OvaScience, Inc.
Form 10-K
February 27, 2014

Use these links to rapidly review the document
TABLE OF CONTENTS
Index to Consolidated Financial Statements of OvaScience, Inc.

Table of Contents

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-K

**(Mark One)**

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

**For the fiscal year ended December 31, 2013**

**OR**

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

**For the transition period from to**
**Commission File Number: 001-35890**

# OVASCIENCE, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **45-1472564** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification Number) |
| **215 First Street, Suite 240 Cambridge, Massachusetts** | **02142** |
| (Address of Principal Executive Offices) | (Zip Code) |

Registrant's telephone number, including area code: **(617) 500-2802**

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

| **Title of each class** | **Name of Each Exchange on Which Registered** |
|---|---|
| Common Stock, par value $0.001 per share | The NASDAQ Stock Market LLC |

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý

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

| Large accelerated filer o | Accelerated filer ý | Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting companyo |
|---|---|---|---|

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

Aggregate market value of voting stock held by non-affiliates of the registrant as of June 28, 2013 (the last day of the registrant's second fiscal quarter of 2013) was: $97.0 million

As of January 31, 2014, there were 18,563,215 shares of the registrant's Common Stock, par value $0.001 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the information required by Part III of Form 10-K will appear in the registrant's definitive proxy statement on Schedule 14A for the 2014 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

Table of Contents

**TABLE OF CONTENTS**

Table of Contents

**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K and the information incorporated by reference in this Annual Report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, or Exchange Act, regarding our strategy, future, operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management. You can identify these forward-looking statements by their use of words such as "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. You also can identify them by the fact that they do not relate strictly to historical or current facts. There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. For a description of these risks and uncertainties, please refer to the section entitled "Risk Factors" in this Annual Report and any other risk factors set forth in any information incorporated by reference in this Annual Report. While we may elect to update forward-looking statements wherever they appear in this Annual Report or in the documents incorporated by reference in this Annual Report, we do not assume, and specifically disclaim, any obligation to do so, whether as a result of new information, future events or otherwise.

**PART I**

**Item 1.** ***Business.***

***Overview***

OvaScience is a global life science company focused on the discovery, development, and commercialization of new fertility treatments. Our patented technology is based on egg precursor cells ("EggPC[SM]"), which are found in the outer layer of a woman's own ovaries. The recent discovery of EggPCs countered a long-held medical belief that women are born with a set number of eggs, thereby enabling new possibilities in the treatment of female infertility.

Our portfolio of fertility treatment options takes advantage of proprietary methods to identify, isolate and concentrate EggPCs from the patient's ovarian tissue. By applying our EggPC technology platform in unique ways, we are developing new fertility treatment options that are designed to improve egg quality and in vitro fertilization ("IVF"). These treatment options under development include the following:

AUGMENT[SM] aims to improve egg quality and potentially increase the success of IVF by transferring mitochondria from a woman's EggPCs to her mature egg during IVF. We plan to introduce AUGMENT in 2014 in at least four international regions.

OvaPrime[SM] is designed to boost a woman's egg reserve by transferring the EggPCs from the outer layer of her ovary (outer cortex) back into the ovary prior to IVF. We expect to introduce OvaPrime outside of the United States in 2015.

OvaTure[SM] seeks to mature a woman's own EggPCs into fertilizable eggs without the need for hormone hyperstimulation.

OvaXon[SM] is a joint venture with Intrexon Corporation, which is focused on developing new applications to prevent inherited diseases by gene editing EggPCs for applications in human and animal health.

We believe our EggPC technology has the potential to make significant advances in the field of fertility because it may enable us to address poor egg and embryo quality due to age and other causes. We believe our EggPC technology could improve IVF by:

*Increasing live birth rates and reducing the number of IVF cycles.* By improving egg quality, we believe we may be able to increase the percentage of IVF treatments which result in live births and, in so doing, reduce the number of IVF cycles required.

*Reducing the incidence of multiple births.* By generating higher quality eggs, we believe our EggPC technology may allow for the transfer of fewer embryos per IVF cycle and, as a result, lower the incidence of multiple births and the associated complications for the mother and baby.

*Lowering the overall cost of IVF.* If we reduce the number of IVF cycles required for a live birth and the incidence of multiple births, we believe our fertility treatment options may also lower the overall costs associated with IVF.

*Reducing the need for hormonal hyperstimulation.* We are designing our OvaTure technology to mature EggPCs into fertilizable eggs *in vitro*. If successful, OvaTure could reduce, or possibly eliminate, the need for hormonal hyperstimulation for the maturation of multiple oocytes prior to egg retrieval in the IVF process.

*Preventing inherited diseases.* By applying gene editing techniques to EggPCs, we believe we may be able to prevent the transmission of inherited diseases, such as Huntington's Disease, in future generations.

**AUGMENT**

The Company's first fertility treatment is AUGMENT℠, which we plan to introduce to international IVF clinics in 2014 through our AUGMENT Centers of Excellence ("ACE") access program. The goal is for physicians to gain experience using AUGMENT and to generate data. In 2014, we expect to establish ACE clinics in at least four international regions, which we anticipate will result in 40 to 60 AUGMENT cycles this year. By year end 2014, we expect to transition these ACE clinics to commercial centers. We are targeting international regions that combine elements of the following key criteria:

Key opinion leaders / high volume IVF clinics

High quality IVF labs

Out-of-pocket pay and high average cost per cycle

Donor egg restrictions

As part of AUGMENT, a woman's eggs may be rejuvenated by injecting mitochondria prepared from her own EggPCs into her egg during IVF. This has the potential to improve egg quality and thereby increase the success of IVF. With higher quality eggs, there is also the potential to reduce the need for multiple embryo transfers, which can result in a lower incidence of conceiving multiples (twins or triplets) and resulting complications.

AUGMENT complements the existing standard of practice for an IVF cycle. Prior to hormone hyperstimulation, a small tissue biopsy is taken from the outer layer of the ovary, where the EggPCs reside. Our proprietary process identifies and isolates the patient's own EggPCs followed next by the removal of her own mitochondria within the EggPCs. The women's own mitochondria are then injected into her egg at the time of intracytoplasmic sperm injection ("ICSI").

The development of assisted reproductive technologies has a long history of innovation based on techniques and tools developed in IVF clinics around the world. In fact, all of the major innovations in fertility treatment have been developed in countries outside of the United States, including IVF and ICSI, and more recently, time-lapse imaging, oocyte vitrification and in vitro maturation of oocytes. This is a main reason why the IVF market is predominantly located outside of the United States where 90% of the 1.6 million annual IVF cycles are performed. Given the market size, as well as the innovative history and acceptance of new fertility methods and technologies internationally, we have always had a strategy to make our fertility treatments available to patients worldwide. We plan to introduce our first fertility treatment, AUGMENT, through a limited commercial launch in international IVF clinics in 2014, and we are preparing to launch a second fertility treatment using this approach in 2015. We believe that we will be able to introduce AUGMENT into these regions without pre-market review and approval, but if applicable regulatory bodies disagree, we may abandon AUGMENT in that region or suffer significant delay or expense in seeking necessary approvals. To gain clinical experience with AUGMENT in the United States ahead of a commercial launch, in December 2012, we initiated a study of AUGMENT in the United States. In September 2013, we received an "untitled" letter from the FDA advising us to file an Investigational New Drug (IND) application for AUGMENT. Following the receipt of the FDA letter, we chose to suspend enrollment in the U.S. study. We anticipate having further discussions in 2014 with the FDA to present details on AUGMENT and to determine the appropriate path forward.

**Scientific Rationale and Supporting Studies**

Fertility decreases with age, and the energy levels in the egg are believed to play a major role in this decrease. After fertilization, the early stage embryo requires energy for cell division. Inadequate energy results in a failure of the newly formed embryo to develop. We believe that the energy level in a

woman's eggs may be enhanced, and the success of embryo development improved, by the insertion of mitochondria prepared from the woman's own EggPCs into her egg at the time of fertilization.

Studies published in peer reviewed medical journals, including *Human Cell* (2004), *Electronic Journal of Biology* (2005), *Reproduction Research* (2006) and *Reproductive Biomedicine* (2011), provided the first evidence of the effects of mitochondria on egg quality. In these studies, which involved a number of species, including bovine, porcine, rabbit and murine, third party scientists demonstrated that the addition of mitochondria to eggs with mitochondrial deficiencies increased cellular energy levels, egg quality and the likelihood of fertilization and healthy live births.

In human studies published in the peer reviewed medical journals *Molecular Human Reproduction* (1998) and *Human Reproduction* (2001), researchers transfused cytoplasm from the eggs of younger women donors into the eggs of older women who failed multiple IVF cycles. The cytoplasm is the liquid portion of a human cell that surrounds the nucleus and contains the egg's mitochondria. Each of these studies increased the rates of fertilization, embryo development, implantation and pregnancy for the older women whose eggs were transfused. Of the approximately 30 women included in the study who had previously failed two to five IVF cycles, 13 achieved pregnancies and delivered 16 healthy offspring. Additional published studies showed similar success rates and rates ranging from 25%-44% were reported for women who had previously failed multiple cycles and had not achieved a pregnancy.

These studies served as the basis for the scientific hypothesis that the addition of healthy donor mitochondria might be used to improve the quality of eggs with mitochondrial deficiencies. However, following publication of these initial human studies, many scientists and clinicians questioned the long term safety of the use of third party donor mitochondria in humans because mitochondria contain DNA. Mitochondria produce energy in all cells of the body. Unlike nuclear DNA, contained in the nucleus, which is inherited from two different people, half from the biological mother and half from the biological father, mitochondrial DNA is inherited solely from the mother. As a result, while the process appeared to be safe with respect to the fertilized egg and the patient, scientists and clinicians questioned whether the presence of mitochondria, and therefore mitochondrial DNA, from two different women might result in health problems later in the child's life. In response to these concerns, the FDA informed sponsors and other researchers that the use of cells in therapy involving the transfer of third party genetic materials, including mitochondrial DNA, requires submission of an investigational new drug application, or IND.

The approach we are using with AUGMENT builds on these studies but uses a woman's own mitochondria from her own EggPCs to improve her fertility instead of third-party donor mitochondria. While all cells contain mitochondria, we believe the mitochondria from cells involved in reproduction, known as germline cells, as opposed to other cells in the body, known as somatic cells, are the ideal source of mitochondria for transfer to improve egg quality. This is because somatic cells are exposed to environmental toxins and cell waste products that may cause mutations or deletions in mitochondrial DNA that will be passed along to subsequent cells. These mutations and deletions can decrease the quality of the mitochondria and the ability to produce energy. In contrast, the mitochondrial DNA from germline cells contain minimal mutations and deletions. Because the mitochondria within an egg are the template for all subsequent cell reproduction in the offspring, we believe that it is necessary to use high-quality mitochondria to improve egg quality.

Based on the above studies, the approach we are using with AUGMENT is to use germline mitochondria from the patient's own EggPCs to improve the quality of the patient's eggs. By using mitochondria from the woman's own EggPCs, instead of from a third party donor, AUGMENT does not involve the transfer of third party genetic material.

**AUGMENT Steps**

We are designing AUGMENT to use mitochondria from a woman's own EggPCs in IVF procedures to improve the energy and quality of the woman's eggs. The following is a summary of the

process that we are using for our ACE program to prepare the patient's own mitochondria for insertion into one of her own mature eggs during IVF:

*Obtain Ovarian Tissue:* Ovarian surface tissue will be obtained by the IVF clinic prior to the AUGMENT procedure.

*Identify and Isolate EggPCs:* Ovarian tissue will be washed, digested with enzymes, and mechanically dissociated to form a solution containing single cells. EggPCs will be separated from the other cells in the single cell solution by a process known as fluorescence activated cell sorting, or FACS. EggPCs can then be processed for isolation of mitochondria (described below) or frozen and stored in vials until the day of egg fertilization in the IVF process.

*Prepare Mitochondria from EggPCs:* EggPCs will be disrupted mechanically and mitochondria isolated by differential centrifugation. Using a standard quantification method, we will assess the number of mitochondria for use in the IVF process.

