phase 3 program for this important indication and plan to further explore a non-ABT dose option.

Turning to the remainder of our attractive pipeline, the future path of ebopiprant was established in 2021 with our license agreement with Organon to develop and commercialize ebopiprant. This collaboration is an important validation of ObsEva's ability to generate value, and we view Organon as the ideal partner for the development and commercialization of ebopiprant to address the significant unmet need in preterm labor. Although preterm birth rates are on the rise, there are currently no other known compounds in development. Under the terms of the agreement, we are entitled to receive tiered double-digit royalties on commercial sales as well as up to \$500 million in upfront and milestone payments. We are working closely with Organon to discuss with the FDA the submission of an Investigational New Drug Application to enable clinical development in the United States.

Finally, we are continuing to advance the development of nolasiban to improve live birth rates in women undergoing IVF (in vitro fertilization). Our partner Yuyuan BioScience Technology is developing nolasiban in China, which has the biggest IVF population in the word. Our agreement with Yuyuan also allows us to use these new clinical trial results, should they support further development in the United States and Europe.

Alongside progress from a regulatory, clinical, and business development standpoint, we also strengthened our funding position in 2021 in preparation for our transition to a commercial stage company. In October 2021, we announced a financing agreement which is structured to provide up to \$135 million in borrowing capacity, available in nine tranches, subject to certain conditions to funding.

Our achievements last year would not have been possible without the tireless work of all employees, and I would like to take this moment to thank them for their contributions as we prepare for critical inflection points for ObsEva.

Looking forward to 2022:

Thanks to the significant progress last year, we enter 2022 stronger and well-positioned for anticipated approvals. Looking ahead, we expect multiple catalysts, including:

Yselty® for uterine fibroids:

- PUDFA target action date of September 13, 2022, as set by the FDA
- European Commission approval expected following December 2021 positive CHMP opinion
- Preparing for commercial launch

Yselty® for endometriosis:

- Additional data from the post-treatment follow-up of the Phase 3 EDELWEISS 3 trial are expected in 2Q 2022 and from the post-treatment follow-up of the extension study in 4Q 2022

Ebopiprant:

- Discussing US clinical development with the FDA

• New opportunities:

- Exploring new indications, partnerships, and other strategic opportunities that enhance ObsEva's value and further our mission of bringing to market novel therapies that improve women's health
- Financing: Furthering ongoing efforts to strengthen the balance sheet

I look forward to driving this momentum forward and working with the ObsEva team to create long-term value for shareholders as we prepare for a pivotal year for the company and deliver on our mission to advance the field of women's health.

Sincerely,

Brian O'Callaghan

Chief Executive Officer

ObsEva SA



Business Update

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to improve women's reproductive health and pregnancy. Through strategic in-licensing and disciplined drug development, we have established a late-stage clinical pipeline with development programs focused on new therapies for the treatment of uterine fibroids, endometriosis, and 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.

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

Linzagolix for the treatment of uterine fibroids and pain associated with endometriosis.

We are developing linzagolix as a novel, oral gonadotropin releasing hormone, or GnRH, receptor antagonist, for the treatment of uterine fibroids and endometriosis in pre-menopausal women. In 2015, ObsEva inlicensed linzagolix from Kissei Pharmaceutical Co. for exclusive worldwide rights ex-Asia. Linzagolix is a novel, orally administered GnRH receptor antagonist that potentially provides effective management of heavy menstrual bleeding, or HMB, associated with uterine fibroids, or UF, and treatment of endometriosis-associated pain while mitigating bone mineral density loss and other adverse effects typically associated with currently approved treatments. Unlike marketed GnRH agonists, linzagolix has the potential to be administered orally once a day, with symptoms relieved within days, while potentially mitigating the initial worsening of symptoms often associated with GnRH agonist treatments. Linzagolix has the potential to dose-dependently lower estradiol levels hence maintaining such levels within an optimal range to mitigate patient bone mineral density loss. Linzagolix has the potential to allow patients to receive the relief needed to live normal lives again and enhance their quality of life with fewer side effects and complications requiring doctor's visits or surgery.

Ebopiprant for the treatment of preterm labor (GA 24-34 weeks).

In July 2021, we and Organon, entered into an agreement whereby Organon licensed the global rights to develop, manufacture and commercialize ebopiprant (formerly OBE022), an investigational, once daily, oral and selective PGF2 α , receptor antagonist for the treatment of preterm labor in weeks 24 to 34 of pregnancy. Under the terms of the agreement, Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. We are entitled to receive tiered double-digit royalties on commercial sales as well as up to \$500 million in upfront and milestone payments, including \$25 million that was paid at signing, up to \$90 million in development and regulatory milestones and up to \$385 million sales-based milestones.

Nolasiban to improve embryo transfer outcomes after IVF.

In January 2020, we and Yuyuan, entered into a sublicense agreement to develop and commercialize Nolasiban, an oral oxytocin receptor antagonist, to improve clinical pregnancy and live birth rates in women undergoing in-vitro fertilization, or IVF, in the People's Republic of China. Under the terms of the agreement, Yuyuan has the exclusive rights to develop and commercialize nolasiban in China and will fund all

development and registration activities in China, starting with the commitment to conduct Phase 1 trials and a Phase 2 proof-of-concept trial in China. We retain all rights to the product outside of China and have agreed to collaborate with Yuyuan on its global development. Our development and commercialization partnership with Yuyuan continues with steering committee meetings to define the development plan for nolasiban in China for women undergoing embryo transfer following IVF.

The following table summarizes key information regarding our current development programs:

Phase 1 Phase 2 Phase 3 **Key Milestones** MAA: CHMP Positive Opinion (Dec 16, 2021) Uterine Fibroids - Ph3 PRIMROSE 2 (EU & US) NDA: PDUFA (Sep 13, 2022) Licensing agreement with Theramex and commercialization relationship established with Syneos Health LINZAGOLIX Oral GnRH Phase 3 positive topline results announced receptor antagonist Endometriosis – Ph3 EDELWEISS 3 (EU & US) Phase 3 Post-Rx F/U data expected (Q2:22) Phase 3 Post-Rx F/U-extension data expected (Q4:22) **EBOPIPRANT** Oral PGF_{2α} Global rights licensed to Organon Preterm Labor – Ph2b (EU & Asia) receptor antagonist **NOLASIBAN** IVF - Ph1/2 (China) China rights licensed to YuYuan Bioscience Oral oxytocin receptor antagonist

Multiple development programs drive value

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 Strengths

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

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

Our Strategy

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

- Continue to advance each of our current product candidates in their respective indications.
- Develop a targeted commercialization strategy for any approved product candidates. As we move our product candidates through development toward regulatory approval, we continue to evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force, entering into strategic marketing partnerships with third party collaborators, including potentially other pharmaceutical or biotechnology companies, or out-licensing our products to other pharmaceutical or biotechnology companies.
- **Pursue additional indications for our current product candidates.** We believe each of our current product candidates have potential for application outside the indications we are currently developing, and we plan to pursue additional indications for our existing product candidates in the near future.
- Leverage our international product development experience and extensive network of clinical experts and pharmaceutical industry executives within women's reproductive health and pregnancy to in-license or acquire novel product candidates. We are focused on identifying, and inlicensing 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.

<u>Linzagolix: Investigational GnRH Receptor Antagonist for Symptoms Associated with Uterine Fibroids and Endometriosis</u>

We are developing linzagolix as an oral GnRH receptor antagonist, which we have observed in our clinical trials to induce a dose-dependent reduction of estradiol levels. Through that mechanism, we expect linzagolix to be indicated for the treatment for symptoms associated with uterine fibroids and endometriosis-associated pain. We believe linzagolix, if approved, has the potential to be a best-in-class oral GnRH receptor antagonist based on its favorable PK and PD profiles, and its potential to provide targeted estradiol suppression to reduce HMB associated with uterine fibroids and pain symptoms associated with endometriosis, while mitigating bone mineral density loss and other adverse effects that are typically associated with full estradiol suppression. A drug's PK profile is its linear pharmacokinetic profile, a predictable dose-dependent suppression of estradiol, which is a form of the hormone estrogen, and a dose range that was well-tolerated and provided symptom relief. A drug's PK profile refers to the specific way in which a given drug is handled by the body over time, including the particular patterns of the specified drug's absorption, distribution and elimination from the body. A drug's PD profile is its pharmacodynamic profile which refers to the biochemical and physiological effects of a drug on the body. We believe that linzagolix has the potential to offer flexible dosing alternatives with or without hormonal add back therapy, or ABT, to address symptoms in broad patient populations, supported by key differentiating product characteristics, including absence of food effect, high bioavailability, low volume of distribution, no induction of a liver enzyme known as cytochrome P450 3A4 (CYP3A40) or organic anion-transporting polypeptide (OATP) 1B1/B3 interaction, and low PK and PD variability. We believe these characteristics are key product differentiators compared to other GnRH receptor antagonists in development.

Background on Uterine Fibroids and Endometriosis

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

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

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

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

The Role of GnRH

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

Limitations of Current Therapies for Uterine Fibroids and Endometriosis

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

Uterine Fibroids

Historically, medical treatment options for heavy menstrual bleeding associated with uterine fibroids have been limited and generally consist of oral contraceptives and short-term pre-surgical use of GnRH agonist injections. Oral contraceptives are generally used as first-line therapy, but are often not effective in reducing heavy bleeding. Upon failure of a first-line therapy or contraindication to oral contraceptives, surgical intervention is generally the next treatment option. Hysterectomy is the most commonly performed surgical treatment. Other procedures include (1) myomectomy, which is selective removal of fibroids, often performed by laparoscopy; this usually preserves fertility, (2) uterine artery embolization, which is a procedure to obstruct the arteries feeding the fibroid, performed by arterial catheterization, and (3) MRI-guided focused ultrasound ablation. In May 2021, Myovant received regulatory approval in the United States for Myfembree® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, Myovant received regulatory approval in the EU for Ryeqo® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

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

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

Endometriosis

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

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

responded to other medical or surgical treatments, a hysterectomy, which is the removal of all or part of the uterus, may be performed. Depending on the woman, removal of the ovaries may also be required, resulting in definitive infertility and immediate menopause.

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

Mechanism of Action and Limitations of GnRH Agonists

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

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

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

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

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

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

- Rapid onset of therapeutic effect. By blocking, as opposed to initially stimulating the GnRH receptor, linzagolix has the potential to suppress LH and FSH within hours, lowering estradiol levels and reducing pain within days while potentially avoiding the initial flare effect which is often associated with GnRH agonist treatments.
- *Ease of administration*. Linzagolix has the potential to be administered orally once daily, and regardless of food intake timing. This potential dosing regime is a more convenient and less invasive treatment option than GnRH agonist intramuscular or subcutaneous injections.
- Optionality for uterine fibroids and endometriosis treatment: stand alone or in combination with hormonal ABT. In contrast to GnRH agonists, for which hormonal ABT is required when treatment exceeds six months, we believe that the 75mg once daily dose tested in our EDELWEISS 1 Phase 2b trial and the 100mg once daily dose tested in our PRIMROSE trials, have the potential to be utilized as a stand-alone treatment for a substantial proportion of patients with endometriosis-associated pain and heavy menstrual bleeding associated with uterine fibroids by maintaining estradiol levels between 20 and 60 pg/ml.

The once daily 200 mg dose of linzagolix will require the addition of hormonal ABT if used long-term to counteract the side effects associated with full suppression of estradiol, i.e. below 20 pg/ml.

These doses of 75 mg or 100mg with or without hormonal ABT, 200 mg with hormonal ABT, and 200 mg without hormonal ABT (for short-term use in uterine fibroids) have been or are being tested in the confirmatory Phase 3 trials.

• Rapid reversibility of effect. As a result of the observed linzagolix half-life of approximately 15 hours, we believe there is the potential for ovarian function to resume within days following the end of treatment. In contrast, a patient's ovarian function can take weeks or months to return to normal after stopping treatment with injectable GnRH agonists.

Potential Clinical Profile of linzagolix

In July 2018, AbbVie Inc. announced that their oral GnRH antagonist elagolix (Orilissa®) received regulatory approval in the U.S. for the treatment of women with moderate to severe endometriosis-associated pain (150mg QD up to 2-year and 400mg (200mg BID) up to 6 months). AbbVie also obtained approval for Oriahnn® in May 2020 for the indication of heavy menstrual bleeding associated with uterine fibroids. Oriahnn® is given as a high dose of elagolix 600mg (300mg BID) with hormonal ABT (E2 1mg/NETA 0.5 mg). AbbVie Inc. is now conducting Phase 3b trials with elagolix 600mg daily dose (300mg BID) in combination with hormonal ABT to assess long-term impact (48 months) of hormonal ABT treatment on BMD.

In addition, Myovant Sciences, Inc. conducted Phase 3 trials with the oral GnRH receptor antagonist relugolix 40mg daily in combination with hormonal ABT for the treatment of symptoms associated with endometriosis and uterine fibroids. This is the only dose level being studied for both indications. In May 2021, Myovant received regulatory approval in the United States for Myfembree® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, Myovant received regulatory approval in the EU for Ryeqo® (relugolix 40 mg, estradiol

1 mg, and norethindrone acetate 0.5 mg) for treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Ryeqo® will be commercialized by Gedeon Richter for the management of heavy menstrual bleeding associated with uterine fibroids. In September 2021, Myovant announced that the FDA accepted for review a supplemental New Drug Application for Myfembree® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for the management of moderate to severe pain associated with endometriosis The FDA set a target action date of May 6, 2022.

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

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

Linzagolix Clinical Development for Uterine Fibroids

We are developing linzagolix for the treatment of bleeding associated with uterine fibroids. We believe linzagolix has the potential to provide an effective oral treatment for uterine fibroids.

Completed Phase 2a Trial in Japanese Patients

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

patients. In addition, most patients in the 100 mg and 200 mg groups stopped bleeding within a few weeks of treatment initiation. A dose-dependent reduction in uterine volume was observed in the active treatment arms.

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

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

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

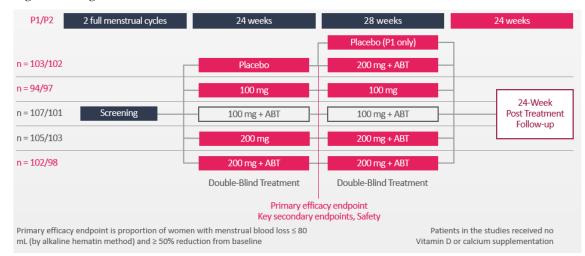


Figure 1: Design of Phase 3 PRIMROSE Clinical Trials

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

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

In December 2019, we announced positive Phase 3 trial results from the PRIMROSE 2 trial of linzagolix for the treatment of HMB due to uterine fibroids. The responder rate was 93.9% (p < 0.001) for patients receiving 200 mg with hormonal ABT and 56.7% for patients receiving 100 mg without hormonal ABT (p < 0.001), compared to 29.4% in the placebo group. Both doses achieved significant rates of amenorrhea (p < 0.001), reduction in

pain (p < 0.001), and improvement in quality of life (p < 0.001). Additionally, significant improvement (p < 0.001) in Hb levels, a reduction in number of days of bleeding and reduction in uterine volume were observed. A significant reduction in fibroid volume was also observed for the 200 mg dose without hormonal ABT (p = 0.008). The overall safety profile was in line with expectations. The most frequently observed adverse events (occurring in > 5% of patients) were headache, hot flushes, and anemia. Mean percentage change from baseline in BMD was consistent with previous clinical data.

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

In July 2020, we also announced positive 52-week treatment results from the PRIMROSE 2 trial. These new data from PRIMROSE 2 demonstrated that continued treatment with linzagolix for 52 weeks provided sustained efficacy. Responder rates of 91.6% and 53.2% were observed in women receiving 200 mg with hormonal ABT and 100 mg without hormonal ABT, respectively, both of which are similar to the responder rates observed at week 24 of the trial. In addition, a small incremental change in BMD was observed at week 52 compared to week 24. In December 2020, we announced positive 52-week treatment results from the PRIMROSE 1 trial, showing that continued treatment with linzagolix led to sustained efficacy for the primary endpoint of reduced heavy menstrual bleeding (defined as menstrual blood loss of at least 50% less than baseline and at or below 80 mL). This was seen across all doses of linzagolix and was in line with the earlier findings in PRIMROSE 2.

We believe that based on pooled week 52 clinical data from these two Phase 3 trials linzagolix has the potential for a best-in-class profile, with a pooled responder rate of 89.3% in women receiving linzagolix 200 mg with hormonal ABT, and 56.4% in women receiving linzagolix 100 mg without hormonal ABT.

In December 2020 and May 2021, we reported additional results for the Phase 3 trials of PRIMROSE 2 and 1, respectively at week 76. These results showed continued pain reduction and demonstrate evidence of BMD recovery after treatment end at 52 weeks.

In November 2020, we submitted a MAA, to the EMA for the treatment of uterine fibroids in adult women of reproductive age. Our application was validated by the EMA in January 2021, and in December 2021, we received a positive opinion from the CHMP recommending approval of linzagolix for the management of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In February 2022, we announced that based on ongoing communications with the EMA, further questions on the MAA for linzagolix may be forthcoming, thereby extending the application timeline. We are in dialogue with the EMA to understand areas that may require further clarification and are committed to promptly addressing any questions that could arise. If approved by the European Commission, linzagolix would be the first and only GnRH antagonist with a non-hormonal option to address the needs of women who cannot or do not want to take hormones. In September 2021, we submitted an NDA, to the FDA, for linzagolix for the treatment of uterine fibroids. The NDA submission includes the positive PRIMROSE 1 and PRIMROSE 2 full data package including week 52 data and post treatment follow-up data up to week 76 for both trials. This NDA was accepted for review by the FDA and assigned a PDUFA target action date of September 13, 2022.

Linzagolix Preclinical and Clinical Development for Pain Associated with Endometriosis

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

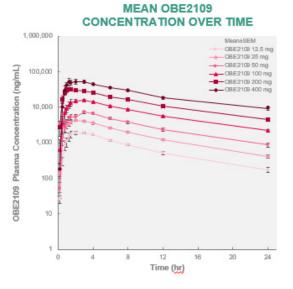
Preclinical Studies and Phase 1 Clinical Trial

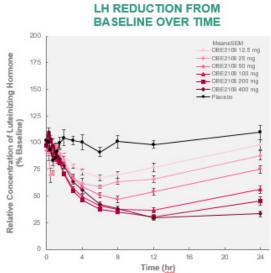
In preclinical studies, linzagolix was observed to be a highly potent and selective antagonist of the GnRH receptor. The preclinical toxicology and safety pharmacology studies did not raise tolerance or safety concerns or potential for DDIs. In the Phase 1 clinical trial, linzagolix was observed to have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

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

Figure 2: Mean linzagolix Concentration Over Time

Figure 3: LH Reduction from Baseline Over Time





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

In 2018, we completed a drug-drug interaction study for the OATP1B1 and OATP1B3, which demonstrated that clinically relevant drug interactions between linzagolix and OATP1B1 / OATP1B3 inhibitors are not to be expected.

Completed Phase 2a Clinical Trials

Kissei completed three Phase 2a clinical trials of linzagolix in patients of Japanese descent with endometriosis in 2013 and 2014. In these studies (KLH1201, KLH1202, and KLH1203), which evaluated doses of 50, 75, 100, or 200 mg of linzagolix or placebo, linzagolix demonstrated improvement in endometriosis-associated pain and showed dose-dependent E2 suppression. These studies supported the design and dose selection for the EDELWEISS 1 Phase 2b trial.

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

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

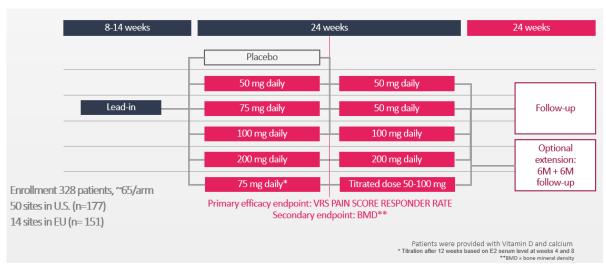


Figure 4: Design of Phase 2b EDELWEISS Clinical Trial

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

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

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

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

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

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

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

We believe the BMD results support our plan to pursue further development of two doses of linzagolix for the treatment of endometriosis, including a 75 mg once daily dose without hormonal ABT, and a 200 mg once daily dose in combination with hormonal ABT. With regards to the titration scheme, although there were some

numerical differences between treatment groups, we did not conclude there was sufficient benefit to continue further development, and are instead focused upon fixed dosing of linzagolix.

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

In May 2019, we initiated our Phase 3 program, which initially consisted of two clinical trials: EDELWEISS 2, designed to enroll approximately 450 patients (150 per arm) in the United States and Puerto Rico, and EDELWEISS 3 designed to enroll approximately 450 patients (150 per arm) across sites in the U.S., as well as Canada, Europe and CIS countries. In these two double-blind, placebo-controlled trials, we evaluated two once daily doses of linzagolix, the 75 mg without hormonal ABT and 200 mg with hormonal ABT. Patients reported their pain on a daily basis with an electronic diary.

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

In January 2021, we announced our decision to discontinue our EDELWEISS 2 and its extension clinical trial, due to challenging patient screening and enrollment, as well as persisting difficult environment of the ongoing pandemic. We are planning to conduct, as soon as is feasible, a new Phase 3 clinical trial for endometriosis with a number of design and operational changes to facilitate faster enrollment, with a goal to maintain the original MAA and NDA filing timelines for this indication.

In January 2022, we announced positive topline results for Linzagolix 200 mg with hormonal ABT in the Phase 3 EDELWEISS 3 Trial in patients with moderate-to-severe endometriosis-associated pain. Two doses were tested, a 200 mg once-daily dose of linzagolix in combination with hormonal ABT and a 75 mg dose of linzagolix without hormonal ABT. The 200 mg dose met the co-primary efficacy objectives, demonstrating reductions in DYS and NMPP at 3 months. There were statistically significant and clinically meaningful improvements in the first five ranked secondary endpoints at 6 months: dysmenorrhea, non-menstrual pelvic pain, dyschezia, overall pelvic pain, and ability to do daily activities. The 75mg dose without hormonal ABT demonstrated a statistically significant reduction versus placebo in DYS at 3 months. Although the 75mg dose showed improvement in NMPP at 3 months, it did not reach statistical significance versus placebo, and thus did not meet the co-primary efficacy objective. The co-primary efficacy endpoints of DYS and NMPP were based on subject-reported symptoms recorded daily via an electronic diary using a VRS of 0 (no pain) through 3 (severe pain). The responder thresholds for monthly pain scores were defined as a reduction of at least 1.1 for DYS and 0.8 for NMPP. P < 0.05 denotes a significant difference from placebo. The responder rates for DYS were 73% for linzagolix 200 mg with hormonal ABT (p<0.001), 44% for linzagolix 75 mg (p<0.001), and 24% for placebo. The responder rates for NMPP were 47% for linzagolix 200 mg with hormonal ABT (p=0.007), 39% for linzagolix 75 mg (p=0.279), and 31% for placebo.

Secondary Endpoints at 6 Months

For linzagolix 200 mg with hormonal ABT, the first five ranked secondary endpoints achieved statistical significance compared to placebo. These were improvements at 6 months in dysmenorrhea, non-menstrual pelvic pain, dyschezia, overall pelvic pain (OPP), and difficulty in doing daily activities. The 75 mg also showed improvements in these endpoints. The complete results for the ranked secondary endpoints are shown in the table below. P<0.05 denotes a significant difference from placebo for each endpoint when p<0.05 for all higher ranked endpoints (including both co-primary endpoints).

Safety Results at 6 Months

Linzagolix was generally well-tolerated with minimal bone mineral density decrease; mean BMD decrease at the lumbar spine was 0.79% for linzagolix 200 mg with hormonal ABT and 0.89% for linzagolix 75 mg. Few adverse events were observed in over 5% of patients in any active treatment arm; these included headache (10.5%, 8.1%, and 8.0%), hot flush (6.8%, 7.5%, and 2.5%), and fatigue (6.8%, 3.8%, and 2.5%) for the 200 mg with hormonal ABT, 75 mg, and placebo groups, respectively.

Both linzagolix doses were generally well-tolerated with minimal BMD decrease and few adverse events occurring in more than 5% of patients up to 6 months.

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

11±5 weeks 24 weeks treatment 24 weeks extension 24 weeks 75 mg daily Placebo 200 mg daily + ABT Post Treatment Follow-up Lead-in 75 mg daily 75 mg daily 200 mg daily + ABT 200 mg daily + ABT Co-Primary efficacy endpoint: DYS/NMPP Responder Analysis Patients are provided with Vitamin D and calcium

Figure 5: Design of Phase 3 EDELWEISS 3 Clinical Trial

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

As of February 2022, 2,591 subjects have been exposed to linzagolix in completed studies and 118 subjects in ongoing clinical studies with linzagolix being generally well tolerated.

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

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

In the PRIMROSE trials in European and US subjects (n=1037), a BMD decrease in line with previous studies was observed. The most frequently observed adverse events (occurring in > 5% of patients in any active treatment group) were headache, hot flushes, anemia and nausea. Headache was reported with a higher incidence in the 200 mg group (11.9%) compared to placebo (5.7%) and other linzagolix groups (\leq 7.2%). The incidence of hot flushes during the first 24 weeks of treatment was dose-dependent. The highest incidence of hot flushes was observed in the linzagolix 200 mg group (33.3%), which is consistent with the mechanism of action of linzagolix. Rates of hot flushes were similar in the 100 mg (10.1%) and 200 mg+ hormonal ABT groups (9.6%), compared with 5.3% in the placebo arm, which demonstrates that the use of hormonal ABT

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

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

In the EDELWEISS 3 Phase 3 clinical trial, linzagolix was generally well-tolerated with minimal bone mineral density decrease; mean BMD decrease at the lumbar spine was 0.79% for linzagolix 200 mg with hormonal ABT and 0.89% for linzagolix 75 mg. Few adverse events were observed in over 5% of patients in any active treatment arm; these included headache (10.5%, 8.1%, and 8.0%), hot flush (6.8%, 7.5%, and 2.5%), and fatigue (6.8%, 3.8%, and 2.5%) for the 200 mg with hormonal ABT, 75 mg, and placebo groups, respectively.

Both linzagolix doses were generally well-tolerated with minimal BMD decrease and few adverse events occurring in more than 5% of patients up to 6 months.

Ebopiprant (formerly OBE022): $PGF_2\alpha$ Receptor Antagonist for the Treatment of Preterm Labor (GA 24-34 weeks) licensed to Organon

Ebopiprant is an investigational, once daily, oral and selective PGF2 α , receptor antagonist for the treatment of preterm labor in weeks 24 to 34 of pregnancy. PGF2 α is a naturally occurring prostaglandin that acts to induce labor in pregnant women. Through specific antagonism of the PGF2 α receptor, ebopiprant is designed to control preterm labor by reducing inflammation, decreasing uterine contractions and preventing cervical changes and membrane ruptures.

In July 2021, we entered into an agreement with Organon whereby Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant.

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

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

The incidence of maternal, fetal and neonatal adverse events were comparable between subjects in the ebopiprant group and the placebo group. Follow-up of infants at 6 and 12 months after birth became available in 2021 and follow-up of infants at 24 months after birth is continuing and results may be available in 2022. Based on the available ASQ-3TM data at 6 and 12 months, infant development was similar between infants born to mothers in the OBE022 group and infants born to mothers in the placebo group in most ASQ3TM domains. There is no evidence that administration of ebopiprant in pregnant women with spontaneous preterm labor has a negative impact on infant development compared to placebo.