Each of the steps described above follows routine clinical laboratory processes and procedures, and none of these steps requires new methods, equipment or technologies to execute. Specifically, the process of isolating the EggPCs will be performed using commercially available separation techniques. We continue to optimize the efficiency of the steps that comprise the AUGMENT process and reduce the anticipated cost of the procedure.

As we stated in August of 2013, we have contracted with a global third party supplier that is compliant with good tissue practices, or cGTPs, to perform the AUGMENT process from the step of isolating the EggPCs to the step of concentrating the mitochondria in ICSI fertilization buffer. In the future, we may establish our own cGTP-compliant facility and perform these steps in the process ourselves, with the goals of maintaining greater control of the process and reducing the cost of manufacturing.

**Development Pipeline**

We have a pipeline of fertility treatments under development, all based on the same EggPC technology. Collectively, it is our goal to offer multiple options so physicians can help patients select the optimal treatment, which could include new solutions for age-related infertility, diminished ovarian reserve, premature ovarian failure, polycystic ovary syndrome, or other conditions affecting fertility.

OvaPrime[SM], the latest addition to our pipeline, is designed to boost a woman's egg reserve using her own EggPCs. Similar to AUGMENT, OvaPrime may be integrated into the IVF cycle starting with a small tissue biopsy of the outer layer of the ovary, where the EggPCs reside. Our proprietary process isolates a woman's own EggPCs, which are next delivered back into the patient's ovaries, where we believe they can mature into fertilizable eggs prior to a standard IVF procedure. We will conduct further studies and continue treatment optimization in 2014 in anticipation of a commercial launch of OvaPrime in 2015 outside of the United States.

OvaTure[SM] seeks to create mature fertilizable eggs *ex vivo* from a woman's own EggPCs without the need for hormone hyperstimulation. Importantly, OvaTure may provide a new treatment option for women with compromised eggs, who are unable to make eggs, or who may be unwilling or unable to undergo hormone hyperstimulation, such as women diagnosed with cancer who seek to preserve their future fertility. To accelerate development, we entered into a collaboration with Intrexon to access their industrialized synthetic biology platform with the goal of completing preclinical studies within two years. We expect we may need to obtain regulatory approval of OvaTure in both the United States and other international markets prior to commercialization. OvaScience owns exclusive human commercial rights for OvaTure in humans.

OvaScience and Intrexon formed a joint venture in December 2013 called OvaXon to develop an innovative approach to the prevention of genetic disease and animal health. The collaboration

combines Intrexon's synthetic biology capabilities with OvaTure to prevent the propagation of inherited diseases such as mitochondrial and other genetic disorders in future generations. Each party contributed $1.5 million to OvaXon and has a 50% equity interest. Research and development costs and profits will be split equally. The joint venture anticipates initially targeting the animal health market, which is estimated to grow to $19 billion by 2018 according to consensus estimates for animal divisions of Elanco, Merck, Sanofi, and Zoetis.

Marketdata Enterprises, Inc., Tampa, Florida, a publisher of independent market research studies, estimates that the U.S. infertility services market reached approximately $4 billion in 2008. According to the 2005 *Fertility, Family Planning and Reproductive Health of U.S. Women Report* prepared by the U.S. Centers for Disease Control and Prevention, or CDC, approximately 1.2 million women sought infertility treatment in the United States in 2002. Additionally, 1.5 million women aged 15-44 are infertile, according to the 2011 Fertility Clinic Success Report, prepared by the CDC. We believe that our planned sales and marketing team would enable us to call on the clinics responsible for the majority of the IVF procedures performed in the United States annually. Due to demographics, earlier market adoption of IVF in the EU and other factors, we believe that the number of women seeking infertility treatment in the EU is substantially larger than in the United States, according to the European Society of Human Reproduction and Embryology public database as compared to U.S. CDC data.

*Egg Precursor Cells*

In 2004, one of our scientific founders, Jonathan Tilly, Ph.D., from the Vincent Center for Reproductive Biology at the Massachusetts General Hospital, or MGH, discovered the existence of EggPCs within the ovaries of adult mice. Subsequent research by Dr. Tilly demonstrated that these EggPCs also exist in human ovaries and have the potential to mature into eggs and, therefore, to replenish a woman's egg supply. This research demonstrated that these EggPCs might provide a source of fresh cellular components, such as mitochondria, that could potentially be used to enhance the quality of existing eggs.

Dr. Tilly discovered the existence of mouse EggPCs by staining the outer cell layer of the ovary using an antibody that binds specifically to a protein found on EggPCs called mouse VASA homologue. Following publication of this discovery in *Nature* in 2004, Dr. Tilly performed additional research, beginning in 2005, which demonstrated the existence of human EggPCs in adult human ovaries. In this research, Dr. Tilly replicated the results obtained with mouse tissue using human ovarian tissue. Dr. Tilly was able to isolate precursor cells in the ovaries of reproductive age women using an antibody that binds to the human VASA analogue protein, which is found on human EggPCs. Dr. Tilly also conducted an experiment in which human EggPCs were isolated *in vitro* and then grafted into female mouse hosts and matured *in vivo* into eggs that exhibited a genetic signature indicating the eggs could be fertilized. Dr. Tilly's research findings with respect to human EggPCs were published in the March 2012 issue of *Nature Medicine*.

Although this research has demonstrated the existence of EggPCs in human ovaries, and suggests that it may be possible to develop human EggPCs into mature, fertilizable eggs, research with respect to human EggPCs is a new and emerging field. As a result, there is ongoing debate regarding the role of EggPCs in human reproduction and whether EggPCs, when isolated from ovarian tissue, can be matured in the laboratory into fertilizable human eggs. We anticipate preclinical proof of concept that human EggPCs can be matured into fertilizable eggs in 2014.

We hold an exclusive license from MGH to issued patents and various patent applications directed to methods of identifying and isolating EggPCs, compositions comprising EggPCs and methods of using EggPCs to treat infertility and related disorders.

**Background**

Infertility is a widespread problem around the world. Infertility is the inability to achieve pregnancy after 12 consecutive months, or for those who are over 35 years of age, six consecutive months, of trying to conceive through regular unprotected intercourse. In 2011, the European Society for Human Reproduction, or ESHRE, the mission of which is to promote the understanding of reproductive biology and medicine, reported that the worldwide prevalence of infertility among women aged 20 to 44 was approximately 9%. According to the *2011 Assisted Reproductive Technology: Fertility Clinic Success Rates Report,* prepared by the CDC, approximately 7.4 million or 12% of women in the United States aged 15 to 44 had used infertility services at some point in their lives.

There are many steps in the process of natural conception. If any of them fails, a woman will not be able to conceive naturally. The steps are as follows:

The process begins when the brain signals the pituitary gland to send a hormone, known as follicle stimulating hormone, or FSH, to the ovaries, prompting the ovaries to prepare for egg ovulation. FSH stimulates a group of follicles, which are fluid filled sacs containing one egg each, to grow in the cortex of the ovary.

Over the next two weeks, the eggs mature and levels of estrogen, a hormone produced by the ovaries, increase.

As the estrogen levels increase, the pituitary gland produces less FSH. The production of luteinizing hormone, or LH, another hormone produced by the pituitary gland, is then triggered at mid-cycle.

The mid-cycle peak of LH signals the ovary to release a mature egg from its follicle in a process known as ovulation. The egg enters the fallopian tube and begins to travel through the tube into the uterus. The egg remains viable for about 24 hours.

For fertilization to occur, a sperm must locate and penetrate the egg while in the fallopian tube. If fertilization occurs, the fertilized egg, or embryo, continues to travel down the fallopian tube into the woman's uterus.

On approximately the seventh day following fertilization, the embryo develops specialized cells on its surface that enable it to attach, or implant, in the lining of the uterus.

Once attached, the embryo continues to grow and receives its blood supply from the mother through blood vessels that grow within the umbilical cord.

There are multiple reasons why the process described above might fail. The reasons attributable to female infertility include:

poor egg quality resulting from a woman's age or other causes;

ovulation disorders, including the inability, or reduced ability, to ovulate;

damage to the ovary caused by cancer or cancer treatments, such as chemotherapy;

problems with the uterus, for example, due to surgery or infection; and

a blocked or damaged fallopian tube.

According to a study published in the peer reviewed medical journal *Human Reproduction* (1996), the quality of a woman's eggs declines with age. In many instances, the decreased egg quality is the result of inadequate amounts of energy. Energy is required for all functions of the egg, especially during times of rapid cell division and early embryo growth. Cellular energy, known as adenosine triphosphate or ATP, is produced by mitochondria.

Table of Contents

Around the world, women are choosing to have children later in life. As reported in a study published in *Human Reproduction* (2004), a peer reviewed medical journal published on behalf of ESHRE, a woman's chance of conceiving naturally within one year decreases from approximately 75% at age 30 to 44% at age 40. According to the CDC, the average age for a woman having her first child was 25 in 2006, as compared to an average age of approximately 21 in 1970. While an increasing number of women are delaying childbearing and pregnancy until their late 30s and early 40s, current treatments often do not meet the needs of infertile women.

***Current Infertility Treatments***

Infertility treatments fall into two broad categories. The first category includes treatments that do not involve the retrieval or handling of an egg from a woman. The two most common types of treatments in this first category are fertility drugs and intrauterine insemination, or IUI. Fertility drugs, such as clomiphene, are administered to a woman to induce ovulation. IUI, also known as artificial insemination, is a procedure that involves placing sperm directly into the uterus. If these treatments are not successful, a couple often will turn to more advanced techniques in the category known as assisted reproductive technology, or ART. ART refers to any fertility treatment involving the handling of both eggs and sperm, including IVF.

IVF procedures typically involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, or *in vitro*, and returning them to the woman's body or donating them to another woman. Because an IVF procedure includes several steps, it is typically referred to as a cycle of treatment.

IVF is the most common type of ART. Approximately 99% of the ART procedures performed in the United States in 2012 involved IVF and similar dynamics are found in international markets. An IVF procedure typically begins with stimulation of the woman's ovaries by a combination of fertility medications in the hormonal hyperstimulation process. Then one or more eggs are taken from the woman's ovarian follicles and fertilized *in vitro*. In the final step, one or more embryos are transferred into the woman's uterus. These steps typically occur over a two week period. The IVF procedure also may be performed using eggs donated from another woman.

During an IVF procedure, fertilization of the egg can occur either by placing a drop of specially washed sperm on the egg and allowing the sperm to penetrate naturally or through a process called intracytoplasmic sperm injection, or ICSI. In an ICSI procedure, a single sperm is injected directly into a mature egg using a small needle to achieve fertilization. ICSI was originally developed for use in couples with severe male factor infertility. Today the procedure is widely used in IVF, even among couples without a diagnosis of male factor infertility. According to the Society of Assisted Reproductive Technologies, or SART, an organization of professionals dedicated to the practice of ART in the United States, ICSI was utilized in 67% of all IVF procedures performed in the United States in 2012. However, according to SART, only 17% of all patients using IVF in the same year had a diagnosis of male factor infertility.

ART and IVF are often categorized according to (1) whether the procedure uses a woman's own eggs or eggs from a donor and (2) whether the embryos used are newly fertilized, referred to as fresh, or previously fertilized, frozen and then thawed. According to data gathered by SART, the percentages of ART cycles performed in the United States in 2012 in these categories were as follows:

| Type of ART Cycle | % of Total ART Cycles |
|---|---|
| Fresh Nondonor | 56% |
| Frozen Nondonor | 20 |
| Fresh Donor | 6 |
| Frozen Donor | 5 |

Table of Contents

Although ART success rates have increased modestly over the last decade, these rates remain relatively low. According to the CDC, of the 163,039 ART cycles performed in the United States in 2011, only 47,818, or 29%, resulted in live births. Couples seeking to preserve a genetic match must use their own (nondonor) egg and sperm for treatments. However, these patients generally have lower success rates than patients using a third person's younger donor eggs, which typically come from women in their 20s or early 30s. According to the CDC, in 2011, 101,213 fresh nondonor ART cycles were started in the United States, of which 36,266, or 36%, led to a pregnancy and 29,598, or 29%, resulted in a live birth. In contrast, the CDC found that in 2011, 55% of the ART cycles in the United States using fresh donor eggs resulted in a live birth. As shown in the table below, according to a CDC report of 2010 data, IVF pregnancy success rates for women over age 35 remain relatively flat, regardless of the woman's age, when using donor eggs.

***Shortcomings of ART***

Current ART procedures have significant shortcomings. These include:

*Low live birth rates and high number of IVF cycles.* In a historical cohort study published in *Fertility and Sterility* (2010), an international peer reviewed journal for professionals who treat and investigate problems of infertility and human reproductive disorders, of the ART patients residing or treated in Massachusetts between 2004 and 2006, approximately 50% received two or more ART cycles, with approximately 25% receiving two cycles and approximately 13% receiving three cycles. In addition, according to this same study, the percentage of women who ultimately achieved a live birth using ART plateaued at approximately 54% after four or more cycles. The need for multiple ART cycles often takes an emotional and physical toll on the woman and significantly increases the costs of ART.

*High incidence of multiple births.* Another problem of IVF is that it entails increased risks of multiple pregnancies and births. In an IVF procedure, it is common practice to transfer several embryos into a woman's uterus in an effort to increase the success rate. However, multiple transfers are also responsible for a high multiple birth rate. According to the CDC, in 2010, there was a 30% rate of multiple births for ART pregnancies using fresh nondonor eggs in the United States. This rate is significantly higher than the 3% rate the CDC reports for multiple births from natural pregnancies in the general United States population. Multiple gestations and births result in increased risks and costs to mother and babies, including preterm birth and low birth weight.

*High cost of treatment.* The average cost to a patient in the United States for a single IVF/ICSI cycle is approximately $16,000, according to studies detailed in *Human Reproduction Update* (2010) and

Table of Contents

*Fertility and Sterility* (2009), as adjusted for inflation. However, a study published by Nachtigall *et al.* in *Fertility and Sterility* (2012) found that, depending on the IVF clinic, the cost of one treatment cycle can exceed $25,000. Since patients frequently require more than one cycle, the IVF cost per live birth can exceed $50,000. We estimate, based on data compiled from the last decade and reported by ESHRE in *Human Reproduction Update* (2010), that the cost of one IVF treatment cycle in the EU ranges from approximately $3,000 to $6,250.

*Need for hormonal hyperstimulation.* The hormonal hyperstimulation used in connection with IVF involves daily injections of fertility drugs for time periods ranging from one week to ten days, which often is inconvenient and uncomfortable. Other problems with hormonal hyperstimulation include the frequent production of eggs of inferior quality, the need to carefully oversee the patient and side effects, including hot flashes, blurred vision, mood swings, stomach pain, weight gain, nausea, dizziness, low blood pressure and headaches. In addition, hormonal hyperstimulation cannot be used by some women, such as those with hormone dependent cancers.

***The IVF Market***

It is estimated that the international markets account for 90% of global IVF. According to ESHRE, approximately 1.6 million ART cycles are performed each year worldwide. ESHRE estimates that, in 2010, over 565,000 ART cycles were performed in Europe. According to SART, approximately 165,000 IVF cycles were performed in the United States in 2012. Examples of other countries in which a large number of IVF cycles are performed include Japan and Australia; Brazil, Latin America, Russia, Turkey and UAE are estimated to be growing at a rate of 30-40%.

Despite relatively low success rates, risks and other shortcomings, the use of IVF treatments has become increasingly common, especially for women faced with declining fertility due to their age.

Table of Contents

In many markets globally, IVF is paid for out of pocket, particularly in high growth areas outside the EU and the U.S. Many third party payors, including national health services or government funded insurance programs, as well as private payors, place significant restrictions on coverage and reimbursement for IVF and other ART procedures. These restrictions include limits on the types of procedures covered, limits on the number of procedures covered and overall annual or lifetime dollar limits on reimbursement for IVF and other ART procedures. Our preliminary market research indicates that this is primarily due to the fact that many women seeking IVF treatments are of advanced maternal age and are concerned that fertility and IVF success rates will continue to decline over time. As a result, women and couples will frequently pay out of pocket for fertility treatments, such as IVF, rather than avail themselves of other step-based approaches to fertility treatment, such as oral fertility drugs to stimulate ovulation or IUI procedures, that may be required by insurance programs.

***Research and Development Spending***

During the years ended December 31, 2013, and 2012 and the period from April 5, 2011 (inception) to December 31, 2011, we spent approximately $15.8 million, $6.3 million and $1.2 million, respectively, on our research and development activities.

***Manufacturing***

We do not own a manufacturing facility. We have contracted with a global third-party supplier to perform the identification and isolation of EggPCs and the preparation of mitochondria steps in the AUGMENT process for our ACE program and early commercial activities. Our supplier has significant experience in tissue and cell therapy manufacturing. In our anticipated launch of AUGMENT and OvaPrime outside the United States, we may use our existing global cGTP-compliant manufacturer, contract with in-country manufacturers or manufacture on-site in clinics using our own equipment and our own employees. We have no experience with manufacturing fertility treatments for commercial purposes and we cannot assure you that our efforts will be successful. In the future, we plan to contract with an additional global supplier and may build our own cGTP-compliant facility to carry out these steps in the AUGMENT process and to manufacture OvaPrime, OvaTure and other potential fertility treatments. In some regions outside of the United States, we may contract with third parties, through partnerships, out-licenses or other arrangements, to process and manufacture our potential fertility treatments.

The FDA has adopted a comprehensive regulatory program for human cellular and tissue-based products, or HCT/Ps. Certain lower risk HCT/Ps that are regulated as 361 HCT/Ps are subject to the FDA's cGTP requirements. By contrast, HCT/Ps that are regulated as drugs or biologics are subject not only to the FDA's cGTP requirements, but also to its current good manufacturing practices, or cGMPs. We believe that AUGMENT meets the legal criteria for regulation as a 361 HCT/P.

***Marketing and Sales***

We are in the process of expanding our global sales and marketing team, initially focused on supporting the limited commercial launch of AUGMENT in four international regions. Our Executive Vice President, Global Commercial Operations, has significant experience in the international female fertility market. In addition, the global IVF market where we intend to introduce AUGMENT is concentrated and we believe would not require a large sales and marketing team to readily target these regions. We anticipate recruiting a few additional employees to support our commercial efforts in select regions as we prepare for the international commercial launch of AUGMENT by the end of 2014 and the introduction of OvaPrime in 2015.

Table of Contents

***Anticipated Foreign Subsidiary***

We are in the process of establishing an international subsidiary to which we plan to license the commercial rights to AUGMENT, OvaPrime, OvaTure and any future products. This arrangement would allow any potential value enhancement and future profits for the assets to be shared between us and the subsidiary.

***Intellectual Property***

We believe we have a strong and growing intellectual property portfolio. We aggressively strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and processes for their manufacture, as well as any other inventions that are commercially important to the development of our business. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend 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 the valid and enforceable patents and proprietary rights of third parties. We will also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

**Patents and Patent Applications**

We have exclusively licensed a portfolio of patent applications owned or co-owned by The General Hospital Corporation, the corporate entity of MGH, pursuant to an agreement that is summarized below. As of February 21, 2014, we held an exclusive license under this agreement to four issued U.S. patents owned by MGH, four pending U.S. non-provisional patent applications owned by MGH, fifty-eight applications pending with patent and trademark offices outside of the U.S. which are owned by MGH, one pending U.S. non-provisional application co-owned by MGH and The President and Fellows of Harvard College, or Harvard, and fifteen applications pending in patent and trademark offices outside of the U.S. which are co-owned by MGH and Harvard.

One family of patents and applications that we have licensed from MGH is directed to compositions comprising, and methods of isolating, female germline stem cells, and various uses for such female germline stem cells, including methods for IVF, methods for egg production, methods to treat infertility and methods to restore ovarian function. This family includes one issued patent and one allowed patent awaiting issuance, both of which will expire in May 2025, and which include claims directed to the composition and processing methods for obtaining isolated non-embryonic stem cells that express the protein markers characteristic of female germline stem cells. We believe that these patents provide protection for therapeutic compositions comprising EggPCs, which are referred to in the patents as female germline stem cells, as well as elements of the manufacturing process for obtaining such therapeutic compositions. A pending U.S. continuation application and pending European and Canadian counterpart applications, if issued as patents, would also expire in May 2025.

A second family of patent applications that we have licensed from MGH is directed to methods and compositions for producing female germline cells from stem cells derived from either bone marrow or peripheral blood). This family includes two pending U.S. non-provisional applications and one Canadian application, which, if issued as patent(s), also would expire in May 2025. We believe that patents issuing from this family may provide protection for an alternative method of obtaining EggPCs.

Table of Contents

A third family of patent applications that we have licensed from MGH is directed to methods and compositions for autologous germline mitochondrial energy transfer. This family includes two allowed U.S. patents awaiting issuance, one pending U.S. non-provisional patent application, and fifty-five counterpart applications that are pending with patent and trademark offices internationally. The allowed patents, and any patents claiming priority to the underlying provisional application, will expire in April 2032. We believe that these allowed patents, and any patents issuing from this family, provide protection for the AUGMENT procedure and several important aspects thereof.

A fourth family of patent applications that we have licensed from MGH and Harvard is directed to methods and compositions for enhancing the bioenergetic status in female germline cells. This family includes one pending U.S. non-provisional patent application, and fifteen counterpart applications that are pending with patent and trademark offices internationally. Any patents claiming priority to the underlying provisional application would expire in April 2032. We believe that patents issuing from this family may provide protection for aspects of the AUGMENT procedure, as well as culture media that we may develop in the future.

In addition to the patent portfolio that we have exclusively licensed from MGH, we have one issued U.S. patent and one pending U.S. non-provisional patent application, with all issued patents expiring in June 2026. We believe that patents issuing from this family may provide protection for an alternative method of producing healthy eggs.

**Trade Secrets**

In addition to patents, we expect to rely on trade secrets and know-how to develop and maintain our competitive positions. For example, significant aspects of the procedure by which we plan to process AUGMENT are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets and know-how may otherwise become known or may be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

**Exclusive License Agreement with Massachusetts General Hospital**

In June 2011, we entered into an exclusive license agreement with MGH under which we acquired an exclusive, worldwide license to specified patent rights owned by MGH and a non-exclusive license under specified know-how disclosed to us under the agreement by MGH which relates to the licensed patent rights. In September 2011, we amended this agreement to include additional patent rights owned by Harvard for which MGH has the right to grant us a license and we have subsequently amended it to broaden our license field. Under the agreement, as amended, we acquired an exclusive, royalty-bearing, worldwide license under the licensed patent rights to make, use and sell products covered by the licensed patent rights or which employ or are based on the licensed know-how and to develop and perform services covered by the licensed patent rights or which employ or are based on the licensed know-how. The license under MGH-owned patent rights and know-how is for human female fertility, the treatment or prevention of inherited (including mitochondrial) diseases or defects in all animals, including humans, assisted and/or artificial reproductive technology in all non-human animals, and the artificial creation of food, research animals and/or animal products; and the license under the MGH and Harvard co-owned patent right is for *ex-vivo* human female fertility treatments.

Table of Contents

Under the agreement, as amended, we agreed to pay MGH upfront license fees and reimbursed patent related fees and costs incurred by MGH and Harvard totaling approximately $0.4 million in the aggregate. We also agreed to pay MGH annual license fees, annual maintenance fees, milestone payments, royalties as a percentage of net sales and a percentage of sublicense income that we receive. Annual license fees are creditable against royalties. Annual maintenance fees are due beginning in the third year of the agreement and are not creditable against royalties. Milestone payments of up to an aggregate of approximately $10.7 million are triggered upon the achievement of specified developmental and commercialization milestones and are not creditable against royalties. Additionally, we are required to pay MGH $1.0 million in connection with the first to occur of our next equity financing, a change of control or a certain date, which payment may be in installments depending upon the proceeds from the triggering event. The royalty rate is in the low single digits as a percentage of net sales. Net sales do not include amounts billed to patients by clinics and medical practices that use licensed products or perform licensed services for such patients, but do include the amounts paid to us by such clinics and medical practices.