Nolasiban in IVF

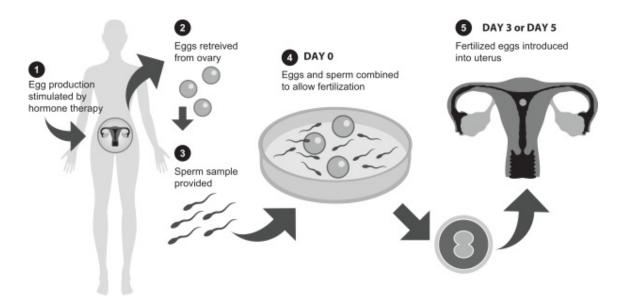
Nolasiban is an oral oxytocin receptor antagonist that is being developed to improve clinical pregnancy and live birth rates in women undergoing embryo transfer following IVF, including intracytoplasmic sperm injection, or ICSI. The mechanism of action of nolasiban supports its potential to improve uterine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

Background on Assisted Reproductive Technology (IVF/ICSI)

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

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

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

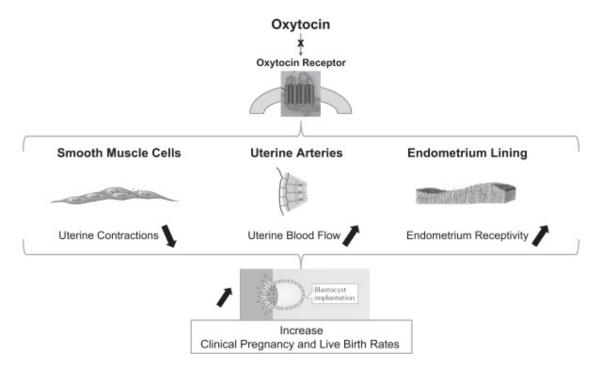


The cost of one IVF cycle varies between \$8,000 to \$15,000 in the United States, EUR 2,000 to EUR 10,000 in Europe and \$3,000 to \$6,000 in Japan. As of 2006, fertility drugs account for more than \$2,000 of the cost of a treatment cycle. Most patients require multiple fertility treatment cycles.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

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

Role of Oxytocin in Embryo Implantation

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



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

Nolasiban clinical development program

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

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

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

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

In November 2019, we announced that the IMPLANT 4 trial did not meet the primary endpoint of an increase in ongoing pregnancy rate at 10 weeks, (39.1 % placebo vs 40.5 % nolasiban) (p = 0.745). As these results did not confirm the prior positive Phase 3 IMPLANT 2 trial findings, we have discontinued our previously ongoing development of nolasiban for IVF, and are exploring potential repositioning of the compound, such as through higher dose levels and earlier and longer exposure of nolasiban, as well as focusing on subjects with a high uterus contraction rate at the time of ET. In addition, we performed an individual patient level meta-analysis of the IMPLANT 1, 2, and 4 studies and showed an overall 5% absolute increase in ongoing pregnancy rate which was statistically significant (p=0.029). Furthermore, population PK analyses indicated that higher exposures of nolasiban were associated with a higher probability of pregnancy. These results have been accepted for publication in the peer-reviewed journal, Human Reproduction. A mechanism of study in health volunteers showed evidence that treatment with nolasiban reduces uterine contractions, increases uterine blood flow, and induces changes in genes reported to be associated with endometrial receptivity. The results also suggested the potential for larger effects with higher doses of nolasiban. This study was published in the peer-reviewed journal RBM online. In connection with this potential repositioning, in January 2020, we and Yuyuan entered into a sublicense agreement to develop and commercialize nolasiban for improving clinical pregnancy and live birth rates in women undergoing embryo transfer as part of an IVF cycle in the People's Republic of China, or PRC. Under the terms of the agreement, Yuyuan has the exclusive rights to develop and commercialize nolasiban in the PRC. They will fund all development and registration activities in the PRC, starting with the obligation to fund and conduct a Phase 1 trial and a Phase 2 proof-of-concept trial in China. We retain all rights to the product outside of PRC, and have agreed to collaborate with Yuyuan on its global development. Our development and commercialization partnership with Yuyuan proceeded during 2021 with steering committee meetings to define the development plan for nolasiban in China for women undergoing ET following IVF.

Commercialization

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 continue to evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force, entering into a strategic marketing partnership with third parties, including other pharmaceutical or biotechnology companies, or out-licensing the product to other pharmaceutical or biotechnology companies. For example, in October 2021 we announced a strategic relationship with Syneos Health, the only fully integrated biopharmaceutical solutions organization, to commercialize linzagolix in the U.S. and Canada. We have also entered into, and may in the future enter into, license agreements to out-license our product candidates, including our sublicense agreement with Yuyuan for Yuyuan to develop and commercialize nolasiban for improving clinical pregnancy and live birth rates in women undergoing embryo transfer following IVF in China, our global license, development and commercialization agreement with Organon for ebopiprant, and our licensing agreement with Theramex for the commercialization of linzagolix across global markets outside of the U.S., Canada and Asia.

Manufacturing

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

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

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

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

Competition

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

With respect to linzagolix, in July 2018, the first compound from the oral gonadotropin-releasing hormone, or GnRH, receptor antagonist class, Orilissa ® (elagolix 150 mg QD and 200mg BID), received regulatory approval in the United States for the treatment of pain associated with endometriosis. AbbVie Inc. has been commercializing Orilissa in the United States since August 2018. In May 2020, AbbVie received regulatory approval in the United States for Orihnn® (elagolix 300mg BID, estradiol 1mg and norethindrone acetate 0.5 mg QD) for the management of heavy menstrual bleeding associated with uterine fibroids. In May 2021, Myovant received regulatory approval in the United States for Myfembree® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for the management of heavy menstrual bleeding associated with uterine fibroids. In July 2021, Myovant received regulatory approval in the EU for Ryego® (relugolix 40 mg, estradiol 1 mg, and norethindrone acetate 0.5 mg) for treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Ryeqo® will be commercialized by Gedeon Richter. In September 2021, Myovant announced that the FDA accepted for review a supplemental New Drug Application for Myfrembree® (relugolix 40 mg, estradiol 1mg, and norethindrone acetate 0.5 mg) for the management of moderate to severe paid associated with endometriosis, with a target action date of May 6, 2022. We also anticipate competing with GnRH receptor agonists, including Lupron (leuprolide acetate), marketed by AbbVie Inc. and Takeda Pharmaceuticals, the progestin Visanne (dienogest), which is approved for the treatment of endometriosis outside the United States and marketed by Bayer, and ulipristal acetate, a Selective Progesterone Receptor Modulator, or SPRM, which is approved for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolization and/or surgical treatment options are not suitable or have failed outside the United States and marketed by Gedeon Richter in Europe and other regions, and by Allergan in Canada. Ulipristal acetate, experienced severe label restrictions of usage in 2018 which were further restricted early in 2021, due to post marketing liver safety issues. Allergan had submitted an NDA for ulipristal acetate but disclosed receipt of a complete response letter from the FDA in August 2018 that the NDA is not approvable in its current form and requesting additional information. Enrollment in Phase 3 clinical trials of vilaprisan, another SPRM developed by Bayer Schering for the treatment of uterine fibroids and endometriosis, was halted by Bayer Schering after long-term toxicology studies in rodents indicated a potential problem. In addition, oral contraceptives and nonsteroidal anti-inflammatory drugs, or NSAIDs, are routinely used as a first-line therapy for the treatment of symptoms associated with endometriosis and uterine fibroids and have a meaningful success rate at mitigating the symptoms associated with these conditions.

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

With respect to nolasiban, there are no other oxytocin receptor antagonists approved either for oral administration or for use in connection with IVF. However, it is our understanding that Ferring Pharmaceuticals Inc. has barusiban in its development pipeline, an oxytocin receptor antagonist, to be administered

subcutaneously, that may be developed for use in connection with IVF. Nevertheless, to our knowledge, no new clinical trial activity has been publicly announced since completion of a Phase 2 in 2015. Ferring Pharmaceuticals' atosiban, an oxytocin receptor antagonist, to be administered by continuous infusion, has been used off-label in investigator-initiated trials in connection with IVF outside the United States.

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

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

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

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

Intellectual Property

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

As of December 31, 2021, our patent portfolio as it pertains to certain of our product candidates included:

seven United States (U.S.) patents, projected to expire between 2034 and 2035, three U.S. patent
applications, which, if granted, project to expire between 2034 and 2037, as well as corresponding
patents and patent applications internationally, directed to nolasiban as a composition of matter
and uses of nolasiban in assisted reproductive technology;

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

As of December 31, 2021, our in-licensed patent portfolio as it pertains to certain of our product candidates included:

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

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

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

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

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

2013 License Agreement with Merck Serono

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

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

2015 License Agreement with Merck Serono

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

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

License and Supply Agreement with Kissei

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

In consideration for the license, we made an initial \$10.0 million upfront payment. We also made two payments of \$5.0 million each to Kissei in 2017 and 2019 related to our commencement of the PRIMROSE and EDELWEISS Phase 3 clinical trials in the uterine fibroid and endometriosis indications, respectively. In addition, we have agreed to make additional aggregate milestone payments of up to \$53.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. With respect to any product we commercialize under the Kissei License and Supply Agreement, we have agreed to make additional aggregate milestone payments of up to \$125.0 million to Kissei upon the achievement of specified commercial milestones.

Pursuant to the Kissei License and Supply Agreement, we have agreed to exclusively purchase the active pharmaceutical ingredient for linzagolix from Kissei. During the development stage, we are obligated to pay Kissei a specified supply price. Following the first commercial sale of licensed product, we are obligated to pay Kissei a royalty payment in the low twenty percent range as a percentage of net sales for product sold outside of North America, which includes payment for Kissei's supply of the active pharmaceutical ingredient, and a tiered single digit royalty of nets sales plus a specified supply price for product sold in North America, in each case 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.

In October 2021, we amended the Kissei license and supply agreement such that first commercial sales milestones for the EU and the United States will now be extended over a 5-year period. In addition, North American royalty payments were lowered to tiered single digit royalties on net sales plus a supply price for the API.

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 nonexclusive 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 developmentrelated obligations for a specified period of time, or if, in connection with a change of control by us, we do not fulfill certain diligence obligations for a specified period of time. Further, under the terms of the Kissei License and Supply Agreement, Kissei is obligated to have a backup supplier based on the pharmaceutical industry standard. We may only gain the right to obtain an alternative source of the supply of linzagolix upon Kissei failing to deliver a substantial percentage of the requested supply, delivering the supply late or delivering the supply of linzagolix in nonconforming manner; provided that Kissei has a specified period of time to cure any of these defects. In the event that Kissei failed to deliver a substantial percentage of requested supply of linzagolix, we may gain the right to obtain an alternative source of supply. Further, we and Kissei are each obligated to maintain a specified percentage of supply in excess of the estimate for yearly requirements that we submit to Kissei.

Sublicense Agreement with Yuyuan

In January 2020, we entered into a sublicense agreement, or the 2020 Sublicense Agreement, with Hangzhou Yuyuan BioScience Technology Co., Ltd., or Yuyuan, pursuant to which we granted to Yuyuan an exclusive sublicense under certain of our patents, trademarks and know-how to use, register, import, develop, market, promote, distribute, offer for sale and commercialize nolasiban for use in humans in the People's Republic of China, including Hong Kong and Macau. Yuyuan will be responsible for the continued development of nolasiban in China at its sole cost, and is required to use commercially reasonable efforts to develop the product in accordance with certain development milestones. Yuyuan will be responsible for commercialization of nolasiban in China at its sole cost. We are obligated to supply Yuyuan with its clinical and commercial requirements of the product at cost. Yuyuan has agreed to not develop, market or sell any oxytocin receptor antagonist other than nolasiban during the term of the 2020 Sublicense Agreement. The development and commercialization activities for nolasiban will be governed by a joint development committee and joint commercialization committee, respectively, with each party having final decision-making authority for its

territory. In consideration for entering into the 2020 Sublicense Agreement, Yuyuan has agreed to make aggregate milestone payments of up to \$17.0 million upon the achievement of specified development, regulatory and first sales milestones and aggregate milestone payments of up to \$115.0 million upon the achievement of additional, tiered sales milestones. In addition, Yuyuan has agreed to pay tiered royalties on net sales at percentages ranging from high-single digit to low-second digits, subject to specified reductions, until the later of the expiration of the last valid claim covering the product in China and ten years from the first commercial sale of the product in China.

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

License Agreement with Organon

In July 2021, we entered into an agreement with Organon whereby Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant.

Under the terms of the agreement, Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. We are entitled to receive tiered double-digit royalties on commercial sales as well as up to \$500 million in upfront and milestone payments, including \$25 million that was paid at signing, up to \$90 million in development and regulatory milestones and up to \$385 million sales-based milestones. Unless terminated earlier, the agreement will continue until expiration of all of Organon's royalty obligations to ObsEva. ObsEva and Organon may each terminate the agreement for the other party's uncured material breach and for certain other "for cause" reasons, and Organon may terminate the agreement for convenience following a certain notice period.

License Agreement with Theramex

In February 2022, we entered into a licensing agreement with Theramex for the commercialization and further development of linzagolix across global markets outside of the U.S., Canada and Asia. Under the terms of the agreement, Theramex has the exclusive right to commercialize linzagolix in women's health indications (with the express exclusion of any oncology indications). Under the terms of the agreement, we are entitled to receive royalties of a mid-thirties percentage on commercial sales, which includes the cost of goods sold to Theramex. Furthermore, the agreement contains up to EUR72.75 million in upfront and milestone payments, including EUR5 million to be paid at signing, up to EUR13.75 million in development and commercial milestones and up to EUR54 million in sales-based milestones. Unless terminated earlier, the agreement will continue until the expiration of all off Theramex's royalty obligations to us. We and Theramex may each terminate the agreement for the other party's uncured material breach and for certain other "for cause" reasons, and Theramex may terminate the agreement should we fail to meet certain regulatory milestones by specific dates.

Government Regulation

FDA Drug Approval Process

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

Approval Process

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

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

- completion of extensive preclinical laboratory tests, animal studies and CMC studies, all performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin. The sponsor must update the IND annually;
- approval of the study by an IRB or ethics committee at each site before the study begins;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practice, or GCP, requirements to establish the safety and efficacy of the drug for each proposed indication to the FDA's satisfaction;
- submission to the FDA of an NDA after completion of all clinical trials;
- potential review of the drug application by an FDA advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the
 product is produced to assess compliance with cGMP regulations and to assure that the facilities,
 methods and controls are adequate to preserve the drug's identity; and
- FDA review and approval of the NDA prior to any commercial marketing or sale of the drug in the United States.

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

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP. The company submits the results of the preclinical testing, together with manufacturing information, analytical data and any

available clinical data or literature to the FDA as part of an IND along with other information, including information about product CMC and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after submitting the initial IND.

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

Clinical Trials

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

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

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

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

- **Phase 1.** These trials typically evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, gain early evidence on effectiveness. Other Phase 1 or clinical pharmacology studies generally evaluate the drug for potential DDI, cardiovascular safety and special population interactions. These studies, if needed, are to be conducted prior to NDA submission but may be conducted in parallel to Phase 2 and Phase 3.
- *Phase 2.* The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy. Phase 2 trials may be denoted as Phase 2a, wherein initial dose-response relationship is explored, and Phase 2b, wherein dose-ranging and proof-of-concept is targeted.

- **Phase 3.** The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug, and to provide an adequate basis for labeling and product approval.
- Phase 4. In some cases, the FDA may condition approval of an NDA for a drug on the company's
 agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily
 conduct additional clinical trials after approval to gain more information about the drug. Companies
 typically refer to such post-approval trials as Phase 4 clinical trials.

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

Submission of an NDA

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

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

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

In addition, under the Pediatric Research Equity Act of 2003, as amended and reauthorized, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on

its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

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

The FDA's Decision on an NDA

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

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

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

Post-approval Requirements

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

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

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

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

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

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

Healthcare Reform

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

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

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. Legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the Supreme Court ruling, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period that remained open from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is also unclear how any such challenges and the healthcare reform efforts of the Biden administration will impact the ACA.

In addition, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted. For example, as a result of the Budget Control Act of 2011, providers are subject to Medicare payment reductions of 2% per fiscal year, which, due to subsequent legislation, including the BBA, will remain in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester.

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

At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to drug pricing that seeks to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the

statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. , in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Coverage, Reimbursement and Pricing

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

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

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for

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

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

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

Sales and Marketing

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

In the United States, clinical research, sales, marketing and scientific/educational programs must also comply with various federal and state laws pertaining to healthcare "fraud and abuse," including anti-kickback laws

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

Given the significant penalties and fines that can be imposed on companies and individuals if convicted, allegations of such violations often result in settlements even if the company or individual being investigated admits no wrongdoing. Settlements often include significant civil sanctions, including fines and civil monetary penalties, and corporate integrity agreements. If the government were to allege or convict us or our executive officers of violating these laws, our business could be harmed. Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. Other healthcare laws that may affect our ability to operate include HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and the federal Physician Payments Sunshine Act, which requires certain manufacturers of products, devices, biologics, and medical supplies to report annually to CMS information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members.

Further, there are an increasing number of state laws that affect our business operations. Some state and local laws require manufacturers to make reports to on pricing and marketing information and impose registration requirements on salespersons within the jurisdiction. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources. Some states maintain anti-kickback and false claims laws that apply to claims involving healthcare items or services reimbursed by any third-party payor, including private insurers. We may also be subject to state laws governing the privacy and security of

health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Many of these state laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs.

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

Foreign Regulation

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

The Foreign Corrupt Practices Act

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

European Union—EMA process

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

Centralized Procedure

Under the centralized procedure, after the Committee for Medicinal Products for Human Use, or CHMP, of the EMA issues an opinion, the European Commission issues a single marketing authorization valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human products that are: derived from biotechnology processes, such as genetic engineering; contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions; and officially

designated orphan drugs. For products that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA as long as the product concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National Authorization Procedures

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

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

Good Manufacturing Practices

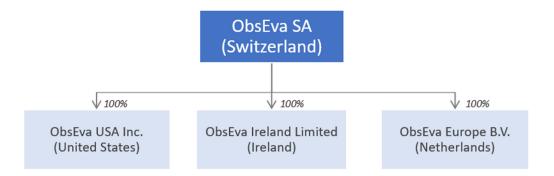
Like the FDA, the EMA, the competent authorities of the European Union Member States and other regulatory agencies regulate and inspect equipment, facilities and processes used in the manufacturing of products prior to approving a product. If, after receiving clearance from regulatory agencies, a company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

Data and Market Exclusivity

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

Organizational Structure

The following diagram illustrates our corporate structure:



Property, Plants and Equipment

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

Financial Review

Financial Review

We are a biopharmaceutical company focused on the development and commercialization of novel therapeutics to improve women's reproductive health and pregnancy. Through strategic in-licensing and disciplined drug development, we have established a late-stage clinical pipeline with development programs focused on treating endometriosis, uterine fibroids, preterm labor, and improving embryo transfer outcomes following in vitro fertilization. Our goal is to build the leading women's reproductive health and pregnancy company focused on conditions where current treatment options are limited and significant unmet needs exist.

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

In November 2020, we submitted a MAA to the EMA, for the treatment of uterine fibroids in adult women of reproductive age. Our application was validated by the EMA in January 2021, and in December 2021, we received a positive opinion from the CHMP recommending approval of linzagolix for the management of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. In February 2022, we announced that based on ongoing communications with the EMA, further questions on the MAA for linzagolix may be forthcoming, thereby extending the application timeline. We are in dialogue with the EMA to understand areas that may require further clarification and are committed to promptly addressing any questions that could arise. If approved by the European Commission, linzagolix would be the first and only approved GnRH antagonist with a non-hormonal option to address the needs of women who cannot or do not want to take hormones. In September 2021, we submitted an NDA to the FDA for linzagolix for the treatment of uterine fibroids. This NDA was accepted for review by the FDA and assigned a PDUFA target action date of September 13, 2022.

We are currently conducting an observational study (PRIMROSE 3) of bone mineral density, or BMD, in women who completed at least 20 weeks of treatment in either of the PRIMROSE 1 or 2 studies. Women who enroll in the study will undergo DXA scanning every six months for a total of 24 months following treatment completion in a PRIMROSE study. The objectives of the study are to describe BMD changes up to 24 months following previous treatment with placebo or linzagolix 100 mg or 200 mg with or without hormonal ABT in the context of the PRIMROSE 1 and 2 studies and to evaluate BMD recovery in these women.

In addition to linzagolix for uterine fibroids, we are presently conducting a Phase 3 clinical trial for the treatment of endometriosis associated pain, EDELWEISS 3 (conducted in Europe and in the United States), which was initiated in May 2019. This Phase 3 trial enrolled approximately 450 patients with endometriosis associated pain, with a co-primary endpoint of patients' response on both DYS and NMPP. This trial includes a 75 mg once daily dose without hormonal ABT (1mg E2 / 0.5mg NETA) and a 200 mg once daily dose with concomitant hormonal ABT. In January 2022, we announced positive topline results for linzagolix 200 mg with hormonal ABT. The 200 mg dose met the co-primary efficacy objectives, demonstrating reductions in DYS and NMPP at 3 months. There were statistically significant and clinically meaningful improvements in the first five ranked secondary endpoints at 6 months: dysmenorrhea, non-menstrual pelvic pain, dyschezia, overall pelvic pain, and ability to do daily activities. The 75mg dose without hormonal ABT demonstrated a statistically significant reduction versus placebo in DYS at 3 months. Although it showed improvement in

NMPP at 3 months, the 75mg does did not reach statistical significance versus placebo, and thus did not meet the co-primary efficacy objective. Improvements were also observed at 6 months in the first five ranked secondary endpoints, as for the 200 mg plus hormonal ABT dose. Both linzagolix doses were generally well-tolerated with minimal BMD decrease and few adverse events occurring in more than 5% of patients up to 6 months.

In October 2021, we announced a strategic relationship with Syneos Health®, the only fully integrated biopharmaceutical solutions organization, to commercialize linzagolix in the U.S. and Canada, if approved.

In February 2022, we entered into a licensing agreement with Theramex for the commercialization and further development of linzagolix across global markets outside of the U.S., Canada and Asia. Under the terms of the agreement, Theramex has the exclusive right to commercialize linzagolix in women's health indications (with the express exclusion of any oncology indications). Under the terms of the agreement, we are entitled to receive royalties of a mid-thirties percentage on commercial sales, which includes the cost of goods sold to Theramex. Furthermore, the agreement contains up to EUR72.75 million in upfront and milestone payments, including EUR5 million to be paid at signing, up to EUR13.75 million in development and commercial milestones and up to EUR54 million in sales-based milestones.

In July 2021, we entered into an agreement with Organon whereby Organon licensed the exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. Under the terms of the agreement, we are entitled to receive tiered double-digit royalties on commercial sales as well as up to \$500 million in upfront and milestone payments, including \$25 million that was paid at signing, up to \$90 million in development and regulatory milestones and up to \$385 million in sales-based milestones.

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

In November 2019, we announced that the IMPLANT 4 trial did not meet the primary endpoint of an increase in ongoing pregnancy rate at 10 weeks, (39.1 % placebo vs 40.5 % nolasiban) (p = 0.745). As these results did not confirm the prior positive Phase 3 IMPLANT 2 trial findings, we have discontinued our previously ongoing development of nolasiban for IVF, and are exploring potential repositioning of the compound, such as through higher dose levels and earlier and longer exposure of nolasiban, as well as focusing on subjects with a high uterus contraction rate at the time of embryo transfer, or ET. In connection with this potential repositioning, in January 2020, we and Yuyuan entered into a sublicense agreement to develop and commercialize nolasiban for improving clinical pregnancy and live birth rates in women undergoing embryo transfer as part of an IVF cycle in the People's Republic of China (PRC). Under the terms of the agreement, Yuyuan has the exclusive rights to develop and commercialize nolasiban in the PRC. We retain all rights to the product outside of PRC and have agreed to collaborate with Yuyuan on its global development. Our development and commercialization partnership with Yuyuan proceeded during 2021 with steering committee meetings to define the development plan for nolasiban in China for women undergoing ET following IVF.

We were founded in November 2012 and our operations to date have included organizing and staffing our company, raising capital, in-licensing rights to linzagolix, ebopiprant and nolasiban and conducting nonclinical studies and clinical trials and preparing for commercialization for linzagolix, if approved. To date, we have not generated any revenue from product sales as none of our product candidates have been approved for commercialization. We have historically financed our operations mostly through the sale of equity. From inception through the date of this Annual Report, we have raised an aggregate of \$496.7 million of net proceeds, including \$88.5 million of net proceeds from our initial public offering in January 2017, \$56.3 million of net proceeds from our private placement with institutional investors in October 2017, \$72.4 million in net proceeds from our underwritten public offering in June 2018 and \$20.0 million in net proceeds from our underwritten public offering and concurrent private placement in September 2020. During 2021, we received proceeds of \$22.1 million from the exercise of warrants associated with the private placement in 2020. In August 2019, we borrowed \$25.0 million under our prior credit facility with Oxford Finance LLC. In

October 2021, we borrowed \$30.0 million under the convertible notes issued to JGB and used these proceeds to pay off the Oxford facility. In addition, between 2018 and 2021, we sold treasury shares from our "at the market" (ATM) program, generating net proceeds of \$91.5 million.

We have never been profitable, have incurred significant net losses in each period since our inception and we have substantial doubt regarding our ability to continue as a going concern. Our net losses were \$58.4 million, \$83.0 million and \$108.8 million for the years ended December 31, 2021, 2020 and 2019, respectively. As of December 31, 2021, we had accumulated losses of \$467.8 million, out of which \$30.6 million were offset with share premium. This reclassification transaction had no impact on total equity. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We used \$70.3 million and \$70.8 million of cash in operations in 2021 and 2020, respectively, and we anticipate that our expenses will remain significant in connection with our ongoing activities as we:

- continue to invest in the clinical development of our product candidates and our ongoing clinical trials, and any additional clinical trials, nonclinical studies and pre-commercial activities that we may conduct for product candidates;
- ✓ hire additional research and development, and general and administrative personnel;
- ✓ maintain, expand and protect our intellectual property portfolio;
- ✓ identify and in-license or acquire additional product candidates;
- prepare for the commercialization of linzagolix, if approved, or any of our other certain product candidates; and
- continue to incur additional costs associated with operating as a public company.

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

We have no manufacturing facilities, and all of our manufacturing activities are contracted out to third parties. We currently utilize third-party contract research organizations, or CROs, to carry out our clinical development and trials. Additionally, we do not yet have a commercialization organization. As we move our product candidates through development toward regulatory approval, we will evaluate several options for each product candidate's commercialization strategy. These options include building our own internal sales force, contracting with a third-party contract sales organization, or CSO, entering into a joint marketing partnership with another pharmaceutical or biotechnology company, or out-licensing the product to another pharmaceutical or biotechnology company.

COVID-19 Business Update

With the global spread of the ongoing COVID-19 pandemic which continues to date, we have implemented a number of plans and policies designed to address and mitigate the impact of the COVID-19 pandemic on our employees and our business. We continue to closely monitor the COVID-19 situation and will evolve our plans and policies as needed going forward. In March 2020, some of our workforce transitioned to working remotely. If the COVID-19 pandemic continues to persist for an extended period and begins to impact essential distribution systems, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing of clinical trial supply.

We may continue to experience a disruption or delay in our ability to initiate trial sites and enroll and assess patients. In January 2021, we announced our decision to discontinue our EDELWEISS 2 and its extension clinical trial, due to challenges with patient enrollment, as well as the persisting difficult environment of the ongoing

pandemic. Enrollment delays may further occur for ongoing trials, and we are working closely with our vendors to manage our supply chain activities and mitigate any potential disruptions to our clinical trial supplies as a result of the COVID-19 pandemic. In addition, we rely on CROs or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business and operations, or the business and operations of our strategic partners, will depend on future developments that are highly uncertain, including the duration and spread of the pandemic, and the actions taken to contain it, such as the impact and effectiveness of current and any future governmental measures implemented in response thereto, or new information that may emerge concerning COVID-19.