If we are required to pay royalties to a third party in consideration of a license or similar right in order to avoid potential infringement of third party patent rights, and the royalty payable to such third party is greater than one percent of net sales, then we may deduct up to 50% of the amounts paid to such third party that are in excess of one percent of net sales, subject to specified limitations, from the payments that we owe to MGH for such licensed product or licensed service; provided, however that the stacking provision does not apply to assisted and/or artificial reproductive technology in all non-human animals.

We are required to use commercially reasonable efforts to develop and commercialize licensed products and licensed services under the agreement. In particular, we are required to achieve specified development and commercialization milestones by specified dates.

MGH and Harvard retain the right to, and may grant licenses to other academic, government and non-profit institutions for the right to practice the licensed patent rights within the licensed fields for research and educational purposes only.

We have the right to terminate the agreement for any reason upon at least 90 days' prior written notice. MGH has the right to terminate the agreement if we fail, subject to a specified cure period, to pay any amounts due and payable under the agreement to MGH, we otherwise materially breach the agreement and fail to cure such breach within a specified cure period, we fail to maintain insurance coverage as required under the agreement, we enter bankruptcy proceedings or make an assignment for the benefit of our creditors, or we or a sublicensee challenges the licensed patent rights in a legal or administrative proceeding. The agreement otherwise terminates upon the expiration or abandonment of all licensed patents and patent applications.

**Collaboration with Intrexon to Accelerate Development of OvaTure**

In December 2013, we entered into a collaboration agreement (the "OvaTure Collaboration") with Intrexon governing the use of Intrexon's synthetic biology technology platform for the accelerated development of our OvaTure platform. The OvaTure Collaboration provides that Intrexon will deliver laboratory and animal data to support the successful filing of a potential IND for OvaTure. Upon the delivery of laboratory and animal data necessary to support the successful filing of a potential IND application, we will incur an obligation to pay Intrexon a mid-single digit royalty on net sales of any OvaTure fertility treatments in the future, and the exact royalty will depend upon whether Intrexon completes the milestone by the targeted deadline of two years after technology transfer.

Table of Contents

We issued to Intrexon 273,224 shares of common stock upon the execution of the OvaTure Collaboration, owe an additional one-time technology access fee of $2.5 million in cash in December 2014, and a commercial milestone payment three months after the first commercial sale of OvaTure. The shares issued to Intrexon are subject to "piggy-back" registration rights that entitle Intrexon to have the shares included in any new registration statement filed in connection with an underwritten public offering, subject to underwriter cutback. The piggy-back registration rights will not be triggered by any offering subject to a previously filed registration statement, including our current universal shelf registration statement.

We may terminate the OvaTure Collaboration after ninety (90) days prior written notice, and either party may terminate after a material breach by the other party that is not cured within sixty (60) days. We may assign the OvaTure Collaboration in the event of a change of control transaction. In the event that we pursue the OvaTure program on its own after terminating the OvaTure Collaboration, the royalty will apply if Intrexon intellectual property is utilized.

**OvaXon Joint Venture with Intrexon**

In December 2013, we also entered into a joint venture with Intrexon to leverage Intrexon's synthetic biology technology platform and our technology relating to EggPCs to pursue the development of potential fertility treatments within fields-of-use defined under the joint venture, which include prevention of genetic disease and animal health.

We and Intrexon formed OvaXon, LLC ("OvaXon") to conduct the joint venture. Each party contributed $1.5 million to OvaXon and each has a 50% equity interest, with research and development costs and profits to be split accordingly. OvaXon will be governed by a board of managers, which initially will have equal representation by OvaScience and Intrexon. Pursuant to an Intellectual Property License between OvaScience and OvaXon, we licensed our technology in the field of the joint venture to OvaXon, and OvaXon entered into a collaboration agreement with Intrexon to develop our technology in the field utilizing Intrexon's synthetic biology platform.

***Competition***

The biotechnology and pharmaceutical industries are highly competitive and subject to rapid technological change. There are a number of pharmaceutical companies, biotechnology companies, universities and research organizations actively engaged in research and development of potential fertility treatments. Some of these treatments, similar to AUGMENT, OvaPrime and OvaTure, are designed to address the shortcomings of IVF.

In particular, we are aware of a number of companies and laboratories that are currently developing potential fertility treatments intended to identify high quality embryos for use in IVF, a university study of the transfer of granulosa cell mitochondria into eggs and a university study of induced pluripotent stem cells, or iPS, showing that iPS cells can be generated from somatic cells and programmed to become differentiated cells, which can include germ line cells such as oocytes. Novocellus Ltd. is developing an embryo viability test, using culture media, to aid in the selection of embryos used in IVF. FertiliTech and Auxogyn, Inc. are developing hardware and software that analyzes embryo development against cell division timing parameters to help identify the highest quality embryo within a group of embryos. If successfully developed, these products could improve outcomes and alleviate some of the other shortcomings of traditional IVF, thereby decreasing the need for our potential fertility treatments. Fertility Focus, along with strategic partner Norgenix, are developing a fertiloscope for the early diagnosis of, and immediate corrective surgery for, the physical causes of infertility. Molecular diagnostic companies like Reprogenetics are developing novel preimplantation genetic diagnosis and screening methods to detect chromosomal and genetic disorders of embryos prior

Table of Contents

to transfer back to the women. Testing embryos in this manner may increase the likelihood of pregnancy, reduce the chances of pregnancy loss, and improve the odds of delivery.

At this time, we cannot evaluate how our potential fertility treatments, if successfully developed and commercialized, would compare technologically, clinically or commercially to any other potential products being developed or to be marketed by competitors. There can be no assurance that we will be able to compete effectively. Our competitors may develop and commercialize new technologies before we do, allowing them to offer products, services or solutions that are superior to those that we may offer or that establish market positions before the time, if any, at which we are able to bring potential fertility treatments to the market. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any treatment we may commercialize and may render our potential fertility treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our potential fertility treatments. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

If we successfully develop AUGMENT and OvaPrime, our ability to gain market acceptance will depend on, among other things, our ability to demonstrate increased IVF success rates, thereby reducing the number of cycles required to produce a live birth, and our ability to reduce multiple births. Our ability to gain market acceptance for OvaTure, if it is approved, will depend on our ability to demonstrate increased pregnancy and live birth rates as compared to traditional IVF and other infertility treatments, reduced multiple births and a reduction in the need for hormonal hyperstimulation for egg retrieval. We anticipate that price also will be an important competitive factor as to both of these potential fertility treatments. At this time, we cannot evaluate how our potential fertility treatments, if successfully developed and commercialized, would compare technologically, clinically or commercially to any other potential products being developed or to be marketed by competitors.

***Government Regulation***

Government authorities around the world regulate, among other things, the development, testing, manufacture, quality, approval, distribution, labeling, packaging, storage, record keeping, marketing, import, export and promotion of drugs, biologics and medical devices, as well as other types of medical products. Authorities also heavily regulate many of these activities for HCT/Ps. The level and nature of regulation applied to a treatment depends on, among other things, how regulators classify that treatment. We believe that some of our fertility treatments may be regulated as drugs or biologics, while others, such as AUGMENT and OvaPrime, could be introduced into the market in certain jurisdictions without the need for pre-market review and approval.

**Foreign Regulatory Requirements**

Regulatory authorities around the world impose requirements related to the development, testing, approval, distribution, marketing and promotion of drugs, biologics, medical devices and HCT/Ps. These requirements can sometimes be more or less burdensome than those imposed in the United States. Also, most countries have both a tissue/organ transplant requirement, as well as a form of Assisted Human Reproduction Act, which regulates how IVF is performed in the country.

Table of Contents

We believe that in certain jurisdictions outside of the United States, we will be able to introduce AUGMENT and OvaPrime into the market in the same way IVF and other assisted reproductive technologies are introduced without the need for pre-market review and approval by the relevant regulatory bodies. Our plans to introduce our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT in 2014 and to generate data, and to transition ACE clinics to commercial centers, depend upon our being able to bring AUGMENT to the market without such pre-review and approval. Also, our plans for a commercial launch of OvaPrime outside of the United States in 2015 depend upon our being able to bring OvaPrime to the market without such pre-review and approval. There can be no assurance that foreign regulatory authorities will agree that AUGMENT or OvaPrime meet the requirements of a class of products exempt from premarket review and approval under applicable regulations. Additionally, foreign regulatory authorities may change their standards for products that are exempt from premarket review and approval. If a particular foreign regulatory authority does not agree that AUGMENT or OvaPrime meets the requirements for such an exemption, we may abandon the use of AUGMENT or OvaPrime in such jurisdictions, or suffer significant delays and expense seeking to obtain any necessary approval.

Regulatory requirements applicable to our potential fertility treatments in foreign markets vary. Solely by way of example, in the EU, medicinal products, including tissue engineered products, require marketing authorization from the competent regulatory authorities, whereas human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. There are, however, EU rules governing the donation, procurement, testing, processing, preservation, storage and distribution of cells and tissues that are not medicinal products. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. We believe that AUGMENT will not be regulated in the EU as a medicinal product. Instead, we believe AUGMENT will be subject to the general rules governing the use of cells and tissues for human applications. Thus, in the EU, we believe that we will be able to commercialize AUGMENT without first applying for or receiving marketing authorization. However, regulators in the EU could disagree with us and we might need to seek market authorization. By contrast, it is more likely that we will be required to submit an application to seek marketing authorization from the EU regulatory authorities for OvaTure and possibly other potential fertility treatments.

While we believe EU marketing authorization is not required for AUGMENT, medical treatments and processes, such as IVF, are regulated at the national level in the EU. Such national regulations may restrict the extent to which the eggs used in IVF treatments may be manipulated and so may prevent us from commercializing AUGMENT, OvaPrime, OvaTure or any other potential fertility treatments in that country.

In addition, certain other countries outside the EU and United States may have regulations that require us to obtain permission prior to commercializing AUGMENT, OvaPrime, OvaTure and any other potential fertility treatments.

**U.S. Requirements Applicable to Biologics**

Although we have not discussed OvaTure with the FDA, the FDA may regulate OvaTure as a biological product. Our other potential fertility treatments may also be regulated as biological products. In the United States, the FDA regulates biologics under the Public Health Service Act, or PHSA, the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. Section 351 of the PHSA prohibits the introduction of a biological product into interstate commerce without an

Table of Contents

FDA-approved application for marketing authorization under that section. For pioneer products, the typical application under section 351 of the PHSA is the biologics license application, or BLA.

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the development process, approval process or after approval may subject a company to significant sanctions, including refusal to approve pending applications, withdrawal of an approval, clinical holds, warning letters, product recalls, product seizures, injunctions, fines, refusals of government contracts, restitution, disgorgement or other civil or criminal penalties.

***Preapproval Regulation.*** The process required by the FDA before a biologic may be marketed in the United States requires numerous steps, including the following:

- completion of preclinical laboratory tests, animal studies and other studies in accordance with current good laboratory practices or other applicable regulations;
- submission to the FDA of an IND, which must become effective before the product can be tested in humans and which must contain preclinical data, together with manufacturing information, analytical data and any available clinical data or literature;
- performance of adequate and well controlled clinical trials in humans according to the FDA's cGCPs, to establish the safety and efficacy, or safety, purity and potency in the case of a biologic, of the product for its intended use(s);
- submission to the FDA of a BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's cGMPs and to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the BLA.

Before testing new drugs or biologics in humans, a potential product must go through the preclinical testing phase. Preclinical tests include laboratory evaluations of the potential product biological characteristics, as well as animal studies. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include an initial protocol detailing the first phase of the proposed clinical investigation and must update the IND with subsequent protocols if the clinical program advances beyond early testing. The IND automatically becomes effective 30 days after receipt by the FDA unless the FDA imposes a clinical hold within that 30 day time period. If the FDA institutes a clinical hold, the sponsor must resolve any and all concerns to the FDA's satisfaction before clinical trials under the IND can begin. The FDA may also impose clinical holds on a potential product due to safety concerns or non-compliance with cGCPs or other regulations at any time before or during clinical trials.