Strategic Licensing Agreements

Linzagolix

Kissei

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

In consideration for the license, we made an initial \$10.0 million upfront payment. In addition, we agreed to make aggregate milestone payments of up to \$63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals. In connection with the initiations of the Phase 3 clinical programs for linzagolix in (i) uterine fibroids in the second quarter of 2017 and (ii) endometriosis in the third quarter of 2019, two milestone payments of \$5.0 million each were made. With respect to any products we commercialize under the Kissei license and supply agreement, we agreed to make further payments of up to an additional \$125.0 million to Kissei upon the achievement of specified commercial milestones.

Pursuant to the Kissei license and supply agreement, and related amendments, we have agreed to exclusively purchase the active pharmaceutical ingredient for linzagolix from Kissei. During the development stage, we are obligated to pay Kissei a specified supply price. For territories excluding North America, following the first commercial sale of licensed product, we are obligated to pay Kissei a royalty in the low twenty percent range as a percentage of net sales. This payment includes Kissei's supply of the active pharmaceutical ingredient until the latest of (i) the date that the valid claim of a patent for the Product has expired, (ii) the expiration of our regulatory exclusivity period, or (iii) 15 years from the first commercial sale of such product on a country-by-country and product-by-product basis. For North America, following the first commercial sale of licensed product, we are obligated to pay Kissei a royalty in the tiered single digit royalties on net sales plus a supply price for the API. 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.

In October 2021, we amended the license and supply agreement with Kissei such that first commercial sales milestones for the EU and the US will now be extended over a 5-year period. In addition, North American royalty payments were lowered to tiered single digit royalties on net sales plus a supply price for the active pharmaceutical ingredient (API).

Theramex

In February 2022, we entered into a licensing agreement with Theramex for the commercialization and further development of linzagolix across global markets outside of the U.S., Canada and Asia. Under the terms of the agreement, Theramex has the exclusive right to commercialize linzagolix in women's health indications (with the express exclusion of any oncology indications). Under the terms of the agreement, we are entitled to receive royalties of a mid-thirties percentage on commercial sales, which includes the cost of goods sold to Theramex. Furthermore, the agreement contains up to EUR72.75 million in upfront and milestone payments, including EUR5 million to be paid at signing, up to EUR13.75 million in development and commercial milestones and up to EUR54 million in sales-based milestones.

Ebopiprant

Merck Serono

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

Organon

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

Nolasiban

Ares Trading

In August 2013, we entered into the 2013 license agreement with Ares Trading S.A., an affiliate of Merck Serono, pursuant to which we received a worldwide exclusive license to develop, manufacture and commercialize compounds covered by the licensed patent rights, including nolasiban. In consideration for the license, we issued 914,069 Series A preferred shares to Merck Serono at the time of our Series A financing, which had a fair-value of \$4.9 million based on an exchange rate of \$1.00 for CHF 0.9244 as of the date of the transaction. With respect to any products we commercialize under the 2013 license agreement, we agreed to pay Merck Serono royalties based on a high-single-digit percentage of annual net sales of each product, subject to specified reductions, until the later of (i) the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis, or (ii) ten years from the first commercial sale of such product on a country-by-country and product-by-product basis.

Yuyuan

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

Components of Results of Operations

Revenue

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

Other operating income consists primarily of gains on disposal of intangible assets that we recognize when entering into certain agreements with partners for the development and/or commercialization of the product candidates we have been developing.

Operating Expenses

Research and Development Expenses

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

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

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

This is due to the numerous risks and uncertainties associated with developing such product candidates, including:

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

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will remain significant and increase in the future to support potential commercialization of linzagolix and to support continued research and development activities. We also anticipate that we will keep spending material accounting, audit, legal, regulatory and compliance costs, as well as investor and public relations expenses, associated with operating as a public company.

Finance Result, Net

Finance result, net, consists mainly of foreign exchange loss and gain, as well as interest expense associated with our lease liabilities and debt instruments.

We anticipate that our finance result, net will increase in the future primarily due to increased interest expense associated with the Securities Purchase Agreement with JGB.

Taxation

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

In 2015, the Canton of Geneva granted us a ten-year tax holiday for all income and capital taxes on a communal and cantonal level commencing in fiscal year 2013 and valid through to 2022, subject to our Swiss domiciliation and compliance with certain reporting provisions. We remain subject to Swiss federal income tax on our profits after tax but have only incurred net losses since our inception. We are entitled under Swiss laws to carry forward any losses incurred for a period of seven years and can offset such losses carried forward against future taxes. As of December 31, 2021, we had tax loss carryforwards totaling \$418.4 million. We do not believe it is probable that we will generate sufficient profits to avail ourselves of these tax loss carryforwards.

Our Irish subsidiary had no activity in 2020 and 2021 Our U.S. subsidiary, as a service organization to the group under cost plus arrangement, was the only entity to generate income tax expenses for the year ended December 31, 2021.

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,
	2021	2020	2019
(in thousands)			
Consolidated Statements of Operations Data:			
Operating income other than revenue	20,113	17	16
Operating expenses:			
Research and development expenses	(53,136)	(67,536)	(88,053)
General and administrative expenses	(21,491)	(12,182)	(19,058)
Total operating expenses	(74,627)	(79,718)	(107,111)
Finance result, net	(3,651)	(3,231)	(1,628)
Income tax (expense) / benefit	(212)	(34)	(67)
Net loss	(58,377)	(82,966)	(108,790)

Years Ended December 31, 2021 and 2020

Operating Income Other Than Revenue

Operating income other than revenue increased by \$20.1 million in 2021 compared to 2020 due to the gain on disposal of the intangible asset for ebopiprant. This gain was associated with the agreement we entered into with Organon in July 2021, pursuant to which Organon licensed the exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. Under the agreement, we received a \$25.0 million upfront fee that was paid at signing. We recorded the gain on the disposal of the intangible asset for ebopiprant net of fees and net of derecognition of intangible asset.

Operating Expenses

Research and Development Expenses

	Year En	Year Ended December 31,		
	2021	2020	Change	
(in thousands)				
Research and development expenses by product candidate:				
Linzagolix	(35,873)	(49,431)	13,558	
Nolasiban	(609)	(1,070)	461	
Ebopiprant	(2,211)	(1,662)	(549)	
Unallocated expenses:				
Staff costs	(11,386)	(12,930)	1,544	
Other research and development costs	(3,056)	(2,443)	(613)	
Total research and development expenses	(53,135)	(67,536)	14,401	

Research and development expenses decreased by \$14.4 million in 2021 compared to 2020. This was primarily due to a reduction of \$13.6 million in costs associated with linzagolix for the partial completion of the EDELWEISS clinical trial and the total completion of the PRIMROSE clinical trial. Staff costs also decreased by \$1.5 million primarily due to lower research and development headcount.

General and Administrative Expenses

	Year Ended December 31,		
	2021	2020	Change
(in thousands)			
Staff costs	(7,401)	(6,714)	(687)
Professional fees	(10,531)	(2,911)	(7,620)
Other general and administrative costs	(3,559)	(2,557)	(1,002)
Total general and administrative expenses	(21,491)	(12,182)	(9,309)

General and administrative expenses increased by \$9.3 million in 2021 compared to 2020 primarily due to increases in professional fees of \$7.6 million associated with commercial preparation activities related to linzagolix and legal fees. Other general and administration expenses increased by \$1.0 million due to increases in insurance costs and staff costs increased by \$0.7 million due to increased headcount and pension costs.

Finance Result, Net

	Year Ended December 31,		
	2021	2020	Change
(in thousands)			
		l	
Foreign exchange loss, net	78	(527)	606
Interest expense	(3,156)	(2,704)	(453)
Change in fair value of derivative liability	790	-	790
Loss on Oxford debt extinguisment	(1,363)	-	(1,363)
Finance result, net	(3,651)	(3,231)	(420)

Finance result, net, in 2021 and 2020 primarily consisted of interest expense associated with our lease liabilities and debt instruments, as well as foreign exchange losses. Interest expense increased due to increased borrowings under our Securities Purchase Agreement with JGB as compared to interest expense in 2020 under our prior credit facility with Oxford. In 2021, we recorded a loss on debt extinguishment in relation to the payoff of the Oxford credit facility.

B. Liquidity and Capital Resources

Sources of Funds

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 and license of our product candidates. From inception through December 31, 2021, we have raised an aggregate of \$441.7 million of net proceeds from the sale of equity securities, through public and private offerings and our at-the-market programs. In July 2021, we received \$25.0 million from Organon in connection with the licensing agreement for ebopiprant. As of December 31, 2021, we had borrowed \$25.0 million under our

prior credit facility with Oxford (repaid in full in October 2021) and \$31.5 million under our Securities Purchase Agreement with JGB.

Oxford Credit Facility

On August 7, 2019, we entered into the Credit Facility Agreement with Oxford for a term loan of up to \$75.0 million, subject to funding in three tranches. We received gross proceeds of \$25.0 million from the first tranche of the credit facility upon entering into the agreement and used the funds as part of our various clinical trials programs. We could not draw the second tranche of \$25.0 million due to the failure to meet the primary endpoint of the Phase 3 IMPLANT 4 clinical trial of nolasiban. In April 2020, we amended the Credit Facility Agreement pursuant to which the third tranche of \$25.0 million was available to be drawn at any time between April 7, 2020 and August 1, 2024 upon our request and at Oxford's discretion. The credit facility was secured by substantially all of our assets, including our intellectual property. The loan bore a floating interest rate (partially based on thirty-day U.S. LIBOR rate) at 8.68% per year in total and was set mature on August 1, 2024.

Securities Purchase Agreement with JGB

On October 12, 2021, we entered into the Securities Purchase Agreement with certain funds and accounts managed by JGB which is structured to provide up to \$135 million in borrowing capacity, available in nine tranches. We received gross proceeds of \$30 million from the first tranche at closing and used the proceeds to repay all amounts outstanding under our existing Credit Facility Agreement with Oxford. Upon payoff, the Credit Facility Agreement was terminated and the security interests in our assets that secured the Credit Facility Agreement were released. We are able to potentially receive gross proceeds of \$16.725 million from the third tranche and \$13.125 million from each remaining tranche thereafter.

On January 28, 2022, we entered into an amendment agreement and an amended and restated securities purchase agreement, or the Amendment Agreements, with JGB to amend the Securities Purchase Agreement. The Amendment Agreements adjusted the principal balance payable at maturity for the notes to be issued in the second tranche to \$10.5 million (\$975,000 of original issue discount) and the conversion price for the notes to be issued in the second tranche to a price of \$1.66 per common share, and accelerated the issuance of the second tranche to January 28, 2022. In addition, as adjusted pursuant to the Amendment Agreements, we issued a warrant to purchase 1,018,716 of our common shares at an exercise price of \$1.87 per share. Additionally, JGB waived certain conditions required to be met to fund the second tranche, including that our volume-weighted average price could not be below \$3.00 per share for five or more trading days during the 30 days prior to the funding date for the second tranche, in exchange for a payment of \$1.25 million and the amended terms for the notes and warrants to be issued in the second tranche. In connection with the Amendment Agreements, we received net proceeds of \$8.25 million from the second tranche, after accounting for expenses and the \$1.25 million waiver payment to JGB.

We are able to potentially receive gross proceeds of \$16.725 million from the third tranche and \$13.125 million from each remaining tranche thereafter under the Securities Purchase Agreement with JGB. The third tranche will be funded in May 2022 and each subsequent tranche will be funded 90 days after the preceding tranche. The subsequent tranches under the Securities Purchase Agreement will be available subject to us meeting certain conditions, including, among others, that our volume-weighted average price is not below \$3.00 per share for five or more trading days during the 30 days prior to a tranche funding date.

The Securities Purchase Agreement is secured by an account control agreement in favor of JGB, and we are obligated to maintain a minimum cash amount of \$25.0 million in such deposit account, subject to additional incremental increases totaling \$27.0 million in aggregate depending on the amount of debt outstanding under the Securities Purchase Agreement. Each tranche under the Securities Purchase Agreement will bear interest at a rate of 9.5% per year, payable monthly, and will be issued with an original issue discount of 4.75%. Each

tranche under the Securities Purchase Agreement will mature three years from the date of issuance, unless earlier converted or prepaid in accordance with their terms. At each tranche, we will also issue to JGB warrants to purchase our common shares in an amount equal to 20% of the funded amount for such tranche. The warrants will be exercisable at a price of \$3.67 per share and will have a four year term from the date of issuance. The Securities Purchase Agreement includes affirmative and negative covenants applicable to us and our subsidiaries. The affirmative covenants include, among other things, requirements to file certain financial reports with the SEC, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. Further, subject to certain exceptions, the Securities Purchase Agreement contains customary negative covenants limiting our ability to, among other things, transfer or sell certain assets, consummate mergers or acquisitions, allow changes in business, incur additional indebtedness, create liens, pay dividends or make other distributions and make investments. As of December 31, 2021, we were in compliance with our covenants.

ATM Program and other sources

During the year ended December 31, 2021, we sold a total of 15,933,420 treasury shares at an average price of \$3.28 per share, as part of our ATM program. These multiple daily transactions generated total gross proceeds of \$53.7 million. Directly related share issuance costs of \$2.3 million were recorded as a deduction in equity. During the year ended December 31, 2021, 6,448,240 warrants were exercised at an average price of \$3.43 per share, resulting in proceeds of \$22.1 million.

As of December 31, 2021, we had \$54.7 million in cash and cash equivalents. Subsequent to December 31, 2021 and through February 28, 2022, we raised additional gross proceeds of \$4.6 million from the sale of additional treasury shares as part of our ATM program. In February 2022, we signed a licensing agreement with Theramex to support the commercialization and market introduction of linzagolix across global markets outside of the U.S., Canada and Asia. and received an upfront payment of EUR5 million upon signing.

Material Cash Requirements

Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. Other than our Securities Purchase Agreement with JGB, we have no other ongoing material financing commitments, such as lines of credits or guarantees.

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

We have incurred recurring losses since inception, including net losses of \$58.4 million for the year ended December 31, 2021. As of December 31, 2021, we had accumulated losses of \$467.8 million, of which \$30.6 million were offset with share premium. We expect to continue to generate operating losses for the foreseeable future. As of December 31, 2021, we had cash and cash equivalents of \$54.7 million. We have prepared our consolidated financial statements assuming that we will continue as a going concern which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary

course of business. In October 2021, we entered into the Securities Purchase Agreement with certain funds and accounts managed by JGB Management, Inc. The Securities Purchase Agreement is structured to provide \$135 million in borrowing capacity, available in nine tranches, with the first tranche funded at the initial closing in October 2021 and the second tranche funded in January 2022 in connection with certain amendments to the Securities Purchase Agreement. The subsequent tranches under the Securities Purchase Agreement will be available subject to us meeting certain conditions, including, among others, that our volume-weighted average price is not below \$3.00 per share for five or more trading days during the 30 days prior to a tranche funding date (the "Minimum Stock Price"). The availability of future funding under the Securities Purchase Agreement is dependent on whether the Minimum Stock Price condition will be met at future tranche dates. To date, we have funded our operations through equity and debt offerings and through payments from licensors. We believe that our current cash and cash equivalents are only sufficient to fund our operating expenses into the third quarter of 2022 and this raises substantial doubt about our ability to continue as a going concern. These factors individually and collectively indicate that a material uncertainty exists that may cast significant doubt about our ability to continue as a going concern within one year from the date of the issuance of the consolidated financial statements. Our future viability is dependent on our ability to raise additional capital to finance our future operations. We have an active ATM program and can potentially raise funds through equity or debt offerings. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to shareholders. We may receive future milestone payments from licensors but that is dependent on achieving certain regulatory or commercial milestones that may never happen. We may seek additional funding through public or private financings, debt financing or collaboration agreements. The inability to obtain funding, as and when needed, would have a negative impact on our financial condition and ability to pursue our business strategies. If we are unable to obtain the required funding to run our operations and to develop and commercialize our product candidates, we could be forced to delay, reduce or eliminate some or all of our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations. Management continues to explore options to obtain additional funding, including through collaborations with third parties related to the future potential development and/or commercialization of our product candidates. However, there is no assurance that we will be successful in raising funds, closing a collaboration agreement, obtaining sufficient funding on terms acceptable to us, or if at all, which could have a material adverse effect on the our business, results of operations and financial conditions. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we currently expect. Our future material cash requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned nonclinical studies and clinical trials for our product candidates;
- the cost and timing of ongoing and planned manufacturing activities including active pharmaceutical ingredient and drug product pharmaceutical development and clinical trial supplies production for linzagolix and nolasiban;
- the timing and amount of milestone and royalty payments we are required to make under our license agreements;
- the extent to which we in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval:
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;

- our ability to establish strategic collaborations; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

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

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

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

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, such as our licensing agreements with Organon for ebopiprant and Theramex for linzagolix, 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 En	Year Ended December 31,		
	2021	2020	2019		
(in thousands)					
Cash and cash equivalents at beginning of period	31,183	69,370	138,640		
Net cash used in operating activities	(70,304)	(70,766)	(90,611)		
Net cash from (used in) investing activities	22,186	(5)	(5,046)		
Net cash from financing activities	71,104	32,249	26,627		
Effect of exchange rates	565	335	(240)		
Cash and cash equivalents at end of period	54,734	31,183	69,370		

Operating Activities

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

During the year ended December 31, 2021, \$70.3 million of cash was used for operating activities, primarily as the result of our net loss before tax of \$58.2 million, plus our non-cash items and changes in net working capital. Non-cash items amounted to \$10.2 million and mainly consisted of our other operating income of \$20.1 million partially offset by share-based compensations of \$5.8 million and finance expense, net of \$3.7 million. Changes in net working capital included primarily a \$3.6 million increase in other receivables, decrease of \$2.2 million in payables and a decrease of \$3.5 million in accrued expenses and other long-term liabilities.

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

Investing Activities

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

During 2021, net cash provided by investing activities consisted of \$22.2 million and were from the proceeds from the disposal of our intangible assets for ebopiprant.

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

Financing Activities

Net cash from financing activities consists primarily of proceeds from the sale of equity securities, warrant exercises, and borrowings under our credit facilities.

Cash flows from financing activities in 2021 mainly consisted primarily of the net proceeds from our credit facility with JGB, the sales of treasury shares under our ATM program and exercise of warrants, which were partially offset by the principal elements of lease payments as well as interest expense associated with our leases and debt instruments.

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

Material Cash Requirements from Contractual Obligations

The following table summarizes the contractual maturity profile of our on-balance sheet liabilities, including interest payments, as of December 31, 2021:

	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	Total
(in thousands)					
Trade and other payables	(7,716)	-	-	-	(7,716)
Borrowings	(2,992)	(36,832)	-	-	(39,824)
Lease liabilities	(712)	(243)	-	-	(955)
Total as of December 31, 2021	(11,420)	(37,075)	-	-	(48,495)

Under our license agreements with Kissei and Merck Serono, we may be required to pay royalties in the future. In addition, pursuant to the Kissei license and supply agreement, we have agreed to make aggregate milestone payments of up to \$63.0 million upon the achievement of specified developmental milestones, such as the initiation of clinical trials and receipt of regulatory approvals, of which we had paid \$10.0 million as of December 31, 2021. With respect to any product we commercialize under the Kissei license and supply agreement, we have agreed to make additional aggregate milestone payments of up to \$125.0 million to Kissei upon the achievement of specified commercial milestones.

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

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

C. Research and Development

For a discussion of our research and development activities, see sections "Business Update" and "Operating Results."

D. Trend Information

For a discussion of trends, see sections "Operating Results" and "Liquidity and Capital Resources."

E. Critical Accounting Estimates

For a discussion of our critical accounting estimates, see note 2 "Accounting principles applied in the preparation of the consolidated financial statements - Critical accounting estimates and judgments" to our consolidated IFRS financial statements.

Corporate Governance

Corporate Governance

ObsEva's articles of association (the "Articles"), organizational regulations (the "Organizational Regulations") and policies provide the basis for the principles of Corporate Governance. This Corporate Governance report has been prepared in accordance with the SIX Swiss Exchange Directive on Information Related to Corporate Governance effective as of October 1, 2014, as amended on April 1, 2016, July 1, 2017, May 1, 2018, January 2, 2020, July 1, 2021 and October 1, 2021.

1 - Group Structure and Shareholders.

Group Structure

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

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

- ObsEva USA, Inc., a limited company registered in Delaware, USA, with principal registered offices located at One Financial Center, 24th Floor, Boston MA 02111, USA, and a share capital of USD 0.50 fully-owned by ObsEva, and
- ObsEva Ireland Ltd, a limited company registered in Ireland, with principal registered offices located at Penthouse Floor, 5 Lapps Quay, Cork, Ireland, and a share capital of EUR 2.00 fully-owned by ObsEva.
- ObsEva Europe B.V., a limited company registered in The Netherlands, with principal registered offices located at Apollolaan 151, 1077AR Amsterdam, and a share capital of EUR 1,000.00 fully-owned by ObsEva.

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

ObsEva's shares have been listed on the Nasdaq Global Select Market ("Nasdaq") since January 26, 2017 under the ticker symbol OBSV and the CUSIP number H5861P103, and on the SIX Swiss Exchange ("SIX") since July 13, 2018 under the ticker symbol OBSN, the ISIN number CH0346177709 and Swiss security number 34'617'770. On December 31, 2021, the market capitalization of ObsEva was USD 169,588,737 on the Nasdaq and CHF 157,657,871 on the SIX.

Significant Shareholders

As of December 31, 2021, based on published notifications to the SIX (unless otherwise indicated), the following shareholders own 3% or more of the Company's share capital:

Shareholder	Number of shares held ⁽¹⁾	% of voting rights (2)	% of capital
ObsEva	5,265,203	6.2%	6.2%
Sofinnova Investments (3)	4,749,623	5.6%	5.6%
New Enterprise Associates 15 L.P.	4,586,563	5.4%	5.4%
Ernest Loumaye	3,915,450	4.6%	4.6%

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

For a comprehensive list of notifications of shareholdings received during 2021 pursuant to article 120 and seq. FMIA and its implementing ordinances, refer to the SIX website (https://www.six-exchange-regulation.com/en/home/publications/significant-shareholders.html).

Cross Shareholdings

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

2 - Capital Structure.

Capital

As of December 31, 2021, the Company's share capital registered with the Swiss Commercial Register, which corresponded also to the issued share capital, amounted to CHF 6,555,420 and 11/13th of a franc, consisting of 85,220,471 registered shares (or "common shares") with a par value of 1/13th of a Swiss franc each. As of December 31, 2021, the Company directly held 5,348,049 of its own shares, recorded as treasury shares.

Authorized Share Capital

As of December 31, 2021, according to the Articles, the Board of Directors (the "Board") is authorized at any time until May 28, 2023 to increase the share capital by a maximum aggregate amount of CHF 3,123,864, which equates to approximately 47.65% of the existing issued share capital as at the reference date, through the issuance of not more than 40,610,232 common shares, which will have to be fully paid-in, with a par value of 1/13th of a Swiss franc each. Increases in partial amounts are permitted. The Board may issue new shares also by means of underwriting or in any other manner by one or more banks and subsequent offer to shareholders or third parties. The Board determines the type of contributions, the issue price, the time of the issue, the conditions for the exercise of the pre-emptive rights, the allocation of pre-emptive rights which have not been exercised, and the date on which the dividend entitlement starts. The Board is authorized to permit, to restrict or to exclude the trading of pre-emptive rights.

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

The Board is authorized to withdraw or limit the pre-emptive rights of the shareholders, and to allocate them to third parties or to the Company, in the event of use of the shares for the purpose of: (i) expanding the shareholder base in certain capital markets or in the context of the listing, admission to official trading or registration of the shares at domestic or international stock exchanges; (ii) granting an over-allotment option ("greenshoe") to one or several underwriters in connection with a placement of shares; (iii) share placements, provided the issue price is determined by reference to market price; (iv) the participation of employees,

⁽²⁾ Based on the share capital registered in the Swiss Commercial Register as of December 31, 2021 (i.e. CHF 6,555,420 and 11/13th of a franc, divided into 85,220,471 registered shares).

⁽³⁾ Beneficial owner of shares reported under Sofinnova Investments is Dr. James I. Healy.

members of the Board or consultant of the Company or of one of its subsidiaries according to one or several equity incentive plans adopted by the Board; (v) the acquisition of companies, company assets, participations, the acquisition of products, intellectual property rights, licenses or new investment projects or for public or private share placements for the financing and/or refinancing of such transactions; (vi) for raising equity capital in a fast and flexible manner as such transaction would be difficult to carry out, or could be carried out only at less favorable terms, without the exclusion of the pre-emptive rights of the existing shareholders; or (vii) the acquisition of a participation in the company by a strategic partner (including in the case of a public takeover offer).

Conditional Share Capital for Financing Purposes

As of December 31, 2021, according to the Articles, the Company's share capital may be increased by a maximum aggregate amount of CHF 1,757,855 and 9/13th of a franc, which equates to approximately 26.82% of the existing issued share capital as at the reference date, through the issuance of not more than 22,852,124 common shares, which will have to be fully paid-in, with a par value of 1/13th of a Swiss franc each, by the exercise of option and conversion rights which are granted in connection with bonds, similar debt instruments, loans or other financial market instruments or contractual obligations of the Company or one of its subsidiaries, and/or by the exercise of option rights issued by the Company or one of its subsidiaries (the "Financial Instruments"). The pre-emptive rights of shareholders are excluded. The right to subscribe for the new shares shall be held by the holders of the Financial Instruments. The Board determines the terms of the Financial Instruments.

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

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

Conditional Share Capital for Equity Plans

As of December 31, 2021, according to the Articles, the Company's share capital may be increased by a maximum aggregate amount of CHF 1,058,316, which equates to approximately 16.14% of the existing issued share capital as at the reference date, through the issuance of not more than 13,758,108 common shares, which will have to be fully paid-in, with a par value of 1/13th of a Swiss franc each, by issuance of shares upon the exercise of options or pre-emptive rights thereof, which have been issued or granted to employees, members of the Board or consultant of the Company or of one of its subsidiaries under the terms of one or more equity incentive plans or regulations adopted by the Board. The pre-emptive rights of shareholders are excluded. The Board determines the terms of the equity incentive plans or regulations and of the issuance of the shares.

Changes in Capital

On July 18, 2019, the Company issued 3,064,048 common shares at par value of 1/13th of a Swiss franc per share. The shares were fully subscribed for by the Group and held as treasury shares.

In 2019, the Company sold a total of 691,133 treasury shares at an average price of USD 5.14 per share.

In 2019, 26,420 options granted to employees under equity incentive plans of the Company have been exercised and 26,420 new shares have been issued from the conditional capital for equity plans at par value of 1/13th of a Swiss franc per share.

On April 14, 2020, the Company issued 3,308,396 common shares at par value of 1/13th of a Swiss franc per share. The shares were fully subscribed for by the Group and held as treasury shares.

On September 3, 2020, the Company completed an underwritten offering of 6,448,240 units at an effective price of USD 2.869 per unit, with each unit comprised of one common share (or pre-funded warrant) and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share. In this context, the Company issued, on September 7, 2020, 5,490,000 common shares for the purpose of the underwritten offering, together with 2,320,266 common shares, at par value, which were subscribed for by the Group and held as treasury shares.

In September 2020, the Company further completed a private placement of 516,352 units at an effective price of USD 2.905 per unit, with each unit comprised of one common share and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share. In this context, our board of directors decided, on September 18, 2020, to issue 516,352 common shares. The increase of our share capital was recorded with the Swiss Commercial Register, on September 29, 2020.

In November 2020, 958,240 pre-funded warrants issued in the context of the underwritten public offering of September 3, 2020, have been exercised and 958,240 new common shares have been issued from the conditional capital for financing purposes at a par value of CHF 1/13th of a Swiss franc per share.

In 2020, the Company sold a total of 5,995,897 treasury shares at an average price of USD 2.82 per share.

On January 27 and February 10, 2021, the Company issued 6,020,248 and 11,591,124 common shares, respectively, at par value of 1/13th of a Swiss franc per share. The shares were fully subscribed for by the Group and held as treasury shares.

In 2021, 6,448,240 warrants issued in the context of the underwritten public offering of September 3, 2020, have been exercised and 6,448,240 new common shares have been issued from the conditional capital for financing purposes at a par value of CHF 1/13th of a Swiss franc per share.

In 2021, the Company sold a total of 15,933,420 treasury shares at an average price of USD 3.28 per share.

For further information on changes in capital in 2021, 2020 and 2019, including changes in reserves, refer to the consolidated statements of changes in equity as well as to note 13 of the consolidated financial statements on pages 90 and 109, respectively, of this annual report.

Shares and Participation Certificates

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

The Company's shares are uncertificated securities (in terms of the Swiss Code of Obligations) and intermediated securities (in terms of the Swiss Federal Intermediated Securities Act). Any shareholder registered in the Company's share register may request from the Company a statement his/her common shares at any time. Shareholders are not entitled to request printing and delivery of certificates. However, the Company may, at any time and at its option: (i) print and deliver certificates for shares; (ii) withdraw uncertificated shares from the custodian system where they have been registered; and (iii) with the consent

of the shareholder, cancel issued certificates that are returned to the Company. If the Company decides to print and deliver share certificates, the share certificates shall bear the signatures of two duly authorized signatories of the Company, at least one of which shall be member of the Board. These signatures may be facsimile signatures.

The Company has no participation certificates.

Dividend-Right Certificates

The Company has no dividend-right certificates.

Limitations on Transferability and Nominee Registrations

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

Convertibles Bonds and Options

As of December 31, 2021, the Company has a convertible note outstanding which may be converted at a price of USD 3.20 per share, into up to 9,842,520 common shares with an aggregate par value of CHF 757,116 and 12/13th of a franc equating to approximatively 11.5% of the Company's share capital then registered with the Swiss Commercial Register, *i.e.* CHF 6,555,420 and 11/13 of a franc. The expiration date of the conversion period is set at October 11, 2024. For information on the convertible note outstanding as of December 31, 2021, refer to note 12 of the consolidated financial statements on page 107 of this annual report.

As of December 31, 2021, the Company has 8,937,473 options issued under the Company's equity incentive plans outstanding, corresponding to an amount of CHF 687,497 and 12/13th of a franc of share capital, and equating to approximately 10.49% of the existing issued share capital as at the reference date. Such options have a 1:1 subscription ratio, vest under a 3-year or 4-year vesting schedule, have a 10-year expiration term and have a strike price in U.S. Dollars equivalent to the closing share price of OBSV on Nasdaq at grant date. For information on the equity incentive plans operated by the Company and details of grants made and options outstanding as of December 31, 2021, refer to note 20 of the consolidated financial statements on page 115 of this annual report.

As of December 31, 2021, the Company has issued 1,634,877 warrants outstanding, each entitling, upon exercise, to one common share, at an exercise price of USD 3.67, corresponding to an aggregate amount of CHF 125,759 and 10/13th of a franc of share capital, and equating to approximatively 1.92% of the existing issued share capital. The expiration date of the warrants is set at October 11, 2025. For information on the warrants outstanding as of December 31, 2021, refer to note 13 of the consolidated financial statements on page 109 of this annual report.

Changes to the capital structure as from December 31, 2020

Share Capital

As of February 28, 2022, the Company's share capital registered with the Swiss Commercial Register, which corresponded also to the issued share capital, amounted to CHF 8,355,420 and 11/13th of a franc, consisting of 108,620,471 common shares with a par value of 1/13th of a Swiss franc each. As of February 28, 2022, the Company directly held 25,805,950 of its own shares, recorded as treasury shares.

Authorized Share Capital

As of February 28, 2022, according to the Articles, the Board is authorized at any time until May 28, 2023 to increase the share capital by a maximum aggregate amount of CHF 1,323,864, which equates to approximately 15.84% of the existing issued share capital as at the reference date, through the issuance of not more than 17,210,232 common shares, which will have to be fully paid-in, with a par value of 1/13th of a Swiss franc each.

Changes in Capital

Between January 1, 2022, and February 28, 2022, the Company issued 23,400,000 common shares at par value of 1/13th of a Swiss franc per share, out of the authorized share capital. The shares were fully subscribed for by the Group and held as treasury shares.

Convertible Bonds and Options

In January 2022, the Company issued a convertible note which may be converted at a price of USD 1.66 per share, into up to 6,325,301 common shares with an aggregate par value of CHF 486,561 and 8/13th of a franc, equating to approximatively 7.42% of the Company's share capital then registered with the Swiss Commercial Register, *i.e.* CHF 6,555,420 and 11/13 of a franc. The expiration date of the conversion period is set at January 27, 2025. The Company also issued 1,018,716 warrants which may be exercised at a price of USD 1.87 and entitle to one common share each. If fully exercised, such warrants entitle to common shares at an aggregate par value of CHF 78,362 and 10/13th of a franc which equates to approximatively 1.20% of the share capital then registered with the Swiss Commercial Register, *i.e.* CHF 6,555,420 and 11/13 of a franc. The expiration date of the exercise period is set at January 27, 2026.

3 - Board of Directors.

The following table sets forth the name, nationality, year joined the Board, terms of office, position and directorship term, as well as committee memberships, of each member of the Board, followed by a short description of each member's business experience, education and activities. The directors are appointed individually, for one-year terms, which expire on the occasion of each annual general meeting, and can be reelected indefinitely. Accordingly, the terms of the directors set forth below will expire at the closing of the 2022 annual general meeting of shareholders. All members of the Board are non-executive members. Dr. Ernest Loumaye, Co-Founder, has been CEO of the Company until December 2020, and Brian O'Callaghan has been CEO of the Company from that date. None of the other non-executive members have held management roles in the Group in the three financial years preceding the period under review, nor have had significant business connections with any entity of the Group.

Ms. Stephanie Brown has been nominated by our board of directors for election to the board of directors at our 2022 annual general meeting. Effective December 1, 2021, Ms. Brown joined the board of directors as an observer.

Name	Nationality	First Appointment	Board	AC (1)	CNCGC (2)
Frank Verwiel	Dutch	2016	Chair	Member	-
Ernest Loumaye	Belgian	2012	Member ⁽³⁾	-	-
Brian OʻCallaghan	American	2021	Member ⁽⁴⁾	-	-
Annette Clancy	British	2013	Member	-	Chair
Anne VanLent	American	2021	Member ⁽⁵⁾	Chair	-
Ed Mathers	American	2016	Member	Member	Member
Catarina Edfjäll	Swiss	2021	Member ⁽⁶⁾	-	Member
Jacky Vonderscher	French	2013	Member ⁽⁷⁾	-	-

⁽¹⁾ Audit Committee

⁽²⁾ Compensation, Nominating and Corporate Governance Committee

⁽³⁾ CEO until December 1, 2020

⁽⁴⁾ BOD member since May 28, 2021. CEO since December 1, 2020.

⁽⁵⁾ BOD member since May 28, 2021.

⁽⁶⁾ BOD member since May 28, 2021.

⁽⁷⁾ BOD member until November 19, 2021



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



Ernest Loumaye is a co-founder and member of our board of directors since its inception in November 2012. He served as our Chief Executive Officer since our inception until December 2020. From 2019 to January 2021, he was a member of the board of directors at AVA, a Zurich-based medtech company active in women's health. Previously, Dr. Loumaye co-founded PregLem, a Swiss specialty biopharmaceutical company sold to Gedeon Richter Plc., and served as its Chief Executive Officer and member of the board of directors from 2006 to October 2012. From 2011 to 2016, Dr. Loumaye served as chairperson and member of the board at Genkyotex, a public biopharmaceutical company developing treatments against various diseases based on enzyme inhibition. Dr. Loumaye holds an M.D. and a Ph.D. from University of Louvain, Belgium, with a specialization in Obstetrics and Gynecology. Dr Loumaye was research fellow at the National Institute of Health (NIH, Bethesda, MD, USA).



Brian O'Callaghan has served as a member of our board of directors since May 2021 and served as our Chief Executive Officer since December 2020 to lead the Company through its future development, regulatory filings and product launches. He is a life science executive with extensive experience within biotech, large pharmaceutical companies and the CRO sector, as well as extensive global experience, having lived and worked in 5 different countries and both coasts of the US. Prior to joining ObsEva, Mr. O'Callaghan has held CEO positions at Petra Pharma (from 2017 to 2020), Acucela (from 2013 to 2015), Sangart (from 2008 to 2014) and BioPartners (from 2000 to 2004), as well as senior management positions at Pfizer (from 1992 to 1994), Merck Serono (from 1996 to 2000), Novartis (from 2004 to 2006), Covance (from 2006 to 2007) and NPS Pharmaceuticals (from 2007 to 2008). Mr. O'Callaghan has experience running both public and private companies, M&A's, IPO's, fundraising, divestments, spin-outs and strategic alliances. He also has extensive Board experience, having served on numerous biotech and 501c3 Boards. In particular, he is currently a member of the Board of Directors of Indaptus Therapeutics, Bolt Biotherapeutics and The Biocom Purchasing Group, all of which are based in California.



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



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



Ed Mathers has served as a member of the Board since February 2016. Mr. Mathers is a General Partner of NEA since August 2008 and is focused on biotechnology and specialty pharmaceuticals investments. He is a director of Rhythm Pharmaceuticals (Nasdag: RYTM), Envisia Therapeutics, Synlogic (Nasdag: SYBX), Amplyx Pharmaceuticals, Senti Biosciences, Inozyme (Nasdaq: INZY), Reneo Pharma, Akouos (Nasdag: AKUS), Trevi Therapeutics (Nasdag:TRVI), Mirium Pharmaceuticals (Nasdag: MIRM), Shape Therapeutics, MBX Biosciences, and Affinia Therapeutics. Previously he was a board member of RA Pharmaceuticals (sold to UCB), Liquidia (Nasdag: LQDA), Lumos Pharma (Nasdaq: LUMO), Curzion Pharmaceuticals (sold to Horizon), Lumena (sold to Shire), Ziarco (sold to Novartis), Motus Therapeutics (sold to Allergan), Plexxikon (sold to Daiichi Sankyo), Intarcia, Satori Pharmaceuticals, Southeast Bio, MedImmune, LLC, the Biotechnology Industry Organization (BIO), and a number of public biopharmaceutical boards. Prior to joining NEA, Mr. Mathers most recently served as Executive Vice President, Corporate Development and Venture, at MedImmune, Inc. Before joining MedImmune in 2002, he was Vice President, Marketing and Corporate Licensing and Acquisitions at Inhale Therapeutic Systems. Mr. Mathers spent 15 years at Glaxo Wellcome, Inc. (GlaxoSmithKline), where he held sales and marketing positions of increasing responsibility. He earned his bachelor's degree in chemistry from North Carolina State University, Raleigh.



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

Catarina Edfjäll has served as a member of the Board since June

Jacky Vonderscher has served as a member of the Company's Board since October 2013 and until November 19, 2021, when he stepped down from his mandate. Since September 2013, Dr. Vonderscher has served as the Chief Executive Officer of Vonderscher & Co GmbH, a consultancy company. Dr. Vonderscher has also served as the Chief Executive Officer of ENYO Pharma SA, a biopharmaceutical company, since July 2016. Dr. Vonderscher serves as a member of the governing board of IMI (Innovative Medicines Initiative), a public-private partnership. He is also a member of the board of LyonBiopole, a business association and of several private companies. From January 2014 until June 2016, Dr. Vonderscher served as the President of ENYO Pharma SA. Prior to joining ENYO Pharma SA, Dr. Vonderscher served as a Senior Vice President of Hoffmann-La-Roche Ltd from 2008 to December 2013. From 1979 to 2008, Dr. Vonderscher held a variety of senior positions at Novartis Pharma AG. Dr. Vonderscher holds an engineering degree in Biological Chemistry from the National Institute of Applied Sciences (INSA), Lyon, France, and a Ph.D. in Biochemistry from the University of Geneva, Switzerland.

Restrictions on Mandates held outside the Company

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

Internal Organizational Structure

Responsibilities of the Board

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

- (i) the ultimate supervision of the Company and the issuing of all necessary directives;
- (ii) the establishment of the Company's organization, including the enactment and amendment of the Organizational Regulations;
- (iii) the structuring of the Company's accounting, financial control and financial planning systems, including the approval of the annual budget;
- (iv) the appointment and removal of the persons entrusted with the management and the representation of the Company, as well as the determination of their signatory authority
- (v) the ultimate supervision of the persons entrusted with the management of the Company, in particular with regard to compliance with the law, the articles of association and the Company's internal regulations and policies;
- (vi) the preparation of the annual report as well as the preparation of the general meeting of shareholders and the implementing of its resolutions;
- (vii) the notification of the court in the event that the Company is over indebted;
- (viii) the other powers and duties that Swiss law requires to be assumed or discharged by the Board; and
- (ix) the adoption of a code of business conduct and ethics for the Company.

Additionally, the Board keeps the power to resolve itself on the following duties:

- (i) approve any loans by the Company to executive officers (to the extent permitted by applicable law and the Articles) and loans by the Company to employees that are not executive officers, where the amount of any such loan exceeds \$10,000, such duty being also delegated to the compensation, nominating and corporate governance committee: and
- (ii) administer the Company's share and equity incentive plans, such duty being also delegated to the compensation, nominating and corporate governance committee and subject to further delegation to the executive committee under certain circumstances, as described in the Compensation Report on page 146 of this annual report.

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

Working method of the Board

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

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

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

The Board meets at least four times per year, on a quarterly basis, for regular face-to-face sessions, or on videoconference when circumstances such as the COVID-19 pandemic require it. In 2021, the Board held four regular meetings via videoconference, which lasted on average four hours, and eight ad-hoc meetings via videoconference, which lasted on average one hour. A vast majority of the Board Members were present at each Board meeting. Members of the Executive Committee are usually invited to attend the meetings of the Board but are required to leave them for the non-Executive session that concludes every meeting.

Committees of the Board of Directors

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

Audit Committee

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

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

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

The audit committee meets as often as it determines is appropriate to carry out its responsibilities, but in any event meets at least four times per year. In 2021, the audit committee held four meetings, which lasted on average one to two hours. A vast majority of the audit committee members were present at each audit committee meeting. The Company's auditors are invited and systematically attend the audit committee meetings. The Chief Financial Officer and other senior members of the financial team are invited to attend the

meetings of the audit committee too, but are required to leave them for the non-Executive session that concludes every meeting.

Compensation, Nominating and Corporate Governance Committee

The CNCG committee consists of three members: Annette Clancy, Catarina Edfjäll and Ed Mathers. The chair of the CNCG committee is Ms. Clancy. The primary purpose of the CNCG committee is to oversee the Company's compensation policies, plans and programs and to review and determine the compensation to be paid to the executive officers, directors and other senior management, as appropriate. The Company is subject to the Swiss Ordinance against excessive compensation in listed stock corporations, known as the "Minder" rules. As a result of the Minder rules, the members of the CNCG committee must be elected by the shareholders.

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

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

- (i) review and approve, or recommend that the Board approves the compensation of the executive officers based on the aggregate compensation approved by the shareholders;
- (ii) review and approve, or recommend that the Board approves the compensation of the members of the Board based on the aggregate compensation approved by the shareholders;
- (iii) review and approve, or recommend that the Board approves the terms of compensatory arrangements with the executive officers:
- (iv) administer the Company's share and equity incentive plans, subject to further delegation to the executive committee under certain circumstances, as described in the Compensation Report on page 156 of this annual report;
- (v) select independent compensation consultants and assess whether there are any conflicts of interest with any of the committees' compensation advisers;
- (vi) review and approve, or recommend that the Board approves incentive compensation and equity plans, and any other compensatory arrangements for the executive officers and other senior management, as appropriate;
- (vii) review and establish general policies relating to compensation and benefits of the employees and reviewing the Company's overall compensation philosophy;
- (viii) identify, evaluate and select, or recommend that the Board approves, nominees for election to the Board;
- (ix) evaluate the performance of the Board and of individual directors;
- (x) consider and make recommendations to the Board regarding the composition of its committees;
- (xi) review developments in corporate governance practices;
- (xii) evaluate the adequacy of the Company's corporate governance practices and reporting;
- (xiii) review management succession plans;
- (xiv) approve any loans by the company to executive officers (to the extent permitted by applicable law and the Articles) and loans by the company to employees that are not executive officers, where the amount of any such loan exceeds \$10,000;
- (xv) develop and make recommendations to the Board regarding corporate governance guidelines and matters; and
- (xvi) oversee periodic evaluations of the Board's performance.

The CNCG committee meets as often as it determines is appropriate to carry out its responsibilities. In 2021, the CNCG committee held three meetings, which lasted on average one hour. A vast majority of the CNCG committee members were present at each CNCG committee meeting. The Chief Executive Officer is invited to attend the meetings of the CNCG committee but is required to leave them for the non-Executive session that concludes every meeting.

Definition of Areas of Responsibility

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

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

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

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

4 - Executive Committee.

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

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

Name	Nationality	Function	Appointment	Term
Brian O'Callaghan	American	Chief Executive Officer	2020	-
Will Brown	American	Chief Financial Officer	2022(1)	-
Elizabeth Garner	American	Chief Medical Officer	2019	-
Katja Bührer	German	Chief Strategy Officer	2022(2)	-
Jean-Pierre Gotteland	French	Chief Scientific Officer and Head of R&D	2015	-
Clive Bertram	British	Chief Commercial Officer	2021(3)	-
Luigi Marro	Italian	Chief Transformation Officer	2021(4)	-
Fabien de Ladonchamps	French	Chief Administrative Officer	2020	-
Wim Souverijns	Belgian	Chief Commercial Officer (former)	2018	2021(5)
David Renas	American	Chief Financial Officer	2021	2022(6)

On January 1, 2022, Will Brown has been appointed as CFO, to succeed to David Renas.

⁽²⁾ On February 1, 2022, Katja Bührer has been appointed as CSO.

⁽³⁾ On May 6, 2021, Clive Bertram has been appointed as CCO, to succeed to Wim Souverijns.

⁽⁴⁾ On September 30, 2021, Luigi Marro has been appointed as Chief Transformation Officer.

⁽⁵⁾ CCO until May 6, 2021.

⁽⁶⁾ CFO until January 1, 2022.



Brian O'Callaghan has served as our Chief Executive Officer since December 2020 and member of the Board since May 2021. For further information on Mr. O'Callaghan biographic details refer to section 3 of this corporate governance report.



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



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



Katja Bührer has served as our Chief Strategy Officer since February 2022. Ms. Bührer is a corporate development executive whose background spans corporate strategy, investor relations advisory, financial journalism, and capital markets. Ms. Bührer was previously Vice President Corporate Development, Investor Relations, and Chief of Staff at Kindred Biosciences, a veterinary biopharmaceutical company, from July 2018 to August 2021. Ms. Bührer led various business initiatives at KindredBio, including business development and the M&A process that resulted in KindredBio's acquisition by Elanco Animal Health in August 2021. From August 2021 to December 2021, she became Chief Operating Officer of KindredBio, a subsidiary of Elanco, during the integration of KindredBio into Elanco. Prior to joining KindredBio, Ms. Bührer was Managing Director at MBS Value Partners from December 2011 to November 2017 and Managing Director at Advisory Growth Advisors from November 2017 to June 2018, both investor relations consultancies. Her experience is further informed by roles in financial journalism and banking, including as an Editor, Reporter, and Columnist at The Australian Financial Review and in Capital Markets and Trading at Citigroup. Ms. Bührer earned her Bachelor Commerce/Arts from the University of New South Wales, Australia.



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



Clive Bertram joined ObsEva with nearly 30 years of experience in commercialization, strategic, corporate and business development. in the pharmaceutical industry. Most recently, he served as CCO at Petra Pharma from 2019 to 2020 and Sangart from 2008 to 2013. Mr. Bertram also served as an independent consultant from 2014 to 2020 leading client thinking for strategic and marketing planning insight as well as launch excellence and implementation. Prior to his CCO roles, Mr. Bertram held senior management positions at Pharmion Limited from 2007 to 2008, Chiron Biopharmaceuticals from 2005 to 2006, Celltech from 2003 to 2004 and Eli Lilly from 1992 to 2003. He holds a BSc (Hons.) in Pharmacology and Chemistry from the University of Sheffield.



Luigi Marro has served as Chief Transformation Officer since October 2021. Mr. Marro is a pharmaceutical and biotech executive with over 20 years of experience. He has a background in finance, operations and has managed global businesses across multiple therapeutic areas from development stages through commercialization. Prior to joining ObsEva, Mr. Marro founded in February 2019 his own consulting company, Martan Market GmbH, to support biotech and pharma startups. From May 2014 to February 2019, he served as Chief Financial Officer at Finox Biotech, which launched the first biosimilar recombinant follicle stimulating hormone (r-FSH) product to market. From November 2012 to July 2013, Luigi held leadership positions at Voisin Life Sciences Consulting SA as Chief Operating Officer. He also acted as Senior Director Strategy Development and Business Performance at Merck Serono from January 2010 to October 2012. Mr. Marro also held elevating strategic roles at Serono, prior to its acquisition by Merck. Mr. Marro holds a university degree in Demographic and Economical Statistic Sciences from La Sapienza in Rome as well as a Master of Business Administration from Luiss Management school in Rome.



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

Wim Souverijns has served as Chief Commercial Officer since November 2018 and until May 2021. Prior to joining ObsEva, Dr. Souverijns spent 11 years, from 2007 to 2018, at Celgene where he contributed to the successful built out of Celgene's product portfolio in diverse strategic (European & Global Marketing), as well as operational (General Manager for the Nordics and the UK & Ireland) roles. He developed a broad pharmaceutical background through various international assignments at PwC Consulting, from 1999 to 2003. and in different market access leadership roles at Amgen, from 2003 to 2007, both in the European headquarter in Luzern, Switzerland, as well as at the global level out of Thousand Oaks, California. He started of his career working for CTG, from 1997 to 1999, an IT services company, in Brussels, Belgium. Dr. Souverijns studied as a bio-engineer at the KU Leuven, Belgium, and obtained a PhD from the same institute.

David Renas has served as Chief Financial Officer since January 2021 and until January 2022. Before joining ObsEva, Mr. Renas served as CFO at Petra Pharma Corporation (from 2017 to 2020) and Sangart, Inc (from 2002 to 2014). Prior to that, he practiced corporate and securities law at Gray Cary Ware & Freidenrich (now DLA Piper), Foley & Lardner and Adkins Black LLP. Earlier in his career he worked as a Certified Public Accountant at Deloitte. Mr. Renas holds a Bachelor of Arts in Economics from Stanford University and a Juris Doctorate from the University of California at Davis.

Restrictions on Mandates held outside the Company

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

Management Contracts

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

5 - Compensation, Shareholdings and Loans.

For a discussion on compensation and shareholdings of the members of the Board and of the Executive Committee, and loans granted to these individuals, refer to the Compensation Report section of this Annual Report on page 156.

6 - Shareholders' Participation Rights.

Voting Rights Restrictions and Representation

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

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

However, a qualified majority of at least two-thirds of the votes represented and the absolute majority of the nominal share capital is required by law or the Articles for resolution pertaining to: (i) changes to the business purpose; (ii) the creation of shares with privileged voting rights; (iii) restrictions on the transferability of registered shares; (iv) an increase of the authorized or conditional share capital; (v) an increase in the share capital by way of conversion of capital surplus, through contribution in kind, or for purposes of an acquisition of assets or the granting of special privileges; (vi) the withdrawing or limitation of pre-emptive rights of shareholders; (vii) a relocation of the registered office; (viii) the dissolution of the Company; (ix) an abrogation

or amendment of the Articles regarding the limitations of outside mandates for the Board members; or (x) the removal of a serving member of the Board. Furthermore, any decision related to a merger, demerger or conversion of the Company shall be taken in accordance with the Swiss Federal Act on Mergers, De-Mergers, Transformations and Transfers of Businesses.

Independent Proxy

Article 18 of the Articles provides the basis for election of the independent proxy. The general meeting of shareholders of May 28, 2021, elected Perréard de Boccard SA, a law firm located at Rue de la Coulouvrenière 29 in Geneva, Switzerland, as the independent proxy of shareholders of the Company.

Quorums Required by the Articles

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

Convocation of the General Meeting of Shareholders

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

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

Inclusion of Items in the Agenda

Shareholders representing at least 10% of the share capital or holding shares of a total par value of one million Swiss francs may require that items be included in the agenda of the meeting. Such request must be made in writing not less than sixty days ahead of the meeting and shall include a brief description of the items to be discussed and the proposals.

Entries in the Share Register

The Board determines the relevant deadlines for registration in the share register giving the right to attend and to vote at the general meetings of shareholders. Such deadlines are published by the Company in its annual report and are mentioned in the invitation to the general meeting of shareholders published in the Swiss Official Commercial Gazette. The registration deadline for the general meeting of shareholders of May 18, 2022 has been set as April 8, 2022 at 22:00 CET. The Company has not enacted any rules on the granting of exceptions in relation to these deadlines.

7 - Changes of Control and Defense Measures.

Duty to Make an Offer

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

Clauses of Changes of Control

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

- (i) 25% of the unvested portion of stock-options granted under the equity incentive plan dated 2017 to an employee that is not a member of the Executive Committee, or an aggregate 271,421 unvested stock-options as of December 31, 2021, shall vest immediately if, within three months before or 12 months following a change in control, (a) the employee is terminated without cause, or (b) the employee resigns for good reason; and
- (ii) all of the unvested portion of stock-options granted under the equity incentive plan dated 2017 to a member of the Executive Committee, or an aggregate of 4,179,019 unvested stock-options as of December 31, 2021, shall vest immediately if, within three months before or 12 months following a change in control, (a) the member of the Executive Committee is terminated without cause, or (b) the member of the Executive Committee resigns for good reason.

8 - Auditors.

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

The Articles provide the basis for election of the Company's auditors. The general meeting of shareholders of May 28, 2021, elected PricewaterhouseCoopers SA as the Company's Auditors and Independent Registered Public Accounting Firm for the fiscal year 2021. PricewaterhouseCoopers SA has served as auditor of the Company since 2013, and PricewaterhouseCoopers SA's lead auditor, Luc Schulthess, has been serving in this capacity since the business year 2020. The previous PricewaterhouseCoopers SA's lead auditor, Mike Foley was in charge up to business year 2019. The Company, through its audit committee, has not adopted a policy regarding the rotation of audit firms yet.

Auditing Fees

Auditing fees charged for 2021 by the auditor amounted to USD 473 thousands and consisted of fees billed for the annual audit of the Company's consolidated financial statements, and the statutory audit of the Company's consolidated and stand-alone financial statements. Audit Fees also include services that only the independent external auditor of the Company can reasonably provide, such as the review of documents filed with the U.S. stock exchange.

Additional Fees

Additional fees charged for 2021 by the auditor amounted to USD 1,047 thousands and consisted of fees billed for assurance and related services that are related to the performance of the audit or review of the financial statements or that are traditionally performed by the external auditor, and mainly include services such as comfort letters issued in connection with securities offerings, due diligence and agreed-upon or expanded audit procedures, as well as advisory services related to tax and commercial readiness matters.

Information Instruments Pertaining to the External Audit

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

9 - Information Policy.

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

10 - Window Periods.

The Company defines the principles related to its general window periods within its Amended and Restated Insider Trading and Window Period Policy (the "Policy"). The Policy provides for window periods during which directors, officers and other employees of the Company are generally prohibited from trading in the Company's securities ("closed window periods"), and other periods ("open window periods") during which such restricted insiders may engage in such transactions with the prior pre-clearance of the Company's Clearing Officer (as defined in the Policy) after confirmation of an open window period by the Clearing Committee (as defined in the Policy). Generally, directors, officers and other employees may buy or sell securities of the Company only during a window period that

- (i) opens after two full trading days have elapsed after the public dissemination of the Company's annual or quarterly financial results; and
- (ii) closes on the tenth trading day prior to the public dissemination of the Company's annual or quarterly financial results.