Each clinical protocol must be submitted to the FDA for review and to an Institutional Review Board ("IRB") for approval. Protocols detail, among other things, the objectives of the clinical trial, dosing procedures, subject inclusion and exclusion criteria and the parameters to be used to monitor subject safety. An IRB is charged with protecting the welfare and rights of study participants, giving consideration to whether the risks to individual study participants are minimized and reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Table of Contents

Clinical testing of a biologic generally proceeds in three phases, though in some cases these phases may overlap or be combined. In Phase 1 trials, the investigational product typically is administered to 20 to 80 healthy volunteers to evaluate the safety, dosage tolerance, and other characteristics of the investigational product. Phase 2 trials are typically conducted in a small patient population to evaluate the effectiveness of the investigational product for a particular indication in patients with the targeted condition. Phase 3 clinical trials are conducted in an expanded patient population, usually at geographically dispersed sites, and are intended to further evaluate the dosage, clinical effectiveness, and safety, as well as to establish the product's overall risk/benefit ratio. Phase 3 trials typically form the primary basis for FDA approval of the product.

Sponsors must submit progress reports at least annually to the FDA, detailing the results of the clinical trials. The sponsor must also submit written IND safety reports to the FDA and to the investigators describing serious and unexpected adverse events or any finding from tests in laboratory animals that suggests a significant risk for human subjects. The FDA, the sponsor or the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to unacceptable health risks. 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 or biologic has been associated with unexpected serious harm to patients. Additionally, sponsors of clinical trials, except Phase 1 trials, are required to submit certain registry and results information for inclusion in a publicly available registry data bank.

***U.S. Review and Approval Process.*** The results of preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a BLA, requesting approval to market the product. The submission of a BLA is typically subject to the payment of substantial user fees.

The FDA reviews all BLAs submitted to ensure that they are sufficiently complete for substantive review before accepting them for filing. The FDA may request additional information rather than accept an application for filing. Once an application is accepted for filing, the FDA begins an in depth substantive review to determine, among other things, whether the biological product is safe, pure and potent, for its intended use(s) and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an application, the FDA typically inspects the facility where the product is manufactured in order to ensure compliance with cGMPs. The FDA will also determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the treatment. If the FDA concludes that a REMS is necessary, the applicant must submit a proposed REMS. The FDA will not approve a marketing application without a REMS, if required.

The development and approval process is lengthy and resource intensive. Ultimately, the FDA may refuse to allow a clinical program to begin, terminate a clinical development program, require submission of additional preclinical or clinical data or refuse to approve an application for numerous reasons. Even if an applicant submits all of the data requested by the FDA, the agency may ultimately decide that the application does not satisfy the criteria for approval. In addition, even if a product is approved, the scope of the approval may be significantly limited in terms of patient populations, indications, other conditions of use or restrictions on distribution and use, for example, through a REMS. The FDA could also require significant contraindications, warnings or precautions be included in the product labeling.

***Patent Term Restoration and Exclusivity.*** If the FDA regulates OvaTure or our other treatments as biologics, certain provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 and the Biologics Price Competition and Innovation Act of 2009 likely would apply.

Table of Contents

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act, certain U.S. patents are eligible for a limited patent term extension of up to five years in order to compensate the sponsor of a new drug or biologic for patent term lost during product testing and FDA review. Only one patent per drug or biologic is eligible for the extension.

The Biologics Price Competition and Innovation Act of 2009 created a 12 year exclusivity period for innovator biologics. The FDA therefore cannot approve a biosimilar application relying on a specific reference product until 12 years after the reference product is first licensed. BLA supplements are not eligible for any additional exclusivity. In addition, a BLA is not entitled to the 12 year exclusivity if it is a subsequent application filed by the same manufacturer or sponsor as an earlier application, or a licensor, predecessor in interest or other related entity, if the subsequent application relates to: (1) a change, not including a modification to the structure of the biological product, that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or (2) a modification to the structure of the biological product that does not result in a change in safety, purity or potency. The FDA has yet to define the key terms in this exclusivity provision, so the robustness of exclusivity for biologics is somewhat uncertain.

***Post-Approval Requirements.*** Any drug or biologic approved for marketing in the United States remains subject to continuing regulation by the FDA. Post-approval requirements include, among other things, record keeping and reporting requirements, packaging requirements, requirements for reporting of adverse drug experiences, import and export controls, restrictions on advertising and promotion and adherence to cGMP requirements. For example, the FDA strictly regulates labeling, advertising and promotion of drugs and biologics. Such products may be promoted only for the FDA-approved indications and in accordance with the provisions of the FDA-approved label. The FDA periodically inspects manufacturing facilities to ensure that the product is being manufactured in accordance with cGMPs and the specifications outlined in the NDA or BLA. Manufacturing facilities must be registered with the FDA and companies must list all of the drugs and biologics they manufacture with the FDA. As a condition of approval, the FDA could also impose one or more post-marketing studies or clinical trials to further assess the benefit to risk profile of the product, which could require the expenditure of significant time and resources. Post-market data may cause the agency to seek significant changes in the labeling for the product including new warnings or a REMS. Even if it does not impose a Phase 4 study or trial on a sponsor, the FDA may withdraw approval for the product if it determines that the benefits of the product no longer outweigh the risks.

As further described below, many states also regulate the manufacture and distribution of drugs and biologics and require companies to register in order to manufacture or distribute products in the state. Failure to comply with these federal and state requirements could subject a company to significant sanctions, including withdrawal of an approval, warning letters, product recalls, product seizures, injunctions, fines, refusals of government contracts, or civil or criminal penalties.

**Requirements Applicable to Medical Devices in the United States**

In conjunction with our plan to expand our offerings for the treatment of infertility, we may develop new products that the FDA may regulate as medical devices. For example, we believe the FDA likely will regulate as a medical device the innovative culture media solution we are planning to develop. The FDA regulates, among other things, the development, testing, manufacturing, labeling, marketing and distribution of medical devices. The level of regulation applied by the FDA generally depends on the class into which the medical device falls: Class I, II or III. Class I medical devices present the lowest risk and Class III medical devices present the highest risk.

Most Class I devices are exempt from the FDA premarket review or approval. With some exceptions, Class II devices may be marketed only if the FDA "clears" the medical device through the 510(k) process, which requires a company to show that the device is "substantially equivalent" to

Table of Contents

certain devices already legally on the market. Also with some exceptions, Class III devices are approved through a premarket approval application, which generally requires an applicant to submit data from one or more clinical trials that provide reasonable assurance of the safety and effectiveness of the device. Clinical data is sometimes required for a 510(k) notification as well. Manufacturers conducting clinical trials with medical devices are subject to similar requirements as those conducting clinical trials with drugs or biologics. For example, a manufacturer must obtain IRB approval and informed consent from all subjects, and a manufacturer of a significant risk device must also obtain approval of an investigational device exemption.

The FDA has broad post-market regulatory and enforcement powers with respect to medical devices, similar to those for drugs and biologics. For example, medical devices are subject to detailed manufacturing standards under the FDA's Quality System Regulations and specific rules regarding labeling and promotion. Medical device manufacturers must also register their establishments and list their products with the FDA.

As further described below, states also impose regulatory requirements on medical device manufacturers and distributors, including registration and record keeping requirements. Failure to comply with the applicable federal and state medical device requirements could result in, among other things, refusal to approve or clear pending applications or notifications, withdrawal of an approval or clearance, warning letters, product recalls, product seizures, total or partial suspension of production, fines, refusals of government contracts, restitution, disgorgement, or other civil or criminal penalties.

Table of Contents

**Requirements Applicable to HCT/Ps**

We believe AUGMENT belongs to a class of products kown as human cell, tissue, or cellular or tissue-based products ("HCT/Ps"). The United States Food and Drug Administration ("FDA") regulates HCT/Ps either as drugs, biologics or medical devices on the one hand, or a special type of product known as a 361 HCT/P, on the other. We believe that AUGMENT meets the legal criteria for regulation as a 361 HCT/P. A 361 HCT/P is an HCT/P that meets certain criteria, and are therefore regulated by the FDA solely under section 361 of the Public Health Service Act, and FDA's implementing regulations in 21 CFR Part 1271. We anticipate having further discussions in 2014 with the FDA to present details on AUGMENT and its qualifications as a 361 HCT/P, and to determine the appropriate path forward. Through a risk based system initially introduced in 1997, the FDA regulates HCT/Ps under a two-tiered framework. Certain HCT/Ps, which the FDA believes pose greater risks, are regulated as drugs, biologics or medical devices. Such products are subject to the IND requirements and the premarket review and approval or clearance requirements described above. Other HCT/Ps, however, are exempt from these requirements because the agency believes that they present a lower risk. Such products frequently are referred to as "361 HCT/Ps," because the FDA regulates them under the authority given to it under section 361 of the PHSA to create regulations to control the spread of communicable diseases.

The FDA will regulate an HCT/P as a 361 HCT/P if it meets all of the following criteria:

(1) the HCT/P is minimally manipulated,

(2) the HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent,

(3) the manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, with a few exceptions, and

(4) either:

the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function, or

the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function and

(a) is for autologous use,

(b) is for allogeneic use in a first or second degree blood relative, or

(c) is for reproductive use.

The FDA defines the term "homologous use" to mean the repair, reconstruction, replacement or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function in the recipient as in the donor. The FDA defines the term "autologous use" to mean the implantation, transplantation, infusion or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered. The term "allogeneic use" refers to the use of cells or tissues taken from one individual within a species and used in another individual of the same species.

HCT/Ps that meet all of these requirements are deemed 361 HCT/Ps and are regulated exclusively under section 361 of the PHSA and the FDA's regulations at 21 C.F.R. Part 1271. They therefore are not subject to the IND requirements or the premarket review and approval requirements described above.

We believe that AUGMENT meets the legal criteria for regulation as a 361 HCT/P. In our view, for AUGMENT, both the mitochondria taken from EggPCs and the eggs into which those mitochondria are injected during IVF (1) are minimally manipulated, (2) are intended for homologous use only,

Table of Contents

(3) do not involve the combination of cells or tissue with another article and (4) are dependent upon the metabolic activity of living cells for their primary function and are for reproductive use.

All HCT/Ps, whether they meet the criteria to be considered a 361 HCT/P or not, are subject to various requirements under the FDA's regulations at 21 C.F.R. Part 1271. While these are the only regulations applicable to HCTP/s that are regulated as 361 HCT/Ps, other FDA regulations apply to HCT/Ps that are regulated as drugs, biologics or medical devices. The FDA's 21 C.F.R. Part 1271 regulations impose requirements relating to registration and listing, donor eligibility testing, cGTPs, adverse event reporting, labeling, and inspections. Failure to comply with these regulations can result in substantial sanctions, including warning letters, product seizure, orders to stop manufacturing and other civil and criminal penalties.

The Tissue Reference Group, or TRG, is a body within the FDA that is designed to provide advisory opinions regarding whether a particular treatment will be regulated as a 361 HCT/P. Manufacturers are not required to consult with the TRG and instead can market their treatments based on their own conclusion that the treatment meets the 361 HCT/P criteria. If, however, the FDA disagrees with the manufacturer's determination and concludes that the treatment should be regulated as a drug, biologic or medical device, the manufacturer could be subject to numerous sanctions, including warning letters, injunctions, fines, product seizures and civil or criminal penalties. In addition, the manufacturer would then need to complete the testing and premarket approval or clearance process discussed above.

We have not consulted the TRG with respect to any of our potential fertility treatments. On September 6, 2013, we received an "untitled" letter from the FDA questioning the status of AUGMENT as a 361 HCT/P and advising us to file an IND for the potential fertility treatment. We continue to believe that AUGMENT qualifies as a 361 HCT/P and plan to engage the agency in further discussions during 2014 to present details on AUGMENT and its qualifications as a 361 HCT/P and to determine the appropriate path forward. The FDA could ultimately disagree with our conclusion, however, in which case AUGMENT likely would be regulated as a biological product.