In addition to an earnings window period, the Company may close the trading window at any time and for any duration pending public release of material news, such as important clinical data or regulatory actions relating to the Company's clinical trials or product candidates. A director or employee who believes that special circumstances require him or her to trade outside a trading window period should consult with the Company's Clearing Officer. Permission to trade outside a trading window period is granted only where the circumstances are extenuating and there appears to be no significant risk that the trade may subsequently be questioned.

The Policy provides for exceptions to window periods and closure of trading windows for material news. According to the Policy, the following trades may occur without restriction to any particular period:

- (i) exercise by directors and employees of options and/or warrants granted for cash under the Company's equity incentive plans; and
- (ii) under certain conditions, purchases or sales of the Company's securities made pursuant to, and in compliance with, a written plan established by a director or employee that meets the requirements of Rule 10b5-1 under the Securities Exchange Act of 1934, as amended.

11 - Controls and Procedures.

Management's Annual Report on Internal Control over Financial Reporting

The Audit Committee oversees the Company's financial reporting process on behalf of the Board. The management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of such. Under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, management assessed the internal control over financial reporting and concluded that such was effective as of December 31, 2021.

Conduct of a Risk Assessment

The Company conducts risk management processes to identify and mitigate risks at an early stage. The responsibility for risk assessment and management is allocated to the Executive Committee and to other specialized corporate functions such as the finance and administrative functions of the Group. Financial risk management is described in more details in note 3 to the Consolidated IFRS Financial Statements for the year ended December 31, 2021.

Insider policy

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

Ethical business conduct

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

Consolidated IFRS Financial Statements

Consolidated IFRS Financial Statements for the year ended December 31, 2021

Consolidated Balance Sheets

			As of December 31,
	Notes	2021	2020
		(in USD '000)	(In USD '000)
ASSETS			
Current assets			
Cash and cash equivalents	4	54,734	31,183
Other receivables	5	3,560	397
Prepaid expenses	6	5,223	5,388
Total current assets		63,517	36,968
Non-current assets			
Right-of-use assets	9	625	1,425
Furniture, fixtures and equipment	7	58	151
Intangible assets	8	24,503	26,608
Other long-term assets	10	288	295
Total non-current assets		25,474	28,479
Total assets		88,991	65,447
LIABILITIES AND EQUITY			
Current liabilities			
Other payables and current liabilities	5	9,038	10,760
Accrued expenses	6	13,783	10,248
Current lease liabilities	9	686	696
Total current liabilities		23,507	21,704
Non-current liabilities			
Non-current lease liabilities	9	240	952
Non-current borrowings	12	25,733	25,300
Post-employment obligations	11	6,581	8,218
Other long-term liabilities	10	591	919
Total non-current liabilities		33,145	35,389
Shareholders' equity			
Share capital	13	6,489	4,574
Share premium	13	430,630	356,822
Reserves	13	32,195	26,353
Accumulated losses	13	(436,975)	(379,395)
Total shareholders' equity		32,339	8,354
Total liabilities and shareholders' equity		88,991	65,447

Consolidated Statements of Comprehensive Loss

Year ended December 3				
(in USD '000, except per share data)	Notes	2021	2020	2019
Operating income other than revenue	14	20,113	17	16
OPERATING EXPENSES				
Research and development expenses	15	(53,136)	(67,536)	(88,053)
General and administrative expenses	15	(21,491)	(12,182)	(19,058)
Total operating expenses		(74,627)	(79,718)	(107,111)
OPERATING LOSS		(54,514)	(79,701)	(107,095)
Finance income	17	600	648	854
Finance expense	17	(4,251)	(3,879)	(2,482)
NET LOSS BEFORE TAX		(58,165)	(82,932)	(108,723)
Income tax expense	18	(212)	(34)	(67)
NET LOSS FOR THE YEAR		(58,377)	(82,966)	(108,790)
Net loss per share				
Basic and diluted	19	(0.78)	(1.67)	(2.49)
OTHER COMPREHENSIVE INCOME / (LOSS)				
Items that will not be reclassified to profit and loss				
Remeasurements on post-employment benefit plans, net of tax		796	982	(4,694)
TOTAL OTHER COMPREHENSIVE INCOME / (LOSS)		796	982	(4,694)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		(57,581)	(81,984)	(113,484)

Consolidated Statements of Cash Flows

(in USD '000)	Notes	2021	2020	2019
(111 03D 000)	110163	2021	2020	2013

NET LOSS BEFORE TAX FOR THE YEAR		(58,165)	(82,932)	(108,723)
Adjustments for:				
Depreciation expense	7&9	736	721	737
Post-employment (benefit) cost		(553)	492	(477)
Share-based compensation expense	20	5,843	6,506	11,884
Income tax paid		_	(52)	(80)
Other operating income	14	(20,095)	_	_
Finance expense, net		3,651	3,231	1,628
Changes in operating assets and liabilities:				
Other receivables	5	(3,198)	326	193
Prepaid expenses, deferred costs and other long-term assets		166	(1,029)	1,356
Other payables and current liabilities		(2,223)	2,141	5,499
Accrued expenses and other long-term liabilities		3,534	(170)	(2,628)
NET CASH FLOWS USED IN OPERATING ACTIVITIES		(70,304)	(70,766)	(90,611)
Net proceeds from disposal of intangible assets	8	22,200	_	
Payments for plant and equipment	7	(14)	(5)	(46)
Acquisition of a license	8	_	_	(5,000)
NET CASH FLOWS FROM (USED IN) INVESTING ACTIVITIES		22,186	(5)	(5,046)
Proceeds from issuance of shares	13	53,226	37,254	3,206
Proceeds from the exercise of warrants	13	22,117	_	_
Oxford loan repayment	12	(26,986)	_	_
Proceeds from issuance of convertible debt	12	27,354	_	_
Proceeds from issuance of warrants	13	2,646	_	_
Issuance costs related to convertible debt and warrant	13	(2,128)	_	_
Proceeds from exercise of stock-options	13	_	_	193
Share issuance costs	13	(1,959)	_	_
Principal elements of lease payments	9	(682)	(630)	(571)
Interest paid		(2,484)	(2,321)	(818)
NET CASH FLOWS FROM FINANCING ACTIVITIES		(71,104)	32,249	26,627
Net (decrease) / increase in cash and cash equivalents	3.2	22,986	(38,522)	(69,030)
Cash and cash equivalents as of January 1,		31,183	69,370	138,640
Effects of exchange rate changes on cash and cash equivalents		565	335	(240)
Cash and cash equivalents as of December 31,	4	54,734	31,183	69,370

Consolidated Statements of Changes in Equity

	Notes	Share capital	Share premium	Share- based payments reserve	Foreign currency translation reserve	Total reserves	Accumulated losses	Total
(All in USD '000)								
December 31, 2018		3,420	314,565	13,347	(489)	12,858	(183,927)	146,916
Loss for the year		-	-	-	-	-	(108,790)	(108,790)
Other comprehensive loss		-	-	-	-	-	(4,694)	(4,694)
Total comprehensive loss		-	-	-	-	-	(113,484)	(113,484)
Issuance of shares - EIP 2013	13	21	2,696	(2,696)	-	(2,696)	-	21
Issuance of shares - ATM program	13	56	3,498	-	-	-	-	3,554
Share issuance costs		-	(130)	-	-	-	-	(130)
Exercise of stock-options - EIP 2017	20	2	326	(134)	-	(134)	-	194
Share-based remuneration	20	-	-	11,884	=	11,884	-	11,884
December 31, 2019		3,499	320,955	22,401	(489)	21,912	(297,411)	48,955
Loss for the year		-	-	-	-	-	(82,966)	(82,966)
Other comprehensive loss		-	-	-	-	-	982	982
Total comprehensive loss		-	-	-	-	-	(81,984)	(81,984)
Issuance of shares - EIP 2013	13	15	2,065	(2,065)	-	(2,065)	-	15
Issuance of shares - Underwritten offering	13	591	19,408	-	-	-	-	19,999
Issuance of shares - ATM program	13	469	16,437	-	-	-	-	16,906
Share issuance costs		-	(2,043)	-	-	-	-	(2,043)
Share-based remuneration	20	-	-	6,506	-	6,506	-	6,506
December 31, 2020		4,574	356,822	26,842	(489)	26,353	(379,395)	8,354
Loss for the year		-	-	-	-	-	(58,377)	(58,377)
Other comprehensive income		-	-	-	-	-	796	796
Total comprehensive loss		-	-	-	-	-	(57,581)	(57,581)
Issuance of shares - ATM program	13	1,360	52,327	-	-	-	-	53,687
Share issuance costs - ATM program		-	(1,959)	-	-	-	-	(1,959)
Value of the conversion rights - convertible notes		-	22	-	-	-	-	22
Reclassification of Warrants		-	1,856	-	-	-	-	1,856
Exercise of warrants	13	555	21,562	-	-	-	-	22,117
Share-based remuneration	20	-	-	5,843	-	5,843	-	5,843
December 31, 2021		6,489	430,630	32,685	(489)	32,196	(436,976)	32,339

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 to improve women's reproductive health and pregnancy. The Group has a portfolio of two mid- to late-stage development in-licensed compounds (linzagolix, and nolasiban) and one out-licensed mid- to late-stage development product (ebopiprant). The Group has no currently marketed products.

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

These consolidated financial statements were authorized for issue by the Company's Board of Directors (the "Board of Directors") on March 7, 2022.

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

2.1 Basis of preparation

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

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

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

2.2 Scope of consolidation

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

The Company currently consolidates the financial operations of its three fully-owned subsidiaries, ObsEva Ireland Ltd, which is registered in Cork, Ireland and organized under the laws of Ireland, ObsEva USA Inc., which is registered and organized under the laws of Delaware, USA, and ObsEva Europe B.V., which is registered in Rotterdam, The Netherlands, and organized under the laws of The Netherlands. Both ObsEva Ireland Ltd and ObsEva Europe B.V. had no operations and no results of operations to report as of December 31, 2021 and 2020.

2.3 Standards and interpretations published by the IASB

The IASB and the International Financing Reporting Standards Interpretations Committee have recently issued new standards and interpretations to be applied to the Group's consolidated financial statements. None of these new standards and amendments applied by the Group in 2021 had a material impact on its consolidated

financial statements. On January 23, 2020, the IASB issued Classification of Liabilities as Current or Non-Currents (Amendments to IAS 1) providing a more general approach to the classification of liabilities under IAS 1 Presentation of Financial Statements. The amendment could have a material impact on the current vs. non-current classification of outstanding convertible notes and is effective for annual reporting periods beginning on or after 1 January 2023. Other than the aforementioned, there are no new standards and amendments published but not yet effective that are expected to have a material impact on the consolidated financial statements of the Group.

2.4 Significant accounting policies

Cash and cash equivalents

Cash and cash equivalents includes cash on hand, an account control agreement in favor of JGB Management, Inc. ("JGB") consisting of USD 25 million (Note 12), deposits held at call with financial institutions, other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities in the balance sheet.

Current assets

Other receivables and prepaid expenses are carried at their nominal value.

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

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

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

Furniture, fixtures and equipment

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

furniturehardwareyearsyears

- leasehold improvement duration of lease

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

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

Leases

On January 1, 2019, the Group adopted IFRS 16 *Leases*, which replaced IAS 17 *Leases and Related Interpretations*, applied by the Group until December 31, 2018. The Group leases various office buildings and equipment, which are recognized as a right-of-use asset and a corresponding liability at the date at which the leased asset is available for use by the Group. Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable,
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as
 of the commencement date,
- amounts expected to be payable by the Group under residual value guarantees,

- the exercise price of a purchase option if the Group is reasonably certain to exercise that option,
- lease payments to be made under reasonably certain extension options, and
- payments of penalties for terminating the lease, if the lease term reflects the Group exercising that option.

The lease payments are discounted using the interest rate implicit in the lease. If that rate cannot be readily determined, which is generally the case for leases in the Group, the lessee's incremental borrowing rate is used, being the rate that the individual lessee would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security and conditions.

Lease payments are allocated between principal and finance cost. The finance cost is charged to profit or loss over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability,
- any lease payments made at or before the commencement date less any lease incentives received,
- any initial direct costs, and
- restoration costs.

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on a straight-line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life. Payments associated with short-term leases of equipment and vehicles and all leases of low-value assets are recognized on a straight-line basis as an expense in profit or loss. Short-term leases are leases with a lease term of 12 months or less. Low-value assets comprise small items of office furniture and equipment.

Intangible assets

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

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

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

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

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

Post-employment benefits

Group companies operate two pension schemes.

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

high-quality corporate bonds that are denominated in the currency in which the benefits will be paid, and that have terms to maturity approximating to the terms of the related pension obligation.

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

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

Borrowings

Borrowings are initially recognized at fair value, net of transaction costs incurred. Borrowings are subsequently measured at amortized cost. Any difference between the proceeds (net of transaction costs) and the redemption amount is recognized in profit or loss over the period of the borrowings using the effective interest method. Borrowings that are due within 12 months after the end of the reporting period are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability until more than 12 months after the reporting period. The company recognizes debt extinguishment in finance income (expense) as the difference between the extinguishment payment and the carrying value of the loan.

Equity

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

Shares held by the Group are disclosed as treasury shares and deducted from equity.

Research and development

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

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

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

Foreign currencies

Functional and presentation currency

Items included in the consolidated financial statements of the Group are measured using the currency of the primary economic environment in which each Group's entity operates (the "functional currencies"). The functional and presentation currencies of the Company is the US dollar (USD), which is also the functional currency of ObsEva USA Inc.

Transactions and balances

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

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

Share-based compensation

The Group operates two equity incentive plans.

A share-based, equity-settled, plan was formally set-up by the Group in 2013 (the "2013 EIP"). Participants eligible for awards under the 2013 EIP are executives, directors, employees, agents and consultants. The fair value of the shares granted under the 2013 EIP is determined at each grant date by using either an option pricing method that uses a Black-Scholes model or a hybrid method, as appropriate, both based on a combination of the discounted cash flow method, under the income approach, and the back solve method. The Group has stopped granting equity instruments under the 2013 EIP in 2016, resulting in the 2013 EIP being fully vested as of December 31, 2020.

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

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

Warrants

Warrants are recognized following IFRS 9 Financial Instruments guidance. Those financial instruments can be recognized as a liability at initial measurement depending on contract terms. When it is determined that the terms requiring liability classification expire, then the classification of the warrants change from liabilities to equity. There is also a remeasurement of the fair value of the warrants, with the change being recorded through the consolidated statements of comprehensive loss.

Deferred income taxes

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

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

Segment information

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

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

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

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

		As of December 31,
	202	1 2020
(in USD '000)		
Switzerland	25,38	27,936
USA	89	543
Total non-current assets	25,474	28,479

The geographical analysis of operating expenses is as follows:

		Year e	Year ended December 31,	
	2021	2020	2019	
(in USD '000)				
		ı		
Switzerland	68,977	77,476	102,492	
USA	5,650	2,242	4,619	
Total operating expenses	74,627	79,718	107,111	

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 may not necessarily equal the related actual outcome. The following areas involve a higher degree of judgement or complexity or are areas where assumptions and estimates can have a significant impact on the consolidated financial statements:

- Post-employment obligations: the actuarial valuation involves making assumptions about discount rates, future salary increases, mortality rates and future pension increases. Due to the long-term nature of these plans, such estimates are subject to significant uncertainty (note 11);
- Leases: the calculation of right of use assets and lease liabilities involves making assumptions
 about lessee's incremental borrowing rate and renewal options, which are subject to judgment
 (note 9);

- **Share-based compensation:** the determination of the fair value of the equity instruments granted involves the use of certain assumptions subject to judgement (note 20);
- Warrants: the determination of the fair value of the equity instruments issued involves the use of certain assumptions subject to judgement (note 12);
- Commencement of depreciation and amortization: the depreciation and amortization starts
 when the assets are available for use in the manner intended by management, which requires
 judgement (notes 7 and 8);
- Research and development costs: the Group recognizes expenditure incurred in carrying out its
 research and development activities until it becomes probable that future economic benefits will
 flow to the Group, which results in recognizing such costs as intangible assets, involving a certain
 degree of judgement (note 15);
- Deferred taxes: the recognition of deferred tax assets requires assessment of whether it is
 probable that sufficient future taxable profit will be available against which the deferred tax assets
 can be utilized (note 18);
- Impairment of assets: as part of impairment tests, the recoverable amounts of tested assets have been determined based on fair value calculations requiring the use of certain assumptions, subject to judgement (note 8);
- Going concern: significant judgement is involved when assessing whether financial statements are to be prepared on a going concern basis or whether there is substantial doubt about the Group's ability to continue as a going concern (note 23).

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

3. Financial risk management

3.1 Financial risk factors

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

Foreign exchange risk

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

The sensitivity of profit or loss to changes in the exchange rates arises mainly from CHF- and EUR-denominated financial instruments held at the end of the reported periods.

CHF positions	Increase /decrease exchange rate vs USD	Effect on profit before tax	Effect on share- holders' equity
		(in USD '000)	(in USD ,000)
2021	+5%	(498)	(498)
	-5%	498	498
2020	+5%	(688)	(688)
	-5%	688	688

EUR positions	Increase /decrease exchange rate vs USD	Effect on profit before tax	Effect on share- holders' equity
		(in USD '000)	(in USD ,000)
2021	+5%	83	83
	-5%	(83)	(83)
2020	+5%	26	26
	-5%	(26)	(26)

Credit risk

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

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

Interest rate risk

Interest rate risks arise from changes in interest rates that may have a negative impact on the Group's financial position and results. Fluctuations in interest rates lead to changes in interest expense on floating-rate liabilities and thus affect the financial result. The financial liabilities subject to interest rate risk are exclusively floating-rate debt instruments denominated in USD, carried at amortized cost. The Group does not hold hedging instruments to manage the interest rate risk. As of December 31, 2021, there are no floating-rate debt instruments.

The below table shows sensitivity to changes in market interest rates for the Group's debt instruments.

	Impact on loss before taxes		
(in USD '000)	2021	2020	
Interest rates - increase by 100 basis points	_	(14)	
Interest rates - decrease by 100 basis points	_	_	

3.2 Capital and liquidity management

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

The Group's objectives when managing capital are to safeguard the Group's ability to continue as a going concern (see Note 23) in order to ensure the financing of successful research and development activities so that future profits can be generated and to maintain sufficient financial resources to mitigate against risks and unforeseen events.

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

A reconciliation of the net debt position is shown in the table below.

(in USD '000)	Borrowings	Lease liabilities	Total liabilities from financing activities	Cash and cash equivalents	Total
Net debt as of December 31, 2019	(25,104)	(2,159)	(27,263)	69,370	42,107
Cash flows	2,206	722	2,928	(38,522)	(35,594)
Interest expense	(2,589)	(92)	(2,681)	-	(2,681)
Foreign exchange adjustments	-	(119)	(119)	335	216
Net debt as of December 31, 2020	(25,487)	(1,648)	(27,135)	31,183	4,048
Cash flows	2,728	744	3,472	22,986	26,458
Interest expense	(2,974)	(61)	(3,035)	-	(3,035)
Foreign exchange adjustments	-	39	39	565	604
Net debt as of December 31, 2021	(25,733)	(926)	(26,659)	54,734	28,075

In addition, the maturity profile of the Group's financial liabilities is presented in the table below.

(in USD '000)	Carrying amount	Total undiscounted cash flows	up to 1 year	1 to 5 years	Maturities more than 5 years
Trade and other payables	(7,716)	(7,716)	(7,716)	_	_
Borrowings	(25,733)	(39,824)	(2,992)	(36,832)	_
Lease liabilities	(926)	(955)	(712)	(243)	_
Total as of December 31, 2021	(34,375)	(48,495)	(11,420)	(37,075)	_

(in USD '000)	Carrying amount	Total undiscounted cash flows	up to 1 year	1 to 5 years	Maturities more than 5 years
Trade and other payables	(9,450)	(9,450)	(9,450)	_	_
Borrowings	(25,487)	(32,646)	(2,200)	(30,446)	_
Lease liabilities	(1,648)	(1,738)	(758)	(980)	_
Total as of December 31, 2020	(36,585)	(43,834)	(12,408)	(31,426)	_

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 (USD 54.7 million) and other receivables (USD 3.6 million) which are classified as financial assets at amortized cost according to IFRS 9. The Group's financial liabilities consist of debt instruments, other payables and accruals which are classified as liabilities at amortized cost according to IFRS 9.

4. Cash and cash equivalents

4. Cash and cash equivalents		
	As	s of December 31,
	2021	2020
(in USD '000)		
Bank deposits	54,734	31,183
Interest bearing deposits	_	_
Total cash and cash equivalents	54,734	31,183
Split by currency:	2021	2020
CHF	1%	2%
USD	96%	87%
EUR	1%	11%
GBP	1%	0%

5. Receivables and payables

As of December 31, 2021 and 2020, other receivables consist mainly of reimbursements to be received from third parties, including VAT, insurance premiums and shared-costs of research and development studies, and other payables and other current liabilities include mainly costs of clinical services. All receivables and payables are due from and to third parties and carried at amortized cost. Subsequent to year end, the Group collected USD 2.9 million of other receivables representing a refund from the U.S. Federal Drug Administration.

All payables have a contract maturity within one year.

6. Prepaid and accrued expenses

As of December 31, 2021 and 2020, prepaid expenses mainly consist of advance or milestone payments made as part of our ongoing clinical trials.

As of December 31, 2021 and 2020, accrued expenses consisted of the following:

	As of Dec	ember 31,
	2021	2020
(in USD '000)		
Accrued research and development expenses	10,123	7,662
Accrued compensation-related expenses	3,125	2,334
Accrued other expenses	535	252
Total accrued expenses	13,783	10,248

7. Furniture, fixtures and equipment

	2021	2020
(in USD '000)		
Net book value as of January 1	151	245
Additions	29	10
Depreciation charge	(13)	(104)
Disposals	(109)	_
Net book value as of December 31	58	151
Total cost	430	652
Accumulated depreciation	(372)	(501)

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

8. Intangible assets

	2021	2020
(in USD '000)		
Net book value as of January 1	26,608	26,608
Additions	_	_
Disposals	(2,105)	_
Amortization charge	_	_
Currency translation effects	_	_
Net book value as of December 31	24,503	26,608
Total cost	24,503	26,608
Accumulated amortization	_	_

As of December 31, 2021, the Group holds a number of licenses to operate several biopharmaceutical product candidates, the value of which is recorded at USD 24.5 million.

In July 2021, the Company entered into an agreement with Organon & Co. ("Organon") to develop and commercialize ebopiprant. Under the terms of the agreement, Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. In consideration for entering into this agreement, the Company is entitled to receive tiered double-digit royalties on commercial sales as well as up to USD 500 million in upfront and milestone payments including USD 25 million that was paid at signing, up to USD 90 million in development and regulatory milestones and up to USD 385 million sales-based milestones. This transaction resulted in the derecognition of the license to develop and commercialize ebopiprant, initially recognized for USD 2.1 million as an intangible asset.

Merck Serono licenses

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

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

Kissei license

On November 19, 2015, the Group entered into an exclusive in-license and supply agreement with Kissei Pharmaceutical Co., Ltd. ("Kissei") to acquire the product candidate linzagolix (formerly OBE2109) for which Kissei successfully completed a Phase 2 trial in Japan. This in-license agreement grants the Group an exclusive license to use, develop and commercialize the product candidate worldwide excluding certain Asian countries. This in-license was acquired for an upfront cash consideration of USD 10 million, with additional contingent payments upon occurrence of certain milestones (note 21).

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

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

In October 2021, the Group amended the exclusive in-license and supply agreement with Kissei such that first commercial sales milestones for the EU and the US will now be extended over a 5-year period. In addition, North American royalty payments were lowered to tiered single digit royalties on net sales plus a supply price for the active pharmaceutical ingredient.

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

Amortization and impairment

The Group's intangible assets are subject to a multi-phase clinical trials process and the licenses are currently not amortized as no regulatory and marketing approvals were obtained as of December 31, 2021.

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

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

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

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

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

The Group has also collectively reviewed its licenses for impairment on the basis of the market capitalization for the entire Group as of December 31, 2021 less the value of its tangible assets as well as cash and cash equivalents. This analysis resulted in a headroom exceeding USD 79 million. The valuation is considered to be Level 3 in the fair value hierarchy and further supported the Group's conclusion that no impairment was identified as of December 31, 2021 and 2020.

9. Leases

The consolidated financial statements show the following amounts relating to leases:

Right-of-use assets

in USD '000	2021	2020
Net book value as of January 1	1,425	2,042
Depreciation charge	(500)	(617)
Derecognition of RoU asset	(300)	_
Net book value as of December 31	625	1,425
Total cost	1,876	2,658
Accumulated depreciation	(1,251)	(1,233)

Rights-of-use assets mainly relate to office buildings.

On June 1, 2021, ObsEva USA Inc. signed a sublease agreement to sublease office spaces located at One Financial Center in Boston, Massachusetts. This sublease covers a period from June 1, 2021 until September 30, 2022. This resulted in the derecognition of the right-of-use asset of USD 0.3 million. The initial net investment of this leasing amounted to USD 0.2 million of which USD 0.1 million was received in 2021.

The expense relating to other short-term or low-value leases is not material. For the years ended December 31, 2021 and 2020, the total cash outflows for leases amounted to USD 0.7 million and USD 0.7 million, respectively.

Lease liabilities

	As	of December 31,
(in USD '000)	2021	2020
Current	686	696
Non-current	240	952
Total lease liabilities	926	1,648

The lease liabilities have been measured based on the Group's weighted average incremental borrowing rate of 4.9%. The maturity of the lease liabilities is provided in note 3.2.

10. Other long-term assets and liabilities

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

The Group's other long-term liabilities consist of a tax provision which amounts to USD 0.6 million (2020 : USD 0.9 million).

11. Post-employment benefits

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

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

In 2021, the conversion rate for retirees changed to 6.2% (2020: 6.5%) which has been considered as a plan amendment.