***HCT/P registration and listing.*** Every establishment that manufactures an HCT/P must register with the FDA and provide a list of every HCT/P that the establishment manufactures. The definition of manufacture is broad and includes any and all steps in the recovery, processing, storage, labeling, packaging or distribution of any human cell or tissue and the screening or testing of the cell or tissue donor.

***Donor eligibility.*** HCT/P manufacturers must maintain procedures for testing, screening and determining the eligibility of donors of cells and tissues used in HCT/Ps. An HCT/P may not be transferred or implanted into an individual until the donor has been determined to be eligible under these procedures. These procedures must involve, among other things, testing donors for certain communicable diseases and the use of quarantines for HCT/Ps that have not yet been shown to meet the eligibility requirements. Cells or tissues that are donated for reproductive use by a sexually intimate partner of the recipient of the HCT/P are exempt from the donor eligibility determination requirements, but must be labeled so as to distinguish the HCT/P from those that have completed donor eligibility testing. Manufacturers must keep detailed records regarding donor eligibility determinations.

***Current Good Tissue Practices.*** HCT/Ps must be recovered, processed, stored, labeled, packaged and distributed in a manner that is consistent with the FDA's cGTPs regulations. Cells and tissues must also be screened and tested according to these regulations. The goal of cGTPs is to prevent the introduction, transmission or spread of communicable diseases. The FDA's cGTPs regulations require companies to establish a comprehensive quality program and to comply with rules related to personnel, facilities and equipment used to manufacture HCT/Ps, as well as rules on how these HCT/Ps are

Table of Contents

processed, labeled and stored. Companies must also keep detailed manufacturing records and product complaint files.

***Adverse Reaction Reports.*** Manufacturers of nonreproductive HCT/Ps must investigate and report to the FDA certain adverse reactions.

***Inspections.*** Establishments that manufacture HCT/Ps must allow the FDA to inspect the establishment and company records.

**Other Regulation of Cellular and Tissue Products**

***Regulation of promotion.*** The Federal Trade Commission, or FTC, and state governments require claims made in promoting a treatment to be supported by adequate substantiation. Similarly, the FTC and state governments generally require that promotion not be false or misleading. In addition, FDA rules limit the claims that may be made in the promotion of a 361 HCT/P. The FDA determines whether an HCT/P is intended for homologous use based on the labeling, advertising and other indications of the manufacturer's intent. Accordingly, the ways in which an HCT/P is promoted may affect whether the FDA regulates it as a 361 HCT/P or a drug, biologic or medical device.

***State regulation.*** Certain states, including New York, California, Florida, Illinois, Maryland, Texas, Massachusetts and others, as well as local governments, extensively regulate facilities and laboratories that recover, test, process, manufacture, store or dispose of certain cells and tissues. These state requirements include, among other things, registration, record keeping, quality and personnel standards. For example, New York requires reproductive tissue banks, which are facilities that possess, store or distribute reproductive tissue for insemination or implantation, to be licensed if the tissues will be distributed into New York. The state also imposes informed consent, storage, record keeping and testing requirements. Some of these state requirements may be more extensive than those imposed by federal law.

***Regulation of clinical laboratories.*** The Clinical Laboratory Improvement Act Amendments of 1988, or CLIA, regulates laboratory testing performed on specimens derived from humans. It is designed to impose quality standards for all such testing to ensure the accuracy, reliability and timeliness of results regardless of where the test is performed. CLIA requires that laboratories become certified and imposes rules for quality control, quality assurance, patient test management, personnel and proficiency testing. Laboratories that perform relatively simple tests are subject to lower levels of regulation, while laboratories that conduct more complicated testing must meet more stringent standards. Certain states also impose similar requirements on clinical laboratories. In New York, for example, clinical laboratories that accept specimens from New York state must have a permit and must meet certain quality standards.

***Health Insurance Portability and Accountability Act.*** The Health Insurance Portability and Accountability Act, or HIPAA, imposes rules on certain "covered entities." "Covered entities" include healthcare providers that conduct certain transactions in electronic format, healthcare clearinghouses and health plans. Covered entities must, among other things, comply with limitations on the use and disclosure of individually identifiable health information, referred to as protected health information, or PHI, apply certain security standards to electronic PHI and enter into written agreements with business associates before disclosing any PHI to them. In addition, many states have their own laws relating to the privacy of medical information. To the extent that they provide greater protection for the privacy of medical information, such state laws are not pre-empted by HIPAA.

**Other U.S. Healthcare Laws and Compliance Regulations**

In the United States, our activities may be subject to regulation by various federal, state and local authorities in addition to the FDA, likely including the Centers for Medicare and Medicaid Services, or

Table of Contents

CMS, other divisions of the U.S. Department of Health and Human Services, such as the Office of Inspector General, and the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, as well as state and local governments. To the extent AUGMENT, OvaPrime, OvaTure or other potential fertility treatments are reimbursed by federal or state healthcare programs, we would be subject to strict regulation by federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws, physician self-referral laws, false claims laws and others. The federal Anti-Kickback Statute, for example, prohibits persons from soliciting, offering, receiving or providing remuneration to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. Similar laws exist at the state level, some of which apply to products reimbursed under private insurance programs. The federal False Claims Act, and similar state laws, prohibit presenting false or fraudulent claims for payment by federal payors such as Medicare or Medicaid. We anticipate there will be minimal reimbursement for our products or services by any third party insurers and that federal healthcare programs will be even less likely than commercial insurers to reimburse for our potential fertility treatments. However, to the extent that our potential fertility treatments are reimbursed under federal programs, we nonetheless will likely be required to operate in compliance with applicable federal laws, and to the extent that there is commercial third party reimbursement, we will likely also be required to operate in compliance with applicable state laws. Failure to comply with these laws can result in significant civil and criminal penalties, including exclusion from participation in federal healthcare programs.

If AUGMENT, OvaPrime, OvaTure or other potential fertility treatments are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements may apply. For example, under the Veterans Health Care Act, or VHCA, drug companies are required to offer certain drug and biological products at a reduced price to a number of federal agencies, including the U.S. Department of Veterans Affairs and the U.S. Department of Defense, the Public Health Service and certain private Public Health Service-designated entities, in order to participate in other federal funding programs including Medicare and Medicaid. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations. In addition, recent legislative changes purport to require that VHCA discounted prices be offered for treatments distributed at retail pharmacies to certain U.S. Department of Defense purchasers for its TRICARE beneficiaries program via a rebate system. We may be subject to these restrictions even though we anticipate that we will receive minimal, if any, revenues from these federal programs.

Similarly, it is unlikely that state Medicaid programs will elect to cover AUGMENT, OvaPrime, OvaTure or our other future fertility treatments. Nonetheless, to the extent that any of our treatments are approved as drugs or biological products, and we wish to retain the possibility of Medicaid coverage for those fertility treatments, we would be required to enter into a rebate agreement with CMS, which requires the payment of substantial rebates to state Medicaid programs and the reporting of certain pricing information to CMS on a monthly and quarterly basis. For drugs that are covered under Medicare Part B, the manufacturer must report such drugs' average sales price to CMS on a quarterly basis. Failure to report this information in a timely and accurate manner can lead to substantial civil and criminal penalties and to liability under the False Claims Act, even if Medicare Part B reimburses for only a small number of doses of the product.

The Affordable Care Act includes new reporting and disclosure requirements for pharmaceutical and device manufacturers with regard to payments or other transfers of value made to healthcare providers. Reports submitted under these new requirements will be placed on a public database. If we fail to provide these reports, or if the reports we provide are not accurate, we could be subject to significant penalties.

Table of Contents

In order to distribute treatments commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical and biological products and medical devices in a state. In certain states, this includes manufacturers and distributors who ship treatments into the state even if such manufacturers or distributors have no place of business within the state. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities or register their sales representatives. Many of these laws also prohibit certain sales and marketing practices. In addition, all of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Failure to comply with the applicable federal and state regulatory requirements could result in, among other things, refusal to approve or clear pending applications, withdrawal of an approval or clearance, warning letters, product recalls, product seizures, total or partial suspension of production, fines, sanctions, injunctions, refusals of government contracts, restitution, disgorgement or other civil or criminal penalties.

In addition to those laws and regulations described above, other federal and state laws that could affect our operations include:

- federal laws requiring reporting to the CDC regarding pregnancy success rates and other data compiled by ART programs;
- the Fertility Clinic Success and Certification Act, which requires the CDC to adopt a model certification program for embryo laboratories, and accompanying quality standards, which can then be adopted by states or independent accrediting organizations certified by the states;
- the U.S. Foreign Corrupt Practices Act, which prohibits companies from making certain improper payments to foreign officials and which requires companies to maintain certain record keeping procedures;
- state and federal laws governing human subject research and animal testing;
- occupational safety and health requirements;
- state and local laws and regulations on the handling and disposal of medical waste; and
- the "sunshine" provisions enacted in the Affordable Care Act, which require manufacturers to report certain transfers of value, such as payment for consulting services, to prescribers or other healthcare providers.

***Pharmaceutical Coverage, Pricing and Reimbursement***

We believe that very few third party payors, either in the EU, the United States or other countries, including national health services and government funded insurance programs as well as private payors, will agree to cover and reimburse for AUGMENT, OvaPrime, OvaTure or other potential fertility treatments we may attempt to commercialize. Thus, it is likely that IVF clinics and physicians will be able to use AUGMENT, OvaPrime, OvaTure and our other potential fertility treatments only if the patient can afford and is willing to pay for our treatment out of pocket. The cost of AUGMENT, OvaPrime, OvaTure, and our other potential fertility treatments may be beyond the means of many patients.

Third party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a treatment or procedure may be separate from the process for setting the price or reimbursement rate that the payor will pay for the treatment or procedure. Even if third party payors were to provide some minimal level of coverage and reimbursement for AUGMENT, OvaPrime,

Table of Contents

OvaTure or our other potential fertility treatments, such third party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness, in addition to the safety and efficacy, of medical products and procedures. In order to obtain reimbursement for AUGMENT, OvaPrime, OvaTure or our other future treatments, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate their medical necessity and cost-effectiveness. The expense of these studies would be in addition to the expense required to obtain any necessary FDA approvals or clearances. Our treatments or procedures may not be considered medically necessary or cost-effective. We believe, however, that even after conducting such studies, very few third party payors will agree to cover and reimburse AUGMENT, OvaPrime, OvaTure or our other potential fertility treatments we may attempt to commercialize.

A third party payor's decision to provide coverage for a treatment or procedure does not imply that an adequate reimbursement rate will be approved. 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 development of AUGMENT, OvaPrime, OvaTure or our other potential fertility treatments. The enactment of sweeping healthcare reform legislation, known as the Affordable Care Act, in 2010 could substantially change the way healthcare is financed by both governmental and private insurers. We anticipate that this legislation will result in additional downward pressure on coverage and reimbursement rates. Such downward pressure could have the effect of reducing the price that we are able to demand for AUGMENT, OvaPrime, OvaTure or our other future treatments. Federal, state and local governments in the United States continue to consider legislation to limit the growth of healthcare costs. Future legislation could limit payments for AUGMENT, OvaPrime, OvaTure, or our other potential fertility treatments.

Different pricing and reimbursement practices exist in other countries. In the EU, governments influence the price of medical products and procedures through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of consumers' medical costs. Some jurisdictions operate positive and negative list systems under which treatments or procedures may be marketed only after a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of our particular treatments or procedures to currently available therapies. Other member states allow medical companies to fix their own prices, but monitor and control company profits. The downward pressure on healthcare costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new treatments and procedures. Moreover, we believe that very few third party payors, either in the EU, the United States or other countries, including national health services or government funded insurance programs as well as private payors, will agree to cover and reimburse for AUGMENT, OvaPrime, OvaTure or our other potential fertility treatments we may attempt to commercialize.

***Employees***

As of December 31, 2013, we had 28 full-time employees, including a total of 17 employees with advanced degrees. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

***Our Corporate Information***

We were incorporated under the laws of the State of Delaware in April 2011 under the name Ovastem, Inc. and changed our name to OvaScience, Inc. in May 2011. Our principal executive offices are located at 215 First Street, Suite 240, Cambridge, Massachusetts 02142 and our telephone number is (617) 500-2802. Our website address is www.ovascience.com. The information contained on, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K. We have included our website address in this Annual Report solely as an inactive textual reference.

Table of Contents

***Available Information***

You may obtain free copies of our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, and amendments to those reports, as soon as reasonably practicable after they are electronically filed or furnished to the United States Securities and Exchange Commission, or the SEC, on the Investors section of our website at www.ovascience.com or by contacting our Corporate Communications department at (617) 500-2802. The contents of our website are not incorporated by reference into this report and you should not consider information provided on our website to be part of this report.

**Item 1A. Risk Factors**

**RISK FACTORS**

*Our business is subject to numerous risks. We caution you that the following important factors, among others, could cause our actual results to differ materially from those expressed in forward looking statements made by us or on our behalf in filings with the SEC, press releases, communications with investors and oral statements. Any or all of our forward looking statements in this Annual Report on Form 10-K and in any other public statements we make may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in the discussion below will be important in determining future results. Consequently, no forward looking statement can be guaranteed. Actual future results may differ materially from those anticipated in forward looking statements. We undertake no obligation to update any forward looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosure we make in our reports filed with the SEC.*

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

***Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We commenced active operations in April 2011. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential fertility treatments, planning for and enrolling patients for our AUGMENT study in humans, planning for the anticipated introduction of our ACE access program into international IVF clinics, planning for studies of OvaPrime, and determining the regulatory path for our potential fertility treatments. We have not yet commenced commercial sale of any fertility treatment and have not yet demonstrated our ability to initiate or successfully complete any clinical trials, obtain marketing approvals or conduct sales, marketing and other activities necessary for successful commercialization of a fertility treatment. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will need to transition from a company focused on in-licensing and research to a company capable of developing multiple potential fertility treatments and supporting commercial activities. We may not be successful in such a transition.

***We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.***

Since our inception, we have incurred significant operating losses. Our net loss was $29.0 million for the year ended December 31, 2013 and $45.2 million for the period from April 5, 2011 (inception) to December 31, 2013. To date, we have not generated any revenues and have financed our operations

Table of Contents

through private placements of our Series A preferred stock, Series B preferred stock and common stock. We have devoted significant efforts to acquiring our technology and developing AUGMENT.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase if and as we:

- introduce our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT and to generate data;
- educate physicians and embryologists regarding the use of AUGMENT;
- conduct any AUGMENT studies;
- incur costs associated with foreign expansion;
- conduct further studies of, continue optimization of and ultimately commercially launch OvaPrime;
- continue our research and preclinical development of OvaTure, both internally and in collaboration with Intrexon, and other potential fertility treatments;
- initiate any clinical trials of OvaTure and other potential fertility treatments;
- collaborate with Intrexon through the OvaXon joint venture to create new applications to prevent inherited diseases for human and animal health;
- seek approval from the FDA and similar regulatory agencies outside of the United States for our potential fertility treatments that require such approval;
- establish a domestic and international sales, marketing, manufacturing and distribution infrastructure to commercialize AUGMENT, OvaPrime and any other potential fertility treatments we successfully develop;
- maintain, expand and protect our intellectual property portfolio;
- hire additional scientific, clinical, quality control and management personnel to support our potential fertility treatment development and commercialization efforts in the United States and abroad;
- add operational and financial personnel to handle the public company reporting and other requirements to which we are subject;
- seek to identify additional potential fertility treatments; and

develop, acquire or in-license other potential fertility treatments and technologies.

To become and remain profitable, we must continue to develop and commercialize AUGMENT and develop and eventually commercialize other potential fertility treatments with significant market potential. This will require us to be successful in a range of challenging activities, including successfully introducing the ACE access program into international IVF clinics, marketing and selling AUGMENT, developing and launching OvaPrime, completing research, preclinical testing and clinical trials of other potential fertility treatments, obtaining marketing approval, if required, manufacturing, marketing and selling those potential fertility treatments that we successfully develop, and addressing the challenges of foreign operations. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. We are currently conducting preclinical research and working to optimize the design of the development program for OvaTure, both internally and in collaboration with Intrexon, and collaborating with Intrexon on the OvaXon joint venture. If we do achieve profitability, we may not be able to sustain or increase profitability on a

Table of Contents

quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

***We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our fertility treatment development programs or commercialization efforts.***

We plan to introduce our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT and to generate data in 2014. We also plan to conduct further preclinical studies and continue optimization of OvaPrime in 2014 in anticipation of a potential commercial launch outside of the United States in 2015. In addition, we expect to incur significant expenses with respect to our research and development of OvaTure and other potential fertility treatments. Any clinical trials that we are required to conduct for these potential fertility treatments will be costly. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate some or all of our research and development programs or commercialization efforts.

Assuming we have no revenue from sales of fertility treatments, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our current operating plan into 2015. Our future capital requirements will depend on many factors, including:

- introducing our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT and to generate data;
- educating physicians and embryologists the use of AUGMENT;
- conducting any AUGMENT studies;
- incurring the costs associated with expansion of foreign operations;
- establishing a domestic and international sales, marketing, manufacturing and distribution infrastructure to commercialize AUGMENT and any other potential fertility treatment, we successfully develop;
- conducting further studies of, continuing optimization of and ultimately commercially launching OvaPrime;
- receiving revenue, if any, from commercial activities of AUGMENT, OvaPrime or any other potential fertility treatments;
- continuing research and preclinical development of OvaTure, both internally and in collaboration with Intrexon, and other potential fertility treatments;
- initiating any clinical trials of OvaTure and other potential fertility treatments;
- collaborating with Intrexon through the OvaXon joint venture to create new applications to prevent inherited diseases for human and animal health;
- following the regulatory process in the United States and abroad, including the premarketing and marketing approval requirements, to which some of our potential fertility treatments may be subject;

following the regulatory or institutional review board review of our potential fertility treatments that are subject to such review;

preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

Table of Contents

establishing collaborations and partnerships on favorable terms, if at all; and

developing, acquiring or in-licensing other potential fertility treatments and technologies.

Identifying and developing potential fertility treatments is a time consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain necessary marketing approvals or achieve sales for our potential fertility treatments. We will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or potential fertility treatments.***

Until the time, if ever, that we can generate material revenue from our potential fertility treatments, we plan to finance our cash needs through some combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. 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 additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or potential fertility treatments or grant licenses on terms that may not be favorable to us.

**Risks Related to Research, Development and Commercialization of Our Potential Fertility Treatments**

***The science underlying our three potential fertility treatments, AUGMENT, OvaPrime and OvaTure, is based on recent discoveries, and OvaPrime and OvaTure have not been tested in humans. We may not be able to successfully develop AUGMENT, OvaPrime, OvaTure or other potential fertility treatments.***

AUGMENT, OvaPrime and OvaTure are based on recent scientific discoveries relating to egg precursor cells, and OvaPrime and OvaTure have not been tested in humans, and human testing of AUGMENT has been limited. As a result, our AUGMENT, OvaPrime and OvaTure programs are subject to a higher level of risk than programs based on longer established science that have been the subject of human clinical trials.

In December 2012, we commenced our AUGMENT study in humans to test the safety and efficacy of AUGMENT. In September 2013, we chose to suspend enrollment in the AUGMENT study in the U.S. This decision followed an "untitled" letter we received from the FDA on September 6, 2013 questioning the status of AUGMENT as a 361 HCT/P and advising us to file an IND application. We anticipate having further discussions with the FDA to present details on AUGMENT and its qualifications as a 361 HCT/P, and to determine the appropriate path forward. We plan to introduce our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT and to generate data. In 2014, we expect to establish ACE clinics in at least four international regions, which we anticipate will result in 40 to 60 AUGMENT cycles in 2014. By the end of 2014, we expect to transition these ACE clinics to commercial centers. The data collected from these clinics, including whether, and by how much, the use of AUGMENT improves egg and embryo quality, increases the pregnancy and live birth rates of IVF and the safety of this potential fertility treatment will impact our ability to commercialize and generate revenues from sales of AUGMENT. If the results at these clinics are unfavorable, AUGMENT may not be viable or significant additional time and

Table of Contents

expense could be required before we are able to commercialize this potential fertility treatment. If we experience delays or difficulties in introducing our ACE program into international IVF clinics, our ability to commercialize AUGMENT could be delayed or prevented.

We plan to conduct further preclinical studies and continue optimization of OvaPrime in 2014, in anticipation of a commercial launch of OvaPrime outside of the United States in 2015. The data collected in our studies, including whether and by how much OvaPrime boosts egg reserves, will impact our ability to launch and generate revenues from sales of OvaPrime. If the results of our studies are unfavorable, OvaPrime may not be viable or significant additional time and expense could be required before we are able to commercialize this potential fertility treatment.

One of our scientific founders has successfully conducted laboratory experiments in animals and experiments with human EggPCs, which forms the basis for some aspects of OvaTure. There are, however, significant aspects of OvaTure that will require additional innovation for us to continue its preclinical and clinical development. In addition, successful development of OvaTure depends on our ability to mature human EggPCs into fertilizable eggs outside of the ovaries. Although our scientific founder's research has demonstrated the existence of EggPCs in human ovaries, research with respect to EggPCs is a new and emerging field. As a result, there is ongoing debate regarding the role of EggPCs in human reproduction as well as the ability of EggPCs to mature into fertilizable eggs when isolated from ovaries. The recent nature of the scientific discoveries underlying OvaTure, the ongoing debate regarding the ability to mature human EggPCs into fertilizable eggs, the need for additional innovation and the absence of information from human clinical trials all increase the risks associated with this potential fertility treatment. In any event, we believe that it will be costly and time consuming to develop OvaTure.

Clinical studies are expensive, difficult to design and implement and uncertain as to outcome. The FDA and IRBs regulate clinical trials and can suspend or terminate them for many reasons. Success in animal and preclinical studies does not ensure that studies in humans will be successful, and interim or preliminary findings do not necessarily predict final results. In addition, the timing of results from and completion of the studies will depend, in part, on our ability to enroll the studies on the timeline expected. Enrollment in the studies could be delayed for a number of reasons, including the unwillingness of patients to undergo, or physicians to prescribe, an additional surgical procedure in connection with IVF.

We may not be able to initiate or continue any future clinical trials for OvaTure or other potential fertility treatments for several reasons. For example, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, we will not be able to commence clinical studies. Patients who are eligible for future clinical trials may decide to use already established fertility treatments or to enroll in other clinical trials.

Patient enrollment is affected by other factors including:

- timing and capacity of GTP processing facilities / third party manufacturers;
- novelty of the potential fertility treatments being tested;
- form of infertility or severity of the condition being treated;
- eligibility criteria for the study in question;
- perceived risks and benefits of the potential fertility treatments under study;
- known side effects of the potential fertility treatments under study, if any;
- efforts of IVF clinics to facilitate enrollment in clinical trials;

Table of Contents

patient referral practices of physicians;

ability to monitor patients adequately during and after treatment; and

proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for any clinical trials for OvaTure and other potential fertility treatments would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our potential fertility treatments, which would cause the value of our company to decline and limit our ability to obtain additional financing.

***OvaXon, our joint venture with Intrexon, is seeking to create new applications to prevent inherited disease for human and animal health that are based on a novel gene editing based technology, which makes it difficult to predict the time and cost of development and subsequently obtaining regulatory approval.***

OvaXon, our joint venture with Intrexon, is developing new gene editing based applications to prevent inherited disease for human and animal health by leveraging Intrexon's synthetic biology technology platform and our technology relating to EggPCs. OvaXon may experience difficulties in the future related to its gene editing platform, which could cause significant delays or unanticipated costs, and which OvaXon may not be able to solve. OvaXon may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring those processes to commercial partners, which may prevent OvaXon from completing studies or commercializing potential fertility treatments on a timely or profitable basis, if at all.