	2	021	2020
(in USD '000)			
Change in defined benefit obligation			
Defined benefit obligation at January 1,	(23,7	248)	(24,705)
Current service cost	(1,	701)	(1,864)
Interest cost		(22)	(46)
Net benefits paid		914	4,643
Currency translation effects		805	(2,208)
Remeasurements:			
Impact of plan amendment		864	_
Effect of changes in demographic assumptions		_	510
Effect of changes in financial assumptions		991	(418)
Effect in experience assumptions	()	246)	840
Defined benefit obligation at December 31,	(21,0	543)	(23,248)

	2021	2020
(in USD '000)		
Change in plan assets		
Fair value of plan assets at January 1,	15,030	16,759
Interest income	15	31
Employer contributions	699	703
Employee contributions	699	703
Net benefits paid	(914)	(4,643)
Currency translation effects	(517)	1,427
Remeasurements: return on plan assets (excluding interest income)	51	50
Fair value of plan assets at December 31,	15,063	15,030

	Year end 2021	ed December 31
(in USD '000)	2021	2020
Components of defined benefit cost		
Current service cost	1,701	1,86
Interest expense on defined benefit obligation	22	4
Interest income on plan assets	(15)	(3
Employee contributions	(699)	(703
Impact of plan amendment	(864)	,
Total included in staff costs (note 16)	145	1,12
		ded December 31
(i LICD (000)	2021	2020
(in USD '000) Remeasurements recognized in other comprehensive loss		
Effect of changes in demographic assumptions	_	510
Effect of changes in financial assumptions	991	(418)
Effect in experience assumptions	(246)	840
Return on plan assets (excluding interest income)	51	5(
Total remeasurements recognized as other comprehensive loss	796	982
Cumulative amount of remeasurements immediately recognized	(7,041)	(7,837)
in other comprehensive loss	(1,011)	(1,031)
in other comprehensive loss	A	s of December 31
		s of December 31
(in USD '000)	A	s of December 31
(in USD '000) Amounts recognized in the statement of financial position	A	s of December 31
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation	A 2021	s of December 31 2020 (23,248)
(in USD '000)	A 2021 (21,643)	s of December 31 2020
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets	(21,643) 15,063 (6,580)	(23,248) (8,218)
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets Net liability	(21,643) 15,063 (6,580)	s of December 31 2020 (23,248) 15,030
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets Net liability (in USD '000)	(21,643) 15,063 (6,580)	(23,248) 15,030 (8,218)
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets Net liability (in USD '000) Change in defined benefit liability	(21,643) 15,063 (6,580) Year en	(23,248 15,030 (8,218 ded December 31
in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets Net liability in USD '000) Change in defined benefit liability Net defined benefit liability at January 1,	(21,643) 15,063 (6,580) Year en 2021	(23,248 15,030 (8,218 ded December 31 2020
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets Net liability (in USD '000) Change in defined benefit liability Net defined benefit liability at January 1, Defined benefit cost included in statement of comprehensive loss	(21,643) 15,063 (6,580) Year en	(23,248 15,030 (8,218 ded December 31 2020 (7,946 (1,176
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets Net liability (in USD '000) Change in defined benefit liability Net defined benefit liability at January 1, Defined benefit cost included in statement of comprehensive loss Total remeasurements included in other comprehensive loss	(21,643) 15,063 (6,580) Year en 2021	(23,248) 15,030 (8,218)
(in USD '000) Amounts recognized in the statement of financial position Defined benefit obligation Fair value of plan assets Net liability (in USD '000) Change in defined benefit liability Net defined benefit liability at January 1, Defined benefit cost included in statement of comprehensive loss	(21,643) 15,063 (6,580) Year en 2021 (8,218) (145) 796	(23,248 15,030 (8,218 ded December 31 2020 (7,946 (1,176

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

The principal actuarial assumptions used were as follows:

	2021	2020
Discount rate	0.35%	0.10%
Salary increase (including inflation)	1.00%	1.00%
Rate of pension increases	0.25%	0.25%
Post-employment mortality table	LPP 2020 G	LPP 2020 G

Sensitivity analysis illustrates the sensitivity of the Group defined benefit obligation at December 31, 2021 by varying the discount rate and the salary increase rate by plus / minus 50 basis points:

	Discount rate	Discount rate	Salary increase	Salary increase	Rate of pension increase	Rate of pension increase
(in USD '000)						
	plus	minus	plus	minus	plus	minus
Sensitivity analysis	50bps	50bps	50bps	50bps	25bps	25bps
Discount rate	0.85%	(0.15)%	0.35%	0.35%	0.35%	0.35%
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	(19,850)	(23,704)	(21,696)	(21,592)	(22,173)	(21,141)
Average duration of the defined benefit obligation					2021	2020
Duration in years					17.8	18.7

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

Expected contributions by the employer to be paid to the post-employment benefit plans during the annual period beginning after the end of the reporting period amount to approximately USD 0.7 million.

12. Borrowings

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

In October, 2021, the Company entered into a convertible note financing agreement (the "Securities Purchase Agreement") with certain funds and accounts managed by JGB, which is structured to provide up to USD 135 million in borrowing capacity, available in nine tranches. In connection with the first tranche which included a borrowing amount of USD 31.5 million (offer issue discount of USD 1.5 million), the Company received gross proceeds of USD 30.0 million at closing and used the proceeds to repay all amounts outstanding under the Company's existing Oxford Credit Facility. Upon payoff, the Oxford Credit Facility was terminated and the security interests in the Company's assets that secured the Oxford Credit Facility were released. At the time of the payoff, the carrying amount of the Oxford Credit Facility was USD 25.6 million and the actual payoff amount was USD27.0 million. The difference between the carrying amount and the payoff amount was USD 1.4 million and was recorded in finance expense on the Company's consolidated statement of comprehensive loss for the year ended December 31, 2021. The Company will issue senior secured convertible promissory notes (each, a "Note") for the debt funded at each tranche. Holders may convert all principal and interest under the Securities Purchase Agreement at any time into the Company's common shares at an initial conversion price of \$3.20 per share (the "Conversion Price"). The Conversion Price is subject to adjustment under certain circumstances in accordance with the terms of the Note Agreement. As of February 28, 2022, the Company is able to potentially receive gross proceeds of USD 16.725 million from the third tranche and USD 13.125 million from each remaining tranche thereafter.

The credit facility is presented in the balance sheet as follows:

(in USD '000)	2021	2020
Borrowings as of January 1	25,487	25,104
Issuance of JGB convertible note	27,333	_
Transaction costs	(1,954)	_
Oxford Loan payoff	(25,623)	_
Interest expense	2,974	2,589
Interest paid	(2,484)	(2,206)
Borrowings as of December 31,	25,733	25,487
Of which are:		
Current	_	187
Non-current	25,733	25,300

The Securities Purchase Agreement is secured by an account control agreement in favor of JGB, and the Company is obligated to maintain a minimum cash amount of USD 25 million in such deposit account, subject to additional incremental increases totaling USD 27.0 million in aggregate depending on the amount of debt outstanding under the Securities Purchase Agreement. Each tranche under the Securities Purchase Agreement will bear interest at a rate of 9.5% per year, payable monthly, and will be issued with an original issue discount of 4.75%. Each tranche under the Securities Purchase Agreement will mature three years from the date of issuance, unless earlier converted or prepaid in accordance with their terms. After payments and deductions for certain transaction costs and offer issue discounts, the effective rate of the Securities Purchase Agreement is 16.2%. At each tranche, the Company will also issue to JGB warrants to purchase common shares of the Company (each, a "Warrant") in an amount equal to 20% of the funded amount for such tranche. The Warrants will be exercisable at a price of \$3.67 per share and will have a four year term from the date of issuance. See Note 13 for valuation of the Warrants.

The fair value of the first tranche was determined to equal the USD 30 million in cash proceeds received and was allocated by using the fair value of the warrants (USD 2.6 million), the fair value of the liability portion of the convertible feature (USD 27.3 million) and the fair value of the conversion option (USD 22 thousand). The initial fair value of the liability portion of the Securities Purchase Agreement was determined using a market interest rate for a non-convertible note with attached warrants at the issue date. The liability is subsequently

recognized on an amortized cost basis until extinguished on conversion or maturity of the first tranche. The total proceeds were first attributed to the liability portion of the Securities Purchase Agreement and the warrants. The remaining proceeds were allocated to the conversion option and recognized in shareholders' equity and not remeasured.

The Securities Purchase Agreement includes affirmative and negative covenants applicable to the Company and its subsidiaries. The affirmative covenants include, among other things, requirements to file certain financial reports with the Securities and Exchange Commission, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. Further, subject to certain exceptions, the Securities Purchase Agreement contains customary negative covenants limiting its ability to, among other things, transfer or sell certain assets, consummate mergers or acquisitions, allow changes in business, incur additional indebtedness, create liens, pay dividends or make other distributions and make investments. As of December 31, 2021, the Company was in compliance with its covenants.

13. Shareholders' equity

(in USD '000)	Number of common shares	Share capital	Share premium	Total
January 1, 2020	44,423,448	3,499	320,955	324,454
Issuance of shares - EIP 2013	168,641	15	2,065	2,080
Issuance of shares - Underwritten offering	6,964,592	591	19,408	19,999
Issuance of shares - ATM program	5,995,897	469	16,437	16,906
Share issuance costs	_	_	(2,043)	(2,043)
December 31, 2020	57,552,578	4,574	356,822	361,396

	Number of common shares	Share capital	Share premium	Total
(in USD '000)				
January 1, 2021	57,552,578	4,574	356,822	361,396
Issuance of shares - ATM program	15,954,450	1,360	52,327	53,687
Share issuance costs	_	_	(81)	(81)
Exercise of warrants	6,448,240	555	21,562	22,117
December 31, 2021	79,955,268	6,489	430,630	437,119

Share capital and share premium

As of December 31, 2021, the total outstanding share capital of USD 6.5 million, fully paid, consists of 79,955,268 common shares, excluding 5,265,203 treasury shares. As of December 31, 2020, the total outstanding share capital of USD 4.6 million, fully paid, consisted of 57,552,578 common shares, excluding 3,608,291 treasury shares. All shares have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date.

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

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

In September 2020, the Company completed an underwritten offering of 6,448,240 units at an effective price of USD 2.869 per unit, with each unit comprised of one common share (or pre-funded warrant) and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share. In addition to the securities being sold in the underwritten offering, the Company's former Chief Executive Officer purchased 516,352 units at an effective price of USD 2.905 per unit, with each unit comprised of one common share and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share, in a concurrent private placement. The net proceeds from the offering and the concurrent private placement, including exercise of pre-funded warrants, were USD 20.0 million, after deducting underwriting discounts, commissions and other offering expenses paid by the Company. As of December 31, 2020, none of the 15-month purchase warrants have been exercised.

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

Equity incentive plans

In 2021, the Company issued no common shares (2020: 168,641) under its 2013 EIP (see note 20). All shares issued under the 2013 EIP have a nominal value of 1/13 of a Swiss franc, translated into USD using historical rates at the issuance date.

Authorized share capital

The authorized share capital that is not outstanding is as follows:

		As of December 31,
Number of common shares	2021	2020
Authorized share capital	40,610,232	17,611,372

Warrants Issued with Securities Purchase Agreement with JGB

On October 12, 2021, in connection with the first tranche from the Securities Purchase Agreement with JGB, the Company issued 1,634,877 warrants to JGB. The warrants have an exercise price of \$3.67 per share. The Company determined the fair value of the warrants on October 12, 2021 using the Black Scholes model by using a risk-free interest rate of 0.64%, an expected term of 3 years, and an implied volatility of 98.5%. The fair value was calculated to be approximately USD 2.6 million on October 12, 2021. This valuation is considered to be Level 2 in the fair value hierarchy. The Company allocated the transaction fees associated with the Securities Purchase Agreement based on the debt balance and the fair value of the warrant liability on October 12, 2021. The allocation of the transaction fees associated with the warrant liability was USD 0.2 million and was recorded as a period cost and included in finance expense on the statements of comprehensive loss.

Because the warrants were not exercisable until its affiliated registration statement was declared effective, the Company had to revalue the warrant liability on the date of the effective date of the registration statement which was November 22, 2021. The Company revalued the fair value of the warrants on November 22, 2021 using the Black Scholes model by using a risk-free interest rate of 0.95%, an expected term of 3 years, and an implied

volatility of 98.2%. The fair value was calculated to be approximately USD 1.8 million on November 22, 2021. The resulting difference in fair values between October 12, 2021 and November 22, 2021 of USD 0.8 million is recorded as a period cost and is included in finance income on the statements of comprehensive loss.

14. Revenue and other operating income

The Group currently derives no revenue from sales of its biopharmaceutical product candidates. In July 2021, the Company entered into an agreement with Organon to develop and commercialize ebopiprant. Under the terms of the agreement, Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. In consideration for entering into this agreement, the Company received an upfront payment of USD 25 million. The Company accounted for this upfront payment in accordance with IAS 38 par 113 and as such, the gain on the disposal of the asset net of fees and net of recognition of intangible asset of USD 20.1 million is recorded in operating income other than revenue on the Company's consolidated statements of comprehensive loss.

15. Operating expenses by nature

		Year ended Do	ecember 31,
USD '000	2021	2020	2019
External research and development costs	38,287	51,803	70,531
Staff costs (note 16)	18,788	19,643	24,556
Professional fees	12,175	3,994	7,072
Rents	60	22	21
Travel expenses	229	156	1,398
Patent registration costs	887	813	882
Depreciation	736	721	737
Other	3,466	2,566	1,914
Total operating expenses by nature	74,627	79,718	107,111

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 2021, research and development expenses amounted to USD 53.1 million (2020: USD 67.5 million, 2019: USD 88.1 million).

Depreciation expense has been allocated as follows:

		Year ended Dec	cember 31,	
	2021	2020	2019	
(in USD '000)				
Research and development expenses	441	447	429	
General and administrative expenses	295	274	308	
Total depreciation	736	721	737	

16. Staff costs

		Year ended	December 31,
	2021	2020	2019
(in USD '000)			
Wages and salaries	11,110	10,262	10,403
Social charges	1,690	1,699	2,124
Post-employment benefits expense	145	1,176	145
Share-based payments	5,843	6,506	11,884
Total staff costs	18.788	19,643	24,556

The Group employed on average 45.8 full-time equivalents ("FTE") in 2021, compared to 46.2 FTE in 2020 and 48.5 FTE in 2019, and 48.3 FTE as of December 31, 2021 compared to 42.7 FTE as of December 31, 2020 and 50.1 FTE as of December 31, 2019.

For the year ended December 31, 2019, the post-employment benefits line included a gain of USD 527 thousand relating to the plan amendments enacted during the year. No amendment occurred during the year ended December 31, 2020. For the year ended December 31, 2021, the post-employment benefit line included a gain of USD 864 thousand relating to the plan amendments enacted during the year.

17. Finance income and expense

Our finance income and expense primarily consist of foreign exchange gain and loss as well as interest expense associated with our lease liabilities and debt instruments.

		Year ended December		
	2021	2020	2019	
(in thousands)				
Foreign exchange gain (loss), net	78	(527)	(442)	
Interest expense	(3,156)	(2,704)	(1,186)	
Change in fair value of derivative liability	790	_	_	
Loss on Oxford debt extinguishment	(1,363)	_	_	
Finance result, net	(3,651)	(3,231)	(1,628)	

18. Income taxes and deferred taxes

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

The Company is subject in Switzerland to a municipal and cantonal income tax rate of 14% (2020: 14%) and to a federal tax rate of 8.5% (2020: 8.5%) on its profits after tax. It is entitled to carry forward any loss incurred for a period of seven years and can offset such losses carried forward against future taxes. In 2015, the Company was granted by the State Council of the Canton of Geneva an exemption of income and capital tax at municipal and cantonal levels for the period from 2013 until 2022. Because of this exemption, and the fact that the Company has incurred net losses since its inception, no income tax expense at the municipal, cantonal or federal levels was recorded in the Company for the years ended December 31, 2021 and 2020. Additionally, due to the uncertainty as to whether it will be able to use its net loss carryforwards for tax purposes in the future, no deferred taxes have been recognized on the balance sheet of the Company as of December 31, 2021 and December 31, 2020.

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

Expiring tax losses

	As of December		
	2021	2020	
(in USD '000)			
2021	_	12,828	
2022	17,372	17,993	
2023	30,603	31,696	
2024	62,631	64,869	
2025	72,763	75,364	
2026	105,879	109,663	
2027	77,340	80,105	
2028	55,480	_	
Total unrecorded tax losses carry forwards	422,068	392,518	

The Company's Irish subsidiary has no activity, and, therefore, no income tax expense was recorded in such entity for the years ended December 31, 2021 and 2020.

The Company's U.S. subsidiary, ObsEva USA Inc., is a service organization for the Group and is therefore subject to taxes on the revenues generated from its services to the Group that are charged based upon the U.S. subsidiary's cost plus arrangement with the Group. The profits of the U.S. subsidiary for the year ended December 31, 2021 and 2020 were subject to a total U.S. income tax rate of 27.3% based on both the U.S. Federal and Massachusetts state tax rates. The income tax for the year ended December 31, 2021 and 2020 was USD 212 thousand and USD 34 thousand, respectively. Additionally, since ObsEva USA Inc. is totally dependent on ObsEva SA for revenue, there is uncertainty as to whether ObsEva USA Inc. will be able to use a deferred tax asset for tax purposes in the future, therefore, no deferred taxes have been recognized on the balance sheet of the Group as of December 31, 2021 and December 31, 2020.

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

	Year ended Dec	ember 31, 2021	
	ObsEva SA	ObsEva USA	Total Group
(in USD '000)			
Net loss before tax	(56,145)	(2,020)	(58,165)
Statutory tax rate (blended at Group level)	7.8%	27.3%	8.5%
Income tax credit at statutory tax rates	(4,398)	(551)	(4,949)
Tax impact of pension and share-based compensation	(38)	116	78
Temporary differences not recognized as deferred tax assets	128	647	775
Tax on losses not recognized as deferred tax assets	4,308	-	4,308
Effective income tax expense	-	212	212
Effective tax rate	0.0%	(10.5)%	(0.4)%

		Year ended Dec	ember 31, 2020
	ObsEva SA	ObsEva USA	Total Group
(in USD '000)			
Net loss before tax	(82,804)	(128)	(82,932)
Statutory tax rate (blended at Group level)	7.8%	27.3%	7.9%
Income tax credit at statutory tax rates	(6,487)	(35)	(6,522)
Tax impact of permanent differences	595	17	612
Temporary differences not recognized as deferred tax assets	(1)	52	51
Tax on losses not recognized as deferred tax assets	5,893	-	5,893
Effective income tax expense	-	34	34
Effective tax rate	0.0%	(26.7)%	0.0%

19. Loss per share

As of December 31, 2021, 2020 and 2019, the Company has one category of shares, which are common shares, since the Company's non-voting shares and series A and series B preferred shares were converted into common shares upon the closing of the IPO on January 25, 2017.

The basic loss per share is calculated by dividing the loss of the period attributable to the ordinary shares by the weighted average number of ordinary shares outstanding during the period as follows:

	Year ended Decembe		
	2021	2020	2019
Net loss attributable to shareholders (in USD '000)	(58,377)	(82,966)	(108,790)
Weighted average number of shares outstanding	75,281,838	49,820,451	43,674,746
Basic and diluted loss per share (in USD)	(0.78)	(1.67)	(2.49)

For the year ended December 31, 2021, 8,937,473 shares issuable upon the exercise of stock-options and 11,477,396 warrants and convertible in relation with the JGB loan which would have an anti-dilutive impact on the calculation of the diluted earnings per share, were excluded from the calculation. For the year ended December 31, 2020, 7,035,388 and 6,964,592 shares issuable upon the exercise of stock-options and warrants, respectively, which would have an anti-dilutive impact on the calculation of the diluted earnings per share, were excluded from the calculation. For the year ended

December 31, 2019, 168,641 non-vested shares and 4,626,385 shares issuable upon the exercise of stockoptions, which would have an anti-dilutive impact on the calculation of the diluted earnings per share, were excluded from the calculation.

20. Share-based compensation

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

	Ye	Year ended December 31,			
	2021	2020	2019		
(in USD '000)					
Employee 2013 EIP	_	220	1,006		
Employee 2017 EIP	5,843	6,286	10,878		
Total share-based compensation	5,843	6,506	11,884		
	-,	-,	,		

Employee equity incentive plan 2013

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

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

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

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

	2021	2020	2019
Number of shares vested under the 2013 EIP	_	168,641	261,984
Expense arising from the 2013 EIP (in USD ,000)	_	220	1,006

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

transaction involving the Company's own securities, using the following assumptions: rights and preferences of the different categories of shares, probability of various liquidity event scenarios, expected timing of a liquidity event, volatility and expected value in a liquidity event.

The Group has stopped granting equity instruments under the 2013 EIP in 2016, resulting in the 2013 EIP being fully vested as of December 31, 2020.

Employee equity incentive plan 2017

The Company established in 2017 the 2017 EIP for Beneficiaries of the Group, under which 3,050,340 and 4,543,952 stock-options were granted during the year ended December 31, 2021 and 2020, respectively. The stock-options typically vest under a 3-year or 4-year vesting schedule, have a 10-year expiration term and have an exercise price equivalent to the share price at grant date. Certain grants also include non-market performance vesting conditions, common to all employees, regularly assessed to determine the numbers of awards expected to vest.

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

		2021		2020
	Average exercise price	Number of options	Average exercise price	Number of options
	(USD)		(USD)	
At January 1,	6.49	7,035,388	10.51	4,626,385
Granted	3.29	3,050,340	2.93	4,543,952
Forfeited / Expired	8.42	(1,148,255)	7.62	(2,134,949)
Exercised	_	_	_	_
At December 31,	5.15	8,937,473	6.49	7,035,388

No exercise of options occurred during the year ended December 31, 2021 and December 31, 2020.

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

	As of December 31	
Range of exercise prices	2021	2020
USD 15.00 to USD 17.99	96,500	361,500
USD 12.00 to USD 14.99	925,418	1,050,143
USD 9.00 to USD 11.99	1,211,075	1,331,981
USD 6.00 to USD 8.99	109,583	161,979
USD 3.00 to USD 5.99	3,539,628	1,977,823
USD 1.50 to USD 2.99	3,055,269	2,151,962
Total outstanding options	8,937,473	7,035,388
out of which are exercisable	3,552,593	2,083,159
Weighted-average remaining contractual life (in years)	8.2	8.6

The weighted average fair value of the stock-options granted during the years ended December 31, 2021 and 2020, determined using a Black-Scholes model was USD 2.57 and USD 2.31, respectively. The significant inputs to the model were:

	2021	2020
Weighted average share price at grant date	USD 3,29	USD 2.93
Weighted average exercise price	USD 3.29	USD 2.93
Weighted average 10-year volatility	76%	77%
Dividend yield	0%	0%
Weighted average 10-year risk free rate	1 45%	1 28%

Since the Company has a short track record as a public company, expected volatility has been determined based on the historical trend of an appropriate sample of public companies operating in the biotech and pharmaceutical industry.

21. Commitments and contingencies

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 and commercial milestones with respect to linzagolix. The total of all potential undiscounted future payments that the Group could be required to make under this arrangement ranges between USD 0 and USD 178 million.

Pursuant to the Kissei license and supply agreement, the Group has agreed to exclusively purchase the active pharmaceutical ingredient ("API") for linzagolix from Kissei. During the development stage, the Group is obligated to pay Kissei a specified supply price. Following the first commercial sale of licensed product, the Group is obligated to pay Kissei a royalty payment in the low twenty percent range as a percentage of net sales, for product sold outside of North America, which includes payment for Kissei's supply of the active pharmaceutical ingredient, and a tiered single digit royalty of nets sales plus a specified supply price for product sold in North America, in each case 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.

In October 2021, the Group amended the Kissei license and supply agreement such that first commercial sales milestones for the European Union and the United States will now be extended over a 5-year period. In addition, North American royalty payments were lowered to the current tiered single digit royalties on net sales plus a supply price for the API.

Merck Serono licenses

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

22. Related parties transactions

As of December 31, 2021, the Group's related parties include key management (Board of Directors and Executive Committee) and members of their immediate families. The following transactions were carried out with related parties:

Key management remuneration

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

	Year ende	Year ended December 31,		
	2021	2020		
(in USD '000)				
Short-term employee benefits (including base and variable	4.201			
(cash remuneration)	4,301	3,388		
Post-employment benefits	42	272		
Share-based payments	6,326	4,038		
Total	10,669	7,698		

Other transactions with related parties

In September 2020, concurrent with the Company's underwritten public offering indicated in note 13, the Company's former Chief Executive Officer, Ernest Loumaye, purchased 516,352 units at an effective price of USD 2.905 per unit, with each unit comprised of one common share and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share, in a private placement. The Company received USD 1.5 million in net proceeds from the private placement.

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

23. Going concern

The Company has incurred recurring losses since inception, including net losses of USD 58.4 million for the year ended December 31, 2021. As of December 31, 2021, the Company had accumulated losses of USD 467.8 million, of which USD 30.6 million were offset with share premium. The Company expects to continue to generate operating losses for the foreseeable future. As of December 31, 2021, the Company had cash and cash equivalents of USD 54.7 million. These consolidated financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. In October 2021, the Company entered into the Securities Purchase Agreement with certain funds and accounts managed by JGB Management, Inc. The Securities Purchase Agreement is structured to provide USD 135 million in borrowing capacity, available in nine tranches, with the first tranche funded at the initial closing in October 2021 and the second tranche funded in January 2022 in connection with certain amendments to the Securities Purchase Agreement as described in Note 24. The subsequent tranches under the Securities Purchase Agreement will be available subject to the Company meeting certain conditions, including, among others, that the Company's volume-weighted average price is not below USD 3.00 per share for five or more trading days during the 30 days prior to a tranche funding date (the "Minimum Stock Price"). The availability of future funding under the Securities Purchase Agreement is dependent on whether the Minimum Stock Price condition will be met at future tranche dates. To date, the Company has funded its operations through equity and debt offerings and through payments from licensors. The Company believes that its current cash and cash equivalents are only

sufficient to fund its operating expenses into the third quarter of 2022 and this raises substantial doubt about the Company's ability to continue as a going concern. These factors individually and collectively indicate that a material uncertainty exists that may cast significant doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these consolidated financial statements. The future viability of the Company is dependent on its ability to raise additional capital to finance its future operations. The Company has an active ATM program and can potentially raise funds through equity or debt offerings. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the Company's ability to pay dividends or make other distributions to shareholders. The Company may receive future milestone payments from licensors but that is dependent on achieving certain regulatory or commercial milestones that may never happen. The Company may seek additional funding through public or private financings, debt financing or collaboration agreements. The inability to obtain funding, as and when needed, would have a negative impact on the Company's financial condition and ability to pursue its business strategies. If the Company is unable to obtain the required funding to run its operations and to develop and commercialize its product candidates, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Management continues to explore options to obtain additional funding, including through collaborations with third parties related to the future potential development and/or commercialization of its product candidates. However, there is no assurance that the Company will be successful in raising funds, closing a collaboration agreement, obtaining sufficient funding on terms acceptable to the Company, or if at all, which could have a material adverse effect on the Group's business, results of operations and financial conditions.

24. Events after the reporting period

Capital increases

In January 2022, the Company announced the issuance of 23,400,000 common shares at par value of 1/13 of a Swiss franc per share. The shares were fully subscribed for by a fully-owned subsidiary of the Company, and listed on the SIX Swiss Exchange accordingly. The shares are held as treasury shares, hence the operation did not impact the Company's outstanding common shares.

ATM proceeds

From January 1, 2022 until February 28, 2022, the Group sold an additional 2,859,253 treasury shares at an average price of USD 1.61 per share, as part of its ATM program. Total gross proceeds amounted to USD 4.6 million.

Amendment to JGB Note Agreement

On January 28, 2022, the Company entered into an amendment agreement (the "Amendment Agreement") with JGB regarding the second tranche of the Note Agreement. The Amendment Agreement adjusted the principal balance payable at maturity for the notes to be issued in the second tranche to USD10.5 million (USD 975,000 of original issue discount) and the conversion price for the notes to be issued in the second tranche to a price of \$1.66 per common share, and accelerated the issuance of the second tranche to January 28, 2022. In addition, as adjusted pursuant to the Amendment Agreement, the Company issued a warrant to purchase 1,018,716 common shares of the Company at an exercise price of \$1.87 per share. Additionally, JGB waived certain conditions required to be met to fund the second tranche, including that the Company's volume-weighted average price could not be below USD 3.00 per share for five or more trading days during the 30 days prior to the funding date for the second tranche, in exchange for a payment of USD 1.25 million and the amended terms for the notes and warrants issued in the second tranche. In connection with the Amendment Agreement, the Company received USD 8.275 million from the second tranche, after accounting for expenses and the USD 1.25 million waiver payment to JGB.

Theramex Licensing Agreement

On February 10, 2022, the Company entered into a strategic licensing agreement with Theramex to support the commercialization and market introduction of linzagolix across global markets outside of the U.S., Canada and Asia. Under the terms of the agreement, the Company is entitled to receive royalties of a mid-thirties percentage on commercial sales, which includes the cost of goods sold to Theramex. Furthermore, the agreement contains up to EUR72.75 million in upfront and milestone payments, including EUR5 million obtained upon signing, up to EUR13.75 million in development and commercial milestones and up to EUR54 million in sales-based milestones.

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

Report from the Auditor on the Consolidated IFRS Financial Statements

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

Report on the audit of the consolidated financial statements

Opinion

We have audited the consolidated financial statements of ObsEva SA and its subsidiaries (the Group), which comprise the consolidated balance sheet as at December 31, 2021 and the consolidated statement of comprehensive loss, consolidated statement of cash flows, consolidated statement of changes in equity, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the consolidated financial statements contained in the section labelled "Consolidated IFRS Financial Statements for the year ended December 31, 2021" on pages 86 to 120 give a true and fair view of the consolidated financial position of the Group as at 31 December 2021 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

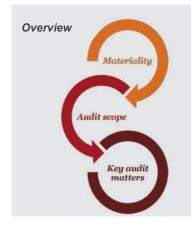
We conducted our audit in accordance with Swiss law, International Standards on Auditing (ISAs) and Swiss Auditing Standards. Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the consolidated financial statements" section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

Material uncertainty related to going concern

We draw your attention to note 23 of these financial statements, which states that the Group has incurred recurring losses since inception and is dependent on the availability of future funding. This, along with other matters as described in note 23, indicates the existence of a material uncertainty which may cast significant doubt about the ability of the Group to continue as a going concern. Our opinion is not qualified in respect of this matter.

Our audit approach



Overall Group materiality: USD 782'000

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.

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

Carrying value of intangible assets

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 782,000

Benchmark applied Total expenses

Rationale for the materiality benchmark applied

We chose total expenses as the materiality benchmark because, in our view, it is the benchmark against which the performance of the Group, that is still in the developmental phase with recurring expenses and no currently marketed products generating revenue, is most commonly measured.

We agreed with the Audit Committee that we would report to them misstatements above USD 78,000 identified during our audit as well as any misstatements below that amount which, in our view, warranted reporting for qualitative reasons.

Audit scope

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 process-es and controls, and the industry in which the Group operates.

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

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. In addition to the matter described in the "Material uncertainty related to going concern" section, we have determined the matter described below to be the key audit matter to be communicated in our report.

Carrying Value of Intangible Assets

Key audit matter

As described in Note 2 Accounting principles applied in the preparation of the consolidated financial statements (page 91) and Note 8 Intangible assets (page 102), the Group has intangible assets totaling USD 24.5 million at December 31, 2021 comprised of licenses for several biopharmaceutical product candidates that have not yet received regulatory and marketing approvals. The intangible assets are not yet ready for use. Therefore, in accordance with IAS 36 'Impairment of asset', each intangible asset was reviewed at least annually for impairment by assessing the fair value less costs of disposal (FVLCOD) (recoverable amount), using a 20-year assuming successful development and commercialization of the various biopharmaceutical product candidates, and comparing this to the carrying value of the assets. In addition, the Group has collectively reviewed its licenses for impairment on the basis of the market capitalization of the entity at year end less the carrying value of its tangible assets as well as cash and cash equivalents. As a result of such reviews, the Group concluded that no impairment was identified as of December 31, 2021.

The principal considerations for our determination that performing procedures relating to the intangible asset valuation is a key audit matter are as follows:

- Intangible assets are significant to the entity. Successful development and commercialization of the various biopharmaceutical product candidates depend on the continuing funding, progress of clinical trials and future market opportunities.
- The forecasts performed by the entity contain a number of significant judgments and estimates, including probabilities of achieving development milestones based on industry standards and a discount factor of 15%.
- The high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating the audit evidence obtained related to the valuation of the intangible asset and management's assumptions.

How our audit addressed the key audit matter

We assessed indicators for potential impairment by reviewing minutes of management, Board of Directors and board committee meetings, performed inquiry with management concerning the ongoing progress of clinical trials, and reviewed external communications, including press releases, other public filings and public communications coming from direct competitors, and considered results of subsequent event procedures performed.

We assessed the reasonableness of key inputs included in the valuation models used by management to determine the recoverable amounts of intangible assets and recalculated the headroom.

We assessed the sensitivity of the FVLCOD models for each of the licenses by assessing the key assumptions used, including the discount factor, over the forecasted period.

We reviewed the budget approved by the Board of Directors which included continued funding for ongoing and new clinical trials for the Group's licenses.

We inquired of management as to whether the progress of clinical trials was satisfactory, discussions with regulatory authorities for new trials were progressing as planned, and enrolment status for ongoing clinical trials was taking place as expected.

We reviewed external analyst reports of the Group, which clinical trials were satisfactory, discussions with regulatory authorities for new trials were progressing as planned, and enrolment status for ongoing clinical trials was taking place as expected.

As a result of our procedures, we determined that the approach applied by management with regard to the carrying value of intangible assets was reasonable and supportable.

Other information in the annual report

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

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

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

Responsibilities of the Board of Directors for the consolidated financial statements

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

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

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

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

As part of an audit in accordance with Swiss law, ISAs and Swiss Auditing Standards, we exercise professional judgment and maintain professional skepticism 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 communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

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

Luc Schulthess Audit expert Auditor in charge Sarah Ellsworth

Genève, 31 March 2022

Statutory Financial Statements of ObsEva SA

Statutory Financial Statements of ObsEva SA for the year ended December 31, 2021

Balance Sheets as of December 31,

Not	es 2021	2020	2021	2020
ASSETS	(in USD)	(in USD)	(in CHF)	(in CHF)
Current assets				
Cash and cash equivalents	54,374,305	30,326,354	49,614,670	26,716,900
Other current receivables	3,459,281	360,522	3,156,474	317,612
Other current receivables - Group Comp.	0	228,757	0	201,530
Deferred costs and prepaid expenses	5,184,777	5,692,725	4,730,929	5,015,175
Total current assets	63,018,363	36,608,358	57,502,073	32,251,217
Non-current assets				
Financial assets	4 206,695	214,083	188,602	188,602
Investments	5 1,185	3	1,081	3
Property, plant and equipment	49,540	71,090	45,204	62,629
Intangible assets	7 24,503,378	24,503,378	22,358,484	21,586,977
Other non-current assets	8 0	871,875	0	768,104
Total non-current assets	24,760,798	25,660,429	22,593,371	22,606,315
Total assets	87,779,161	62,268,787	80,095,444	54,857,531
LIABILITIES & SHAREHOLDERS' EQUITY				
Current liabilities				
Trade payables	7,714,167	9,450,160	7,038,909	8,325,399
Other current liabilities	1,031,346	1,304,247	941,068	1,149,014
Other current liabilities - Group Comp.	1,442,785	0	1,316,492	0
Accrued expenses	13,067,038	10,015,915	11,923,219	8,823,817
Total current liabilities	23,255,336	20,770,322	21,219,688	18,298,230
Non-current liabilities				
Non-current borrowings	31,496,063	26,509,354	28,739,067	23,354,200
Other long-term liabilities	591,387	918,784	539,620	809,430
Total non-current liabilities	32,087,450	27,428,138	29,278,687	24,163,630
Shareholders' equity				
Share capital	6,948,220	4,877,893	6,575,471	4,689,626
Treasury shares	(459,191)	(304,338)	(405,016)	(277,555)
Legal reserve from capital contribution	409,878,969	337,948,342	396,914,340	330,876,411
Accumulated deficit	(383,931,623)	(328,451,570)	(373,487,727)	(322,892,810)
Total shareholders' equity 1	32,436,375	14,070,327	29,597,069	12,395,672
Total liabilities & shareholders' equity	87,779,161	62,268,787	80,095,444	54,857,531

Plan les Ouates, March 25, 2022

Frank Verweil Chairman Will Brown CFO Statements of Loss for the years ended December 31,

	2021	2020	2021	2020
	(in USD)	(in USD)	(in CHF)	(in CHF)
INCOME				
Other income, net	22,218,179	16,568	20,337,006	15,545
Total income	22,218,179	16,568	20,337,006	15,545
OPERATING EXPENSES				
Staff costs	(10,895,057)	(11,057,759)	(9,972,592)	(10,374,755)
External research and development costs	(38,190,008)	(51,803,425)	(34,956,529)	(48,603,683)
Patent costs	(886,915)	(812,679)	(811,822)	(762,482)
Professional fees	(14,089,277)	(3,959,588)	(12,896,363)	(3,715,016)
Professional fees - Group Companies	(3,651,325)	(2,158,902)	(3,342,174)	(2,025,553)
Facilities	(3,693,482)	(2,586,743)	(3,380,762)	(2,426,968)
Other operating expenses	(396,311)	(539,459)	(362,756)	(506,139)
Depreciation	(44,725)	(58,017)	(40,938)	(54,434)
Total operating expenses	(71,847,100)	(72,976,573)	(65,763,936)	(68,469,029)
OPERATING LOSS	(49,628,921)	(72,960,005)	(45,426,929)	(68,453,484)
Finance income	688,881	889,933	630,555	834,964
Finance expense	(6,540,013)	(3,146,245)	(5,986,282)	(2,951,910)
NET LOSS BEFORE TAX	(55,480,053)	(75,216,317)	(50,782,657)	(70,570,431)
Income tax expense 14	-	-	-	_
NET LOSS FOR THE PERIOD	(55,480,053)	(75,216,317)	(50,782,657)	(70,570,431)

Plan les Ouates, March 25, 2022

Frank Verweil Chairman Will Brown CFO

Notes to the Financial Statements 2021

1. General information

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

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

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

Current assets

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

Non-current assets

Property, plant and equipment is carried at cost less depreciation. Depreciation is calculated using the straight-line method, on the basis of the following useful lives:

furniturehardwareyearsyears

- leasehold improvement duration of lease

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

- Recognition of income

Income is recognized if its amount can be reliably measured and it is sufficiently probable that the economic benefits will flow to the company.

- Foreign currencies

Monetary and non-monetary items in foreign currency are translated into the company functional currency as follows:

- the exchange rates used for balance sheet items are the rates prevailing on 31 December;
- the exchange rates used for transactions conducted during the course of the year and for items in the profit and loss statement are the exchange rates prevailing at the dates of the transactions or valuations where items are re-measured.

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

	USD/CHF prevailing rate	USD/CHF rate used for year ended December 31, 2021	USD/CHF rate used for year ended December 31, 2020
Statement of loss	Average rate for the period	0.91533	0.93823
Shareholders' equity	Historical rates	_	_
Balance sheet, other line items	Closing rate as of December 31	0.91247	0.88098

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

3. Full-time positions

The Company employed on average 40.7 full-time equivalents (FTE) in 2021 (2020: 41.1 FTE) and 42.2 FTE as at December 31, 2021 (December 31, 2020: 38.7 FTE).

4. Pledges on assets to secure own liabilities

	December 31,			December 31,	
	2021	2020	2021	2020	
	(in USD)	(in USD)	(in CHF)	(in CHF)	
Escrow accounts	206,695	214,083	188,602	188,602	
Total	206,695	214,083	188,602	188,602	

As at December 31, 2021, USD 206,695 (CHF 188,602) were held on escrow accounts as security rental deposits (December 31, 2020: USD 214,083 (CHF 188,602)).

5. Investments

ObsEva SA owned as of December 31, 2021:

Company	Business	Capital	Interest in capital	Voting Rights
ObsEva Netherlands, BV Rotterdam, Netherlands	Research and development	EUR 1000.00	100%	100%
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:

	202	December 31, 1 2020	2021	December 31, 2020
	(in USD	in USD)	(in CHF)	(in CHF)
Shareholding ObsEva Netherlands BV	1,182	0	1,079	0
Shareholding ObsEva Ireland Ltd	2	2	2	2
Shareholding ObsEva USA Inc.	1	1	1	1
Total	1,185	3	1,082	3

6. Property, plant and equipment

(in USD)	Furniture	Hardware	Leasehold improvement	Total
Net book value as of 1st Jan. 21	24,359	28,906	17,825	71,090
Additions	_	23,175	_	23,175
Depreciation charge	(11,971)	(27,047)	(5,707)	(44,725)
Net book value as of 31 Dec. 21	12,388	25,034	12,118	49,540
Total cost	109,733	205,225	122,402	437,360
Accumulated depreciation	(97,345)	(180,191)	(110,284)	(387,820)

	Furniture	Hardware	Leasehold improvement	Total
(in USD)			•	
Net book value as of 1st Jan. 20	43,187	62,389	23,531	129,108
Additions	_	_	_	_
Depreciation charge	(18,829)	(33,483)	(5,707)	(58,018)
Net book value as of 31 Dec. 20	24,359	28,906	17,825	71,090
Total cost	109,733	182,050	122,402	414,185
Accumulated depreciation	(85,374)	(153,144)	(104,577)	(343,095)

	Furniture	Hardware	Leasehold improvement	Total
(in CHF)				
Net book value as of 1st Jan. 21	21,459	25,466	15,703	62,628
Additions	_	21,146	_	21,146
Currency translation difference	768	910	562	2,240
Depreciation charge	(10,923)	(24,679)	(5,207)	(40,809)
Net book value as of 31 Dec. 21	11,304	22,843	11,057	45,204
Total cost	97,440	182,439	108,395	388,274
Accumulated depreciation	(86,136)	(159,596)	(97,337)	(343,069)

	Furniture	Hardware	Leasehold improvement	Total
(in CHF)				
Net book value as of 1st Jan. 20	41,759	60,326	22,753	124,838
Additions	_	_	_	_
Currency translation difference	(2,634)	(3,445)	(1,696)	(7,774)
Depreciation charge	(17,666)	(31,415)	(5,354)	(54,435)
Net book value as of 31 Dec. 20	21,459	25,466	15,703	62,629
Total cost	96,672	160,383	107,833	364,889
Accumulated depreciation	(75,213)	(134,917)	(92,130)	(302,260)

7. Intangible assets

As at December 31, 2021 the Company holds a number of licenses to operate several pharmaceutical compounds, which were acquired for USD 24,503,378 (CHF 22,428,721) (December 31, 2020: USD 24,503,378 (CHF 21,586,977)).

8. Borrowings

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

In October, 2021, the Company entered into a convertible note financing agreement (the "Securities Purchase Agreement") with certain funds and accounts managed by JGB, which is structured to provide up to USD 135 million in borrowing capacity, available in nine tranches. In connection with the first tranche which included a borrowing amount of USD 31.5 million (offer issue discount of USD 1.5 million), the Company received gross proceeds of USD 30.0 million at closing and used the proceeds to repay all amounts outstanding under the Company's existing Oxford Credit Facility. Upon payoff, the Oxford Credit Facility was terminated and the security interests in the Company's assets that secured the Oxford Credit Facility were released. At the time of the payoff, the net carrying amount of the Oxford Credit Facility was USD 25.6 million and the actual payoff amount was USD27.0 million. The difference between the net carrying amount and the payoff amount was USD 1.4 million and was recorded in finance expense for the year ended December 31, 2021. The Company will issue senior secured convertible promissory notes (each, a "Note") for the debt funded at each tranche. Holders may convert all principal and interest under the Securities Purchase Agreement at any time into the Company's common shares at an initial conversion price of \$3.20 per share (the "Conversion Price"). The Conversion Price is subject to adjustment under certain circumstances in accordance with the terms of the Note Agreement.

The Securities Purchase Agreement is secured by an account control agreement in favor of JGB, and the Company is obligated to maintain a minimum cash amount of USD 25 million in such deposit account, subject to additional incremental increases totaling USD 27.0 million in aggregate depending on the amount of debt outstanding under the Securities Purchase Agreement. Each tranche under the Securities Purchase Agreement will bear interest at a rate of 9.5% per year, payable monthly, and will be issued with an original issue discount

of 4.75%. Each tranche under the Securities Purchase Agreement will mature three years from the date of issuance, unless earlier converted or prepaid in accordance with their terms. After payments and deductions for certain transaction costs and offer issue discounts, the effective rate of the Securities Purchase Agreement is 16.2%. At each tranche, the Company will also issue to JGB warrants to purchase common shares of the Company (each, a "*Warrant*") in an amount equal to 20% of the funded amount for such tranche. The Warrants will be exercisable at a price of \$3.67 per share and will have a four year term from the date of issuance.

The Securities Purchase Agreement includes affirmative and negative covenants applicable to the Company and its subsidiaries. The affirmative covenants include, among other things, requirements to file certain financial reports with the Securities and Exchange Commission, maintain insurance coverage and satisfy certain requirements regarding deposit accounts. Further, subject to certain exceptions, the Securities Purchase Agreement contains customary negative covenants limiting its ability to, among other things, transfer or sell certain assets, consummate mergers or acquisitions, allow changes in business, incur additional indebtedness, create liens, pay dividends or make other distributions and make investments. As of December 31, 2021, the Company was in compliance with its covenants.

9. Amounts due to pension funds

As at December 31, 2021, amounts due to pension funds amounted to 367,052 (CHF 334,922) (December 31, 2020: USD 366,959 (CHF 323,283)).

10. Lease commitments not reported in the balance sheet

Operating lease commitments

	December 31,			December 31,
	2021	2020	2021	2020
	(in USD)	(in USD)	(in CHF)	(in CHF)
Within 1 year	485,581	502,936	443,076	443,076
Later than 1 year and no later than 5 years	242,791	754,403	221,538	664,614
Later than 5 years	_	_	_	_
Total	728,372	1,257,339	664,614	1,107,690

11. Shareholders' equity

	Share capital	Legal reserve from capital cont.	Accumulated deficit	Shareholders' equity
(in USD)				
January 1, 2021	4,573,555	337,948,342	(328,451,570)	14,070,327
Issuance of shares - ATM offering	1,360,264	52,327,239	_	53,687,503
Issuance of shares - Underwritten offering	555,210	21,562,253	_	22,117,463
Costs of share issuance - ATM	_	(1,958,865)	_	(1,958,865)
Net loss for the year	_	_	(55,480,053)	(55,480,053)
December 31, 2021	6,489,029	409,878,969	(383,931,623)	32,436,375
	Share capital	Legal reserve from capital cont.	Accumulated deficit	Shareholders' equity
(in USD)				
January 1, 2020	3,513,968	304,146,301	(253,235,253)	54,425,017
Issuance of shares - ATM offering	468,703	16,436,970	_	16,905,673
Issuance of shares - Underwritten offering	590,884	19,408,171	_	19,999,055
Costs of share issuance – ATM	_	(2,043,101)	_	(2,043,101)
Net loss for the year	_	_	(75,216,317)	(75,216,317)
December 31, 2020	4,573,555	337,948,342	(328,451,570)	14,070,327
	Share capital	Legal reserve from capital cont.	Accumulated deficit	Shareholders' equity
(in CHF)				
January 1, 2021	4,412,071	330,876,411	(322,892,810)	12,395,672
Issuance of shares - ATM offering	1,245,093	47,896,638		49,141,731
Issuance of shares - Underwritten offering	513,292	19,934,303		20,447,595
Costs of share issuance – ATM		(1,793,011)		(1,793,011)
Currency translation differences Net loss for the year	_		187,740 (50,782,657)	187,740 (50,782,657)
December 31, 2021	6,170,455	396,914,340	(373,487,727)	29,597,069
	Share capital	Legal reserve	Accumulated deficit	Shareholders' equity
(in CHF)				
January 1, 2020	3,430,417	299,527,292	(250,332,475)	52,625,234
Issuance of shares – ATM offering	443,116	15,539,648		15,982,763
Issuance of shares - Underwritten offering	538,538	17,688,818	_	18,227,356
Costs of share issuance - ATM	_	(1,879,347)		(1,879,347)
Currency translation differences			(1,989,904)	(1,989,904)
Net loss for the year	4 412 071		(70,570,431)	(70,570,431)
December 31, 2020	4,412,071	330,876,411	(322,892,810)	12,395,672

Outstanding Share Capital and Non-Voting Share Capital

As of December 31, 2021, the total outstanding share capital of USD 6,489,029 (CHF 6,170,455), fully paid, consists of 85,220,471 common shares, less 5,265,203 treasury shares. All shares have a nominal value of 1/13 of a Swiss franc.

As at December 31, 2020, the total outstanding share capital of USD 4,573,555 (CHF 4,412,071), fully paid, consists of 61,160,859 common shares, less 3,608,281 shares held by the Company as treasury shares. All shares have a nominal value of 1/13 of a Swiss franc.

Significant Changes in Shareholders' Equity

Throughout the year ended December 31, 2019, the Company sold a total of 691,133 treasury shares at an average price of USD 5.14 per share, as part of its ATM program initiated in May 2018. These multiple daily transactions generated total gross proceeds of USD 3,554,548 (CHF 3,375,387).

On July 18, 2019, the Company issued 3,064,048 common shares at par value of 1/13 of a Swiss franc per share. The shares were fully subscribed for by the Company, and were initially held as treasury shares, hence the operation did not impact the share capital.

During the year ended December 31, 2020, the Company sold a total of 5,995,897 treasury shares at an average price of USD 2.82 per share, as part of its ATM program. These multiple daily transactions generated total gross proceeds of USD 16,905,673 (CHF 15,982,763). Directly related share issuance costs of USD 507,170 (CHF 479,483) were recorded as a deduction in equity.

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

In September 2020, the Company completed an underwritten offering of 6,448,240 units at an effective price of USD 2.869 per unit, with each unit comprised of one common share (or pre-funded warrant) and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share. In addition to the securities being sold in the underwritten offering, the Company's former Chief Executive Officer purchased 516,352 units at an effective price of USD 2.905 per unit, with each unit comprised of one common share and one 15-month purchase warrant to purchase one common share at an exercise price of USD 3.43 per share, in a concurrent private placement. The net proceeds from the offering and the concurrent private placement, including exercise of pre-funded warrants, were approximately USD 20.0 million (CHF 18.2 million), after deducting underwriting discounts, commissions and other offering expenses paid by the Company. As of December 31, 2020, none of the 15-month purchase warrants have been exercised.

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

Treasury shares

The changes in the number of treasury shares owned by the company in 2021 and 2020 are as follows:

(number of treasury shares)	2021	2020
At January 1,	3,608,281	3,975,516
Sale of treasury shares	(15,933,420)	(5,995,897)
Purchase of treasury shares	17,590,342	5,628,662
At December 31,	5,265,203	3,608,281

12. Authorized capital and conditional capital

The authorized share capital and conditional share capital as at December 31, 2021 and December 31, 2020 are as follows:

	December 31, 2021	December 31, 2020
(in CHF)		
Authorized share capital	3,123,864	1,354,721
Conditional share capital	2,816,171	1,921,519

13. Other operating income

In July 2021, the Company entered into an agreement with Organon & Co. ("Organon") to develop and commercialize ebopiprant. Under the terms of the agreement, Organon gained exclusive worldwide rights to develop, manufacture and commercialize ebopiprant. In consideration for entering into this agreement, the Company is entitled to receive tiered double-digit royalties on commercial sales as well as up to USD 500 million in upfront and milestone payments including USD 25 million that was paid at signing, up to USD 90 million in development and regulatory milestones and up to USD 385 million sales-based milestones. Other operating income of USD 25.0 million (CHF 22.9 million) is shown net of transaction fees amounting to USD 2.8 million (CHF 2.6 million).

14. Income tax

Subsequent to the enforcing of the "Federal Act on Tax Reform and AHV Financing" (TRAF) on January 1, 2020, the Company is subject in Switzerland to a municipal and cantonal income tax rate of 14% (2020: 14%) and to a federal tax rate of 8.5% on its profits after tax. It is entitled to carry forward any loss incurred for a period of seven years and can offset such losses carried forward against future taxes. In 2015, the Company was granted by the State Council of the Canton of Geneva an exemption of income and capital tax at municipal and cantonal levels for the period from 2013 until 2022. Because of this exemption, and the fact that the Company has incurred net losses since its inception, no income tax expense at the municipal, cantonal or federal levels was recorded in the Company for the years ended December 31, 2021 and 2020.

15. Major Shareholders

A list of our major shareholders is disclosed in the Corporate Governance section of this Annual Report (page 65).

16. Going Concern

The Company fulfills its obligations by the use of its cash reserves. The Company has incurred recurring losses since inception, including net losses of USD 55.5 million (CHF 50.8 million) for the year ended December 31, 2021. As of December 31, 2021, the Company had accumulated losses of USD 383.9 million (CHF 373.5 million). The Company expects to continue to generate operating losses for the foreseeable future. As of December 31, 2021, the Company had cash and cash equivalents of USD 54.4 million (CHF 49.6 million). These financial statements have been prepared assuming that the Company will continue as a going concern which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. In October 2021, the Company entered into the Securities Purchase Agreement with certain funds and accounts managed by JGB Management, Inc. The Securities Purchase Agreement is structured to provide USD 135 million in borrowing capacity, available in nine tranches, with the first tranche funded at the initial closing in October 2021 and the second tranche funded in January 2022 in connection with certain amendments to the Securities Purchase Agreement as described in Note 8. The subsequent tranches under the Securities Purchase Agreement will be available subject to the Company meeting certain conditions, including, among others, that the Company's volume-weighted average price is not below USD 3.00 per share for five or more trading days during the 30 days prior to a tranche funding date (the "Minimum Stock Price"). The availability of future funding under the Securities Purchase Agreement is dependent on whether the Minimum Stock Price condition will be met at future tranche dates. To date, the Company has funded its operations through equity and debt offerings and through payments from licensors. The Company believes that its current cash and cash equivalents are only sufficient to fund its operating expenses into the third quarter of 2022 and this raises substantial doubt about the Company's ability to continue as a going concern. These factors individually and collectively indicate that a material uncertainty exists that may cast significant doubt about the Company's ability to continue as a going concern within one year from the date of the issuance of these consolidated financial statements. The future viability of the Company is dependent on its ability to raise additional capital to finance its future operations. The Company has an active ATM program and can potentially raise funds through equity or debt offerings. The sale of additional equity may dilute existing shareholders and newly issued shares may contain senior rights and preferences compared to currently outstanding common shares. Issued debt securities may contain covenants and limit the company's ability to pay dividends or make other distributions to shareholders. The Company may receive future milestone payments from licensors but that is dependent on achieving certain regulatory or commercial milestones that may never happen. The Company may seek additional funding through public or private financings, debt financing or collaboration agreements. The inability to obtain funding, as and when needed, would have a negative impact on the company's financial condition and ability to pursue its business strategies. If the Company is unable to obtain the required funding to run its operations and to develop and commercialize its product candidates, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Management continues to explore options to obtain additional funding, including through collaborations with third parties related to the future potential development and/or commercialization of its product candidates. However, there is no assurance that the Company will be successful in raising funds, closing a collaboration agreement, obtaining sufficient funding on terms acceptable to the Company, or if at all, which could have a material adverse effect on the Groups business, results of operations and financial conditions.

17. Events after the balance sheet date

Capital increases

In January 2022, the Company announced the issuance of 23,400,000 common shares at par value of 1/13 of a Swiss franc per share. The shares were fully subscribed for by a fully-owned subsidiary of the Company, and listed on the SIX Swiss Exchange accordingly. The shares are held as treasury shares, hence the operation did not impact the Company's outstanding common shares.

ATM proceeds

From January 1, 2022 until February 28, 2022, the Group sold an additional 2,859,253 treasury shares at an average price of USD 1.61 per share, as part of its ATM program. Total gross proceeds amounted to USD 4.6 million.

Amendment to JGB Note Agreement

On January 28, 2022, the Company entered into an amendment agreement (the "Amendment Agreement") with JGB regarding the second tranche of the Note Agreement. The Amendment Agreement adjusted the principal balance payable at maturity for the notes to be issued in the second tranche to USD10.5 million (USD 975,000 of original issue discount) and the conversion price for the notes to be issued in the second tranche to a price of \$1.66 per common share, and accelerated the issuance of the second tranche to January 28, 2022. In addition, as adjusted pursuant to the Amendment Agreement, the Company issued a warrant to purchase 1,018,716 common shares of the Company at an exercise price of \$1.87 per share. Additionally, JGB waived certain conditions required to be met to fund the second tranche, including that the Company's volume-weighted average price could not be below USD 3.00 per share for five or more trading days during the 30 days prior to the funding date for the second tranche, in exchange for a payment of USD 1.25 million and the amended terms for the notes and warrants issued in the second tranche. In connection with the Amendment Agreement, the Company received we of USD 8.275 million from the second tranche, after accounting for expenses and the USD 1.25 million waiver payment to JGB.