The clinical study requirements of the FDA, the EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential product candidate. The regulatory approval process for novel gene based fertility treatments such as those that OvaXon will pursue likely will be more expensive and take longer than for other, better known or extensively studied product candidates.

The FDA has never approved any gene therapy or gene editing technology for use in humans or other animals. Only one gene therapy product, UniQure's Glybera, which received an EU marketing authorization in 2012, has been approved in the Western world, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for OvaXon's potential treatments.

OvaXon's technologies involve the use of synthetic biologically engineered products or synthetic biological technologies. Public perception about the safety and environmental hazards of, and ethical concerns over, genetically engineered products and processes could influence public acceptance of OvaXon's technologies, potential products and processes. If OvaXon is not able to overcome the ethical, legal and social concerns relating to synthetic biological engineering, any potential treatments it develops may not be accepted. These concerns could result in increased expenses or abandonment of any potential fertility treatments OvaXon develops.

Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future. Further, most of the laws and regulations concerning synthetic biology relate to the end products produced using synthetic biology, but that may change. For example, the Presidential Commission for the Study of Bioethical Issues in December 2010 recommended that the federal government oversee, but not regulate, synthetic biology research. The Presidential Commission also recommended that the government lead an ongoing review of developments in the synthetic biology field and that the government conduct a reasonable risk assessment before the field release of synthetic organisms. Synthetic biology may become subject to additional government regulations as a result of

Table of Contents

the recommendations, which could require OvaXon to incur significant additional expenses in complying with these laws and regulations.

Regulatory review agencies, committees and advisory groups and any new requirements and guidelines they promulgate may lengthen the regulatory review process, require OvaXon to perform additional studies, increase OvaXon's development costs, which we share with Intrexon, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions. As OvaXon advances its potential new treatments in human and animal health, it will be required to consult with these regulatory and advisory groups and comply with applicable requirements and guidelines. If OvaXon fails to do so, we may be required to delay or discontinue development of its potential fertility treatments. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential fertility treatment to market could decrease our ability to generate sufficient revenue to maintain our business.

***Preclinical testing and potential clinical trials of OvaTure and any of our other potential fertility treatments that require such testing and trials may not be successful. If we are unable to commercialize our potential fertility treatments or experience significant delays in doing so, our business will be materially harmed.***

We intend to invest a significant portion of our efforts and financial resources in the identification, preclinical development and clinical trials of potential fertility treatments. Our ability to generate revenues will depend heavily on the successful development and eventual commercialization of our potential fertility treatments. Although we have not discussed OvaTure with the FDA, we believe that the FDA is likely to regulate OvaTure and other potential fertility treatments, as drugs, biologics or medical devices under the PHSA or FDCA. This means, among other things, that we will not be able to market such potential fertility treatments in the United States unless and until we have successfully completed required testing (including clinical testing) and received marketing authorization from the FDA in the form of a NDA or BLA or, for medical devices, a 510(k) clearance or premarket approval application. We have not received approval to market any potential fertility treatments from regulatory authorities in any jurisdiction. We have only limited experience in conducting preclinical testing and clinical trials and filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties, including contract research organizations, to assist us in this process.

Prior to initiating any clinical trials of OvaTure or other potential fertility treatments, we may need to submit an IND to the FDA, or a similar application to other regulatory authorities outside of the United States, based on preclinical, animal and other tests. Upon submitting such an IND or similar application, the FDA or other regulatory authorities might determine that the risks involved in OvaTure or our other potential fertility treatments are too great to justify proceeding with a clinical study and impose a partial or full clinical hold. They may require us to do significant and costly additional preclinical work before commencing our clinical trials or may not allow us to proceed with clinical trials at all. In addition, an IRB must review and approve any clinical trial before we can commence that trial. The IRB responsible for reviewing any of our clinical trials may decline to grant approval for a variety of reasons, including that they do not believe that patient rights would adequately be protected. OvaTure and our other potential fertility treatments rely on new and complex technology that impacts human reproductive systems. Therefore, the FDA, equivalent foreign regulatory authorities and IRBs may all be especially cautious in reviewing and approving our clinical protocols for such potential fertility treatments.

If INDs for OvaTure or other potential fertility treatments do become effective, we will be required to conduct extensive clinical trials to demonstrate the safety, efficacy, purity and potency of our potential fertility treatments in humans. We will need to follow this same process for any future potential fertility treatments that are regulated by the FDA as a biologic or new drug. We will need to

Table of Contents

follow a similar process for any future product candidates that are regulated by the FDA as a medical device.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. The FDA, equivalent foreign regulatory authorities or an IRB can suspend or terminate our clinical development programs at any time, for a number of reasons, including that further study presents unreasonable risk to human subjects or that the rights of those subjects are not protected.

We may experience numerous unforeseen events during, or as a result of, clinical trials, which could delay or prevent our ability to receive marketing approval or commercialize our potential fertility treatments, including:

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may have delays in reaching, or fail to reach agreement on, acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our potential fertility treatments may produce negative or inconclusive results, or results subject to varying interpretations, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon potential fertility treatment development programs;
- the number of patients required for clinical trials, and/or the necessary duration of clinical trials of our potential fertility treatments may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;
- we or our third party contractors may fail to comply with regulatory requirements, such as conducting trials in accordance with current good clinical practices, and our contractors may fail to meet their contractual obligations to us in a timely manner or at all;
- we may have to suspend or terminate clinical trials of our potential fertility treatments for various reasons, including discovery that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our potential fertility treatments may be greater than we anticipate; and
- the supply or quality of our potential fertility treatments or other materials necessary to conduct clinical trials of our potential fertility treatments may be insufficient or inadequate.

If we are required to conduct additional clinical trials or other testing of our potential fertility treatments beyond those that we contemplate, if we are unable to successfully complete clinical trials or other testing of our potential fertility treatments, if the results of these trials or tests are not positive or are only modestly positive or if there are any safety concerns regarding our potential fertility treatments, we may:

- be delayed in obtaining marketing approval for our potential fertility treatments;
- not obtain marketing approval at all;

34

Table of Contents

obtain approval for indications or patient populations that are not as broad as we intend or desire;

obtain approval with labeling that includes significant restrictions on distribution or safety warnings, including boxed warnings;

be subject to additional post-marketing testing requirements; or

have the treatment removed from the market after obtaining marketing approval.

Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations and changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. In addition, securing FDA approval requires the submission of information about the product manufacturing process to, and successful inspection of manufacturing facilities by, the FDA. Our potential fertility treatment development costs will also increase if we experience delays in testing or obtaining marketing approvals. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our potential fertility treatments or allow our competitors to bring potential fertility treatments to market before we do. Such events could impair our ability to successfully commercialize our potential fertility treatments and may harm our business and results of operations. Even if clinical trials for our potential fertility treatments are completed as planned, the FDA may still conclude that the risks inherent in our potential fertility treatments outweigh the demonstrated benefits, and may refuse to grant us marketing authorization. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved potential fertility treatments not commercially viable. If we experience delays in obtaining, or if we fail to obtain any required approvals of OvaTure or other potential fertility treatments, our ability to generate revenues will be materially impaired and our business will be materially harmed.

***If serious adverse or inappropriate side effects are identified during the development of our potential fertility treatments or with any procedures with which our potential fertility treatments are used, we may need to abandon or limit our development of those potential fertility treatments.***

None of our potential fertility treatments has been proven effective and safe in humans through clinical trials. It is impossible to predict when or if any of our potential fertility treatments will prove effective or safe in humans or, to the extent required, will receive marketing approval. If our potential fertility treatments are associated with undesirable side effects or have characteristics that are unexpected with respect to the patient or the child conceived using our potential fertility treatments, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, if any of the procedures with which our potential fertility treatments are used is determined to be unsafe, we may be required to delay or abandon our fertility treatment development or commercialization. For example, we expect AUGMENT will be administered as part of the ICSI process and OvaPrime will be administered as part of the IVF process. To the extent physicians limit or abandon the use of ICSI, IVF or other procedures with which AUGMENT or OvaPrime is used, we may need to delay or abandon our development or commercialization of AUGMENT or OvaPrime.

***Even if we are able to commercialize any of our potential fertility treatments, they may fail to achieve the degree of market acceptance by physicians, patients and others in the medical community necessary for commercial success.***

If we are able to commercialize AUGMENT or OvaPrime or if any of our other potential fertility treatments receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients and others in the medical community. For example, doctors may continue to rely

Table of Contents

on current treatments, including fertility drugs and traditional IVF, which are well established in the medical community. In addition, the novel nature of AUGMENT, OvaPrime and OvaTure may affect market acceptance by physicians and patients. If our potential fertility treatments do not achieve an adequate level of acceptance, we may not generate significant treatment revenues and we may not become profitable. The degree of market acceptance of AUGMENT, OvaPrime and our other potential fertility treatments, after receipt of any necessary approvals for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages as compared to traditional IVF or other alternative treatments;
- ability to reduce the number of IVF cycles required to achieve a live birth;
- ability to reduce the cost of traditional IVF;
- ability to reduce the incidence of multiple births;
- the willingness of the target population to undergo, and of physicians to prescribe, an additional surgical procedure in connection with IVF;
- convenience compared to alternative treatments;
- adverse effects on patients or children conceived using our potential fertility treatments;
- ability to improve the side effect profile of infertility treatment;
- the willingness of the target population and of physicians to try new therapies based on recent scientific discoveries;
- limitations on the existing infrastructure to support AUGMENT, OvaPrime or other potential fertility treatments, including adequately trained embryologists and the willingness of IVF clinics to incorporate the process into their current treatment regimen;
- the willingness of patients to pay out of pocket for our potential fertility treatments, which, in the case of AUGMENT and OvaPrime, will be in addition to the price of a standard IVF procedure;
- any negative publicity or political action related to our or similar potential fertility treatments or IVF; and
- the strength of marketing and distribution support.

In addition, our ability to successfully commercialize our potential fertility treatments will depend on the continued use and acceptance of IVF, ICSI and fertility treatments generally. To the extent that the medical community or patient population determines that these procedures are unsafe or are otherwise not generally accepted, the market for our potential fertility treatments and, therefore, our business would be negatively affected.

***If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our potential fertility treatments we may not be successful in commercializing them.***

We are in the process of expanding on global sales and marketing team, initially focused on supporting the limited commercial launch of AUGMENT in four international regions. To achieve commercial success for any potential fertility treatment, we must either develop a sales and marketing team or outsource these functions to third parties. Our Executive Vice President, Global Commercial Operations, has significant experience in the international female fertility market. We also plan to recruit appropriate sales and marketing resources for countries in which we determine to provide or launch AUGMENT or OvaPrime on our own. In the future, we may choose to expand the sales force for AUGMENT, OvaPrime or other potential fertility treatments.

Table of Contents

There are risks involved both with establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any fertility treatment launch. If the commercial launch of AUGMENT, OvaPrime or another potential fertility treatment for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our treatment revenues or the profitability of these treatment revenues to us are likely to be lower than if we were to market and sell any potential fertility treatment ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our potential fertility treatments or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our potential fertility treatments effectively and in compliance with applicable laws.

***We may not be successful in our efforts to identify or discover additional potential fertility treatments. If we do identify additional potential fertility treatments, we may expend our limited resources to pursue a particular potential fertility treatment and fail to capitalize on potential fertility treatments that may be more profitable or for which there is a greater likelihood of success.***

An important element of our strategy is to identify and develop additional potential fertility treatments based on our EggPCs technology. We may be unable to identify any such potential fertility treatments. If we do identify additional candidates, we may not advance such candidates into clinical development for a number of reasons, including:

there may be evidence that such candidates may have harmful side effects;

preclinical studies may put into question the efficacy of such candidates;

we may determine that such candidates are unlikely to achieve marketing approval or market acceptance; or

such candidates may be too costly to manufacture or market.

Because we have limited financial and managerial resources, we focus on research programs and potential fertility treatments based on which candidates we believe have the highest likelihood of success and commercial value. As a result, we may forego or delay pursuit of opportunities with other potential fertility treatments that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial treatments or profitable market opportunities. Our spending on current and future research and development programs and potential fertility treatments may not yield any commercially