Theramex Licensing Agreement

On February 10, 2022, the Company entered into a strategic licensing agreement with Theramex to support the commercialization and market introduction of linzagolix across global markets outside of the U.S., Canada and Asia. Under the terms of the agreement, the Company is entitled to receive royalties of a mid-thirties percentage on commercial sales, which includes the cost of goods sold to Theramex. Furthermore, the agreement contains up to EUR72.75 million in upfront and milestone payments, including EUR5 million obtained upon signing, up to EUR13.75 million in development and commercial milestones and up to EUR54 million in sales-based milestones.

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

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

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

Report on the audit of the financial statements

Opinion

We have audited the financial statements of ObsEva SA, which comprise the balance sheet as at December 31, 2021, the statement of loss and notes for the year then ended, including a summary of significant accounting policies.

In our opinion, the financial statements contained in the section labelled "Statutory Financial Statements of ObsEva SA for the year ended December 31, 2021" on pages 127 to 139 comply with Swiss law and the company's articles of incorporation.

Basis for opinion

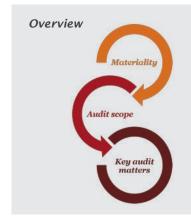
We conducted our audit in accordance with Swiss law and Swiss Auditing Standards. Our responsibilities under those provisions and standards are further described in the "Auditor's responsibilities for the audit of the financial statements" section of our report.

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.

Material uncertainty related to going concern

We draw your attention to note 16 of these financial statements, which states that the entity has incurred recurring losses since inception and is dependent on the availability of future funding. This, along with other matters as described in note 16, indicates the existence of a material uncertainty which may cast significant doubt about the ability of the entity to continue as a going concern. If it is not possible for the entity to continue as a going concern, the financial statements will need to be prepared on the basis of liquidation values. This would lead to a substantiated concern that the company's liabilities exceed its assets within the meaning of article 725 para. 2 CO, requiring compliance with the corresponding legal provisions. Our opinion is not modified in respect of this matter.

Our audit approach



Overall materiality: USD 777,000

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

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

Carrying Value of Intangible Assets

Materiality

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

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

Overall materiality USD 777,000

Benchmark applied Total expenses

Rationale for the materiality benchmark applied

We chose total expenses as the materiality benchmark because, in our view, it is the benchmark against which the performance of the entity, that is still in the developmental phase with recurring expenses and no currently marketed products generating revenue, is most commonly measured.

We agreed with the Audit Committee that we would report to them misstatements above USD 77,000 identified

Audit scope

qualitative reasons.

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.

during our audit as well as any misstatements below that amount which, in our view, warranted reporting for

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

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In addition to the matter described in the "Material uncertainty related to going concern" section, we have determined the matter described below to be the key audit matter to be communicated in our report.

Carrying value of intangible assets

Key audit matter

As described in Note 2 Accounting principles applied in the preparation of the financial statements (page 130) and Note 7 Intangible assets (page 133), the entity has intangible assets totaling USD 24.5 million at December 31, 2021 comprised of licenses for several biopharmaceutical product candidates that have not yet received regulatory and marketing approvals. The intangible assets are not yet ready for use. Therefore, each intangible asset was reviewed at least annually for impairment by assessing the fair value less costs of disposal (FVLCOD) (recoverable amount), using a 20-year forecast, assuming successful development and commercialization of the various biopharmaceutical product candidates, and comparing this to the carrying value of the assets. In addition, the entity has collectively reviewed its licenses for impairment on the basis of the market capitalization of the entity at year end less the carrying value of its tangible assets as well as cash and cash equivalents. As a result of such reviews, the entity concluded that no impairment was identified as of December 31, 2021.

The principal considerations for our determination that performing procedures relating to the intangible asset valuation is a key audit matter are as follows:

- Intangible assets are significant to the entity. Successful development and commercialization of the various bio-pharmaceutical product candidates depend on the continuing funding, progress of clinical trials and future market opportunities.
- The forecasts performed by the entity contain a number of significant judgments and estimates, including probabilities of achieving development milestones based on industry standards and an entityspecific discount factor
- The high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating the audit evidence obtained related to the valuation of the intangible asset and management's assumptions

How our audit addressed the key audit matter

We assessed indicators for potential impairment by reviewing minutes of management, Board of Directors and board committee meetings, performed inquiry with management concerning the ongoing progress of clinical trials, and reviewed external communications, including press releases, other public filings and public communications coming from direct competitors, and considered results of subsequent event procedures performed.

We assessed the reasonableness of key inputs included in the valuation models used by management to determine the recoverable amounts of intangible assets and recalculated the headroom.

We assessed the sensitivity of the FVLCOD models for each of the licenses by assessing the key assumptions used, including the discount factor, over the forecasted period.

We reviewed the budget approved by the Board of Directors which included continued funding for ongoing and new clinical trials for the entity's licenses.

We inquired of management as to whether the progress of clinical trials was satisfactory, discussions with regulatory authorities for new trials were progressing as planned, and enrolment status for ongoing clinical trials was taking place as expected.

We reviewed external analyst reports of the entity, which clinical trials was satisfactory, discussions with regulatory authorities for new trials were progressing as planned, and enrolment status for ongoing clinical trials was taking place as expected.

As a result of our procedures, we determined that the approach applied by management with regard to the carrying value of intangible assets were reasonable and supportable.

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 skepticism 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 communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, actions taken to eliminate threats or safeguards applied.

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.

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

PricewaterhouseCoopers SA

Luc Schulthess Audit expert Auditor in charge Sarah Ellsworth

Genève, 31 March 2022



Compensation Report of ObsEva SA for the year ended December 31, 2021

This compensation report has been prepared in accordance with the Federal Ordinance Against Excessive Compensation in Stock Exchange Listed Companies ("Ordinance"), effective as from January 1, 2014, and the SIX Swiss Exchange Directive on Information Related to Corporate Governance ("DCG"), effective as of October 1, 2014, as amended on April 1, 2016, July 1, 2017, May 1, 2018 and January 2, 2020. The Ordinance and DCG are applicable to ObsEva SA (the "Company") as from its Initial Public Offering ("IPO") on the Nasdaq Global Select Market in January 2017, and the subsequent listing of its shares on the SIX Swiss Exchange in July 2018, respectively.

A. GUIDING PRINCIPLES

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

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

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

B. ORGANIZATION AND COMPETENCIES

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

The Committee supports the Board in establishing and reviewing the Company's compensation strategy, guidelines and the performance targets. The Committee may also submit proposals to the Board in other compensation-related issues. For a more detailed description of the Committee, please refer to section 3 of the Corporate Governance Report on page 69.

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

- a) during the first semester of each business year, to review and make recommendations to the Board regarding the proposals to be made to the Annual General Meeting of Shareholders ("AGM") of such year, as required under Swiss law, regarding the maximum aggregate compensation, on a prospective basis, for (i) the Board Members for the period from the AGM of such year until the AGM of the following year and (ii) the Executive Officers for the following business year; and
- b) in the first months of each business year, to review and make recommendations to the Board, based on the maximum aggregate compensation approved by the shareholders, regarding (i) the fixed cash compensation to be paid to the Board Members for the period from the AGM of such year until the following AGM; (ii) the variable cash compensation to be paid to the Executive Officers for the previous business year; (iii) the fixed cash compensation to be paid to the Executive Officers for the current business year; (iv) the grant of equity instruments to the Board Members for the current business year as part of their fixed non-cash compensation; and (v) the grant of equity instruments to the Executive Officers for the current business year as part of their variable non-cash compensation.

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

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

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

Maximum Aggregate Compensation subject to Shareholders' Approval

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

C. COMPENSATION COMPONENTS

Compensation Review Process of the Committee and General Philosophy

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

For the business year 2021 and 2020, the peer groups used for benchmark purposes were composed of:

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

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

Board of Directors Members Annual Cash Compensation

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

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

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

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

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

Executive Committee Members Annual Cash Compensation

The annual cash compensation of the Executive Officers consists of fixed and variable compensation elements.

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

Variable compensation comprises performance-related cash bonuses that are based on target bonuses which could be of 40% or 50% of the base salary, depending on the Executive Officer's position and level of responsibility, and as determined under the review process of the Committee and approved by the Board. Actual amount of cash bonus awarded for a specific year to an Executive Officer ranges from 50% to 150% of the target bonus for such Executive Officer, subject to such Executive Officer continued employment at the time the cash bonus is paid. Adjustment rate applied to target bonus of an Executive Officer is determined at the beginning of every year based on the Company's general performance and the Executive Officer individual performance for the previous business year, which performance is being assessed based on annual corporate and individual objectives. The Company doesn't use specific metrics to calculate the adjustment rates, which are determined at the sole and full discretion of the Committee and subject to Board approval. The average adjustment rate to target bonuses of Executive Officers was approximately 80% for the business year 2020, and was of approximately 107% for the business year 2021, as a result of the Company's general performance.

For both 2021 and 2020, on average, variable cash compensation represented approximately 29% and 24%, respectively, of the total cash compensation of the Executive Officers, or 35% and 26%, respectively, of their fixed cash compensation.

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

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

Equity incentive plans

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

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

Under 2013 EIP, the Company has granted the Beneficiaries non-voting shares that were converted into common shares upon completion of the Company's IPO in January 2017. The Company has stopped granting equity instruments under the 2013 EIP in 2016, and all common shares remaining outstanding under the 2013 EIP vested in 2020. Under 2017 EIP, the Company has been granting stock-options to the Beneficiaries.

The grant of equity instruments under 2013 EIP or 2017 EIP is at the discretion of the Board, which has delegated authority to the Committee and, collectively, to certain Executive Officers to grant equity instruments under certain circumstances to new joiners that are not Board Members or Executive Officers, and subject to semi-annual reporting to the Committee when grants are approved by such Executive Officers.

The Board, the Committee or the designated Executive Officers, depending on the delegation of competences, determine grant, vesting, exercise and forfeiture conditions. In particular, they may provide for continuation, acceleration or removal of vesting and exercise conditions, for payment or grant of compensation based upon assumed target achievement, or for forfeiture, in each case in the event of pre-determined events such as a change-of-control or termination of an employment or mandate agreement. Key factors considered by the Board when approving grants of equity instruments include the amount of outstanding authorized or conditional share capital approved by shareholders. The Company may procure the required shares through purchases in the market, either directly or through companies controlled by it, or by issuing new shares. The Board has the authority to amend 2013 EIP and 2017 EIP.

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

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

Value of equity instruments granted in 2021 and 2020 represented approximately 67% and 53%, respectively, of the total compensation of the Board Members and 53% and 64%, respectively, of the total compensation of the Executive Officers.

Indirect benefits

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

Loans, credits and guarantees

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

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

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

Article 32: Compensation Principles

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

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

performance targets. Long-term variable compensation elements shall be governed by performance metrics that take into account strategic and/or financial objectives, as well as retention elements.

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

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

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

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

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

Article 33: Loans, credits and retirement benefits

Subject to other decision from the general meeting of shareholders, the Company is not allowed to grant loans or credit facilities to Board Members or Executive Officers.

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

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

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

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

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

D. COMPENSATION FOR PERIODS UNDER REVIEW (audited)

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

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

Compensation of the Board Members for the financial years 2021 and 2020

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

	First				
Name	Appointment	Elected until	Board	AC (1)	CNCGC (2)
Frank Verwiel	2016	2022	Chair	Member	-
Brian O'Callaghan	2021	2022	Member, CEO	_	_
Brian o Canagnan	2021	2022	Since Dec 1, 2020	_	-
Ernest Loumaye	2012	2022	Member, CEO	_	_
Efficie Edullaye	2012	2022	until Dec 1, 2020		-
Annette Clancy	2013	2022	Member	-	Chair
Anne VanLent	2021	2022	Member	Chair	-
Catarina Edfjäll	2021	2022	Member	-	Member
Ed Mathers	2016	2022	Member	Member	Member
Jacky Vonderscher	2013	2022 ⁽³⁾	Member	-	-
The following members did i	not stand for reelection	at the AGM 2021:			
Barbara Duncan	2016	2021	Member	Chair	-
Jim Healy	2013	2021	Member	-	Member
Rafaèle Tordjman	2013	2021	Member	-	Member

⁽¹⁾ Audit Committee

The compensation received by the Board Members for the financial year 2021 in US dollars, the functional currency of the Company, and as converted in Swiss francs according to an USD/CHF exchange rate of 0.913846 corresponding to the average USD/CHF exchange rate for the year 2021, was as follows:

(in USD thousand	- '

Name	Cash-based comp.	Social charges(1)	Pension contrib.	Equity granted(2)	Total comp.
Frank Verwiel	78	14	-	72	164
Ernest Loumaye	55	7	-	72	134
Annette Clancy	55	7	-	72	134
Anne VanLent	33	7	-	112	152
Barbara Duncan	22	9	-	72	103
Catarina Edfjäll	22	13	-	116	151
Ed Mathers	55	12	-	72	139
Jim Healy	19	8	-	72	99
Rafaèle Tordjman	19	8	-	72	99
Jacky Vonderscher	35	4	-	72	111
Total	393	89	-	804	1,286

 $^{^{(2)}}$ Compensation, Nominating and Corporate Governance Committee

⁽³⁾ Jacky Vonderscher stepped down from his mandate on November 19, 2021.

(in	CUE	thousands	١
un	(Hr	tnousanas	1

Name	Cash-based comp.	Social charges(1)	Pension contrib.	Equity granted ⁽²⁾	Total comp.
Frank Verwiel	71	13	-	66	150
Ernest Loumaye	50	6	-	66	122
Annette Clancy	50	6	-	66	122
Anne VanLent	30	6	-	102	138
Barbara Duncan	20	8	-	66	94
Catarina Edfjäll	20	12	-	106	138
Ed Mathers	50	11	-	66	127
Jim Healy	17	7	-	66	90
Rafaèle Tordjman	17	7	-	66	90
Jacky Vonderscher	32	4	-	66	102
Total	357	80	-	736	1,173

⁽¹⁾ Include social charges on cash-based compensation and fair value of equity instruments granted

The compensation received by the Board Members for the financial year 2020 in US dollars, the functional currency of the Company, and as converted in Swiss francs according to an USD/CHF exchange rate of 0.938965 corresponding to the average USD/CHF exchange rate for the year 2020, was as follows:

(in USD thousands)

(,					
Name	Cash-based comp.	Social charges(1)	Pension contrib.	Equity granted(2)	Total comp.
Frank Verwiel	78	14	-	74	166
Annette Clancy	55	7	-	74	136
Barbara Duncan	55	12	-	74	141
Ed Mathers	55	12	-	74	141
Jim Healy	48	11	-	74	133
Rafaèle Tordjman	48	11	-	74	133
Jacky Vonderscher	40	5	-	74	119
Total	379	72	-	518	969

(in CHF thousands)

Name	Cash-based comp.	Social charges(1)	Pension contrib.	Equity granted(2)	Total comp.
Frank Verwiel	73	13	-	69	155
Annette Clancy	52	7	-	69	128
Barbara Duncan	52	11	-	69	132
Ed Mathers	52	11	-	69	132
Jim Healy	45	10	-	69	124
Rafaèle Tordjman	45	10	-	69	124
Jacky Vonderscher	38	5	-	69	112
Total	357	67	-	483	907

 $^{^{(1)}}$ Include social charges on cash-based compensation and fair value of equity instruments granted

Brian O'Callaghan, who served as Chief Executive Officer since December 1, 2020, was employee during the financial years 2020 and 2021 and received no additional compensation for his services as member of the Board.

Ernest Loumaye, who served as Chief Executive Officer until December 1, 2020, was employee during the financial year 2020 and received no additional compensation for his services as member of the Board in business year 2020.

The compensation of USD 1.3 million received by the Board Members in business year 2021 was made of fixed elements, and increased by USD 0.3 million compared to the business year 2020 due to the appointment of new Board Members at the AGM 2021.

⁽²⁾ Fair value of equity instruments granted during the period, as determined under IFRS 2

⁽²⁾ Fair value of equity instruments granted during the period, as determined under IFRS 2

The total compensation received by the Board Members during the period from the AGM 2020 until the AGM 2021 amounted to USD 1.1 million, and was within the maximum aggregate compensation of USD 2.5 million approved for the period by the AGM 2020.

Compensation of the Executive Committee for the financial years 2021 and 2020

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

Name	Function	Appointment	Term
Brian O'Callaghan	Chief Executive Officer	2020(1)	-
Ernest Loumaye	Chief Executive Officer	2013	2020(1)
David Renas	Chief Financial Officer	2021(2)	2022
Tim Adams	Chief Financial Officer	2017	2020 (2)
Elizabeth Garner	Chief Medical Officer	2019	-
Jean-Pierre Gotteland	Chief Scientific Officer and Head of R&D	2015	-
Clive Bertram	Chief Commercial Officer	2021 ⁽³⁾	-
Wim Souverijns	Chief Commercial Officer	2018	2021 ⁽³⁾
Luigi Marro	Chief Transformation Officer	2021	-
Fabien de Ladonchamps	Chief Financial Officer, <i>ad interim</i> Chief Administrative Officer	2020 ⁽²⁾ 2021 ⁽²⁾	2021 ⁽²⁾ -

⁽¹⁾ On December 1, 2020, Brian O'Callaghan was appointed Chief Executive Officer to succeed to Ernest Loumaye.

The compensation received by the Executive Officers for the financial year 2021 in US dollars, the functional currency of the Company, and as converted in Swiss francs according to an USD/CHF exchange rate of 0.913846 corresponding to the average USD/CHF exchange rate for the year 2021, was as follows:

(in USD thousands) Name	Cash-based comp.	Social charges ⁽¹⁾	Pension contrib.	Equity granted(2)	Total comp.
Brian O'Callaghan	992	123	9	730	1,854
Other executives ⁽³⁾	3,010	538	164	3,939	7,651
Total	4,002	661	173	4,669	9,505

(in CHF thousands) Name	Cash-based comp.	Social charges(1)	Pension contrib.	Equity granted(2)	Total comp.
Brian O'Callaghan	907	112	8	667	1,694
Other executives(3)	2,751	491	149	3,600	6,991
Total	3,658	603	157	4,267	8,685

⁽¹⁾ Include social charges on cash-based compensation and fair value of equity instruments granted

⁽²⁾ On January 4, 2021, David Renas was appointed Chief Financial Officer, to succeed to Fabien de Ladonchamps who was appointed Chief Administrative Officer, after his previous appointment as Chief Financial Officer, ad interim, to succeed to Tim Adams in April 2020.

⁽³⁾ On May 10, 2021, Clive Bertram was appointed Chief Commercial Officer, to succeed to Wim Souverijns.

⁽²⁾ Fair value of equity instruments granted during the period, as determined under IFRS 2

⁽³⁾ Include compensation received by Wim Souverijns up to his departure from the Executive Committee, and David Renas, Clive Bertram and Luigi Marro, as from their appointments to the Executive Committee on January 4, May 10 and October 1, 2021, respectively.

The compensation received by the Executive Officers for the financial year 2020 in US dollars, the functional currency of the Company, and as converted in Swiss francs according to an USD/CHF exchange rate of 0.938965 corresponding to the average USD/CHF exchange rate for the year 2020, was as follows:

(in USD thousands) Name	Cash-based comp.	Social charges ⁽¹⁾	Pension contrib.	Equity granted(2)	Total comp.
Brian O'Callaghan(3)	70	404	1	3,045	3,520
Ernest Loumaye(3)	753	183	37	1,656	2,629
Other executives(4)	1,999	383	122	2,457	4,961
Total	2,822	970	160	7,158	11,110

(in CHF thousands) Name	Cash-based comp.	Social charges(1)	Pension contrib.	Equity granted(2)	Total comp.
Brian O'Callaghan(3)	66	379	1	2,859	3,305
Ernest Loumaye(3)	707	172	35	1,555	2,469
Other executives ⁽⁴⁾	1,877	360	114	2,307	4,658
Total	2,650	911	150	6,721	10,432

⁽¹⁾ Include social charges on cash-based compensation and fair value of equity instruments granted

The compensation of USD 9.5 million received by the Executive Officers in business year 2021 was made of approximately 66% of variable elements and 34% of fixed elements, and decreased by USD 1.6 million compared to business year 2020, mainly due to the equity granted for the appointment of the new Chief Executive Officer in the business year 2020.

The total compensation of USD 9.5 million received by the Executive Officers for the year ended December 31, 2021 was within the maximum aggregate compensation of USD 13.0 million approved for the year by the AGM 2020.

E. SHARE OWNERSHIP INFORMATION (audited)

Board of Directors

The Board Members held the following equity instruments as of December 31, 2021(1).

	Common Shares			Stock-options		
Name	Vested	Unvested	Total	Vested	Unvested	Total
Frank Verwiel	45,500	-	45,500	108,185	4,095	112,280
Ernest Loumaye	3,915,450	-	3,915,450	785,628	360,222	1,145,850
Annette Clancy	97,500	-	97,500	101,685	4,095	105,780
Anne VanLent	-	-	-	9,555	39,585	49,140
Catarina Edfjäll	-	-	-	8,190	40,950	49,140
Ed Mathers ⁽²⁾	4,586,563	-	4,586,563	122,685	4,095	126,780
Total	8,645,013	-	8,645,013	1,135,928	453,042	1,588,970

⁽¹⁾ Excluding Brian O'Callaghan, CEO, whose holdings are listed under Executive Committee

 $^{^{(2)}}$ Fair value of equity instruments granted during the period, as determined under IFRS 2

⁽³⁾ On December 1, 2020, Brian O'Callaghan was appointed Chief Executive Officer to succeed to Ernest Loumaye who stepped down from the Executive Committee on the same date.

⁽⁴⁾ Include compensation received by Tim Adams up to his departure from the Executive Committee, and Fabien de Ladonchamps, as from his appointment to the Executive Committee, as from April 10, 2020.

⁽²⁾ Includes shares held directly and indirectly through vehicles controlled by the Director

The Board Members held the following equity instruments as of December 31, 2020(1):

	Common Shares			Stock-options		
Name	Vested	Unvested	Total	Vested	Unvested	Total
Frank Verwiel	45,500	-	45,500	78,156	9,554	87,710
Annette Clancy	97,500	=	97,500	71,656	9,554	81,210
Barbara Duncan	-	-	-	97,656	9,554	107,210
Ed Mathers (2)	4,586,563	-	4,586,563	92,656	9,554	102,210
Jim Healy (2)	4,749,623	=	4,749,623	92,656	9,554	102,210
Rafaèle Tordjman	-	-	-	92,656	9,554	102,210
Jacky Vonderscher	36,400	=	36,400	79,656	9,554	89,210
Total	9,515,586	-	9,515,586	605,092	66,878	671,970

 $^{^{(1)}}$ excluding Ernest Loumaye, CEO, whose holdings are listed under Executive Committee

Executive Committee

The Executive Officers held the following equity instruments as of December 31, 2021:

	Common Shares			Stock-options		
Name	Vested	Unvested	Total	Vested	Unvested	Total
Brian OʻCallaghan	-	-	-	401,450	1,775,512	2,176,962
David Renas ⁽¹⁾	-	-	-	-	400,000	400,000
Elizabeth Garner	-	-	-	282,481	373,522	656,003
Jean-Pierre Gotteland	136,500	-	136,500	260,828	260,922	521,750
Clive Bertram ⁽²⁾	-	-	-	-	400,000	400,000
Luigi Marro	-	-	-	-	400,000	400,000
Fabien de Ladonchamps ⁽¹⁾	146,500	-	146,500	156,084	212,936	369,020
Total	283,000		283,000	1,100,843	3,822,892	4,923,735

⁽¹⁾ David Renas was appointed to the Executive Committee on January 4, 2021 as Chief Financial Officer, to succeed to Fabien de Ladonchamps who was appointed Chief Administrative Officer on same date.

The Executive Officers held the following equity instruments as of December 31, 2020:

	Common Shares			Stock-options		
Name	Vested	Unvested	Total	Vested	Unvested	Total
Brian O'Callaghan(1)	-	-	-	-	1,926,962	1,926,962
Ernest Loumaye ⁽¹⁾	3,915,450	-	3,915,450	875,144	762,488	1,637,632
Tim Adams ⁽²⁾	N/A	N/A	N/A	-	-	-
Elizabeth Garner	-	-	-	95,980	420,023	516,003
Jean-Pierre Gotteland	136,500	-	136,500	124,140	257,610	381,750
Wim Souverijns	4,150	-	4,150	104,167	275,833	380,000
Fabien de Ladonchamps ⁽²⁾	146,500	-	146,500	58,620	200,400	259,020
Total	4,202,600	-	4,202,600	1,258,051	3,843,316	5,101,367

⁽¹⁾ Brian O'Callaghan was appointed to the Executive Committee on December 1, 2020, to succeed to Ernest Loumaye who stepped down from the Executive Committee on the same date.

⁽²⁾ includes shares held directly and indirectly through vehicles controlled by the Director

⁽²⁾ Clive Bertram was appointed to the Executive Committee on May 10, 2021 as Chief Commercial Officer, to succeed to Wim Souverijns who stepped down from the Executive Committee on June 30, 2021.

⁽²⁾ Fabien de Ladonchamps was appointed to the Executive Committee on April 10, 2020, to succeed to Tim Adams who stepped down from the Executive Committee on the same date.

Report from the Auditor on the Compensation Report of ObsEva SA

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

We have audited the accompanying remuneration report of ObsEva SA for the year ended 31 December 2021. The audit was limited to the information according to articles 14-16 of the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance) contained in the sections labelled 'audited' on pages 146 to 157 of the remuneration report.

Board of Directors' responsibility

The Board of Directors is responsible for the preparation and overall fair presentation of the remuneration report in accordance with Swiss law and the Ordinance against Excessive Compensation in Stock Exchange Listed Companies (Ordinance). The Board of Directors is also responsible for designing the remuneration system and defining individual remuneration packages.

Auditor's responsibility

Our responsibility is to express an opinion on the remuneration report. We conducted our audit in accordance with Swiss Auditing Standards. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the remuneration report complies with Swiss law and articles 14–16 of the Ordinance.

An audit involves performing procedures to obtain audit evidence on the disclosures made in the remuneration report with regard to compensation, loans and credits in accordance with articles 14–16 of the Ordinance. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatements in the remuneration report, whether due to fraud or error. This audit also includes evaluating the reasonableness of the methods applied to value components of remuneration, as well as assessing the overall presentation of the remuneration report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Opinion

In our opinion, the remuneration report of ObsEva SA for the year ended 31 December 2021 complies with Swiss law and articles 14-16 of the Ordinance.

PricewaterhouseCoopers SA

Luc Schulthess Audit expert Auditor in charge Sarah Ellsworth

Genève, 31 March 2022

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 ongoing and future trials of linzagolix, ebopiprant and nolasiban;
- our or our collaborators' ability to obtain and maintain regulatory approval of our product candidates, including linzagolix, ebopiprant and nolasiban, in any of the indications for which we plan to develop them, and any related restrictions, limitations or warnings in the label of an approved product;
- our ability to continue as a going concern and to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our product candidates, and the terms on which we are able to raise that additional capital;
- our plans to research, develop and commercialize our product candidates;
- the timing of our regulatory filings for our product candidates;
- the clinical utility of our product candidates;
- the size and growth potential of the markets for our product candidates;
- · our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- the timing and amount of milestone and royalty payments we are required to make under our license agreements;
- our ability to attract and retain qualified employees and key personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the activities of our competitors and the success of competing therapies that are or become available;
- our plans to in-license or acquire additional product candidates;
- how long we will qualify as an emerging growth company or a foreign private issuer;
- our estimates regarding future revenue, expenses and needs for additional financing;
- · our ability to build our commercialization organization;
- · the duration, severity and impact on our operations and clinical trials of the COVID-19 pandemic;
- · regulatory developments in the United States and foreign countries; and
- · other risks and uncertainties, including those listed in this section of this Annual Report.

You should refer to the section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report 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 and have filed as exhibits to 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.

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

This Annual Report 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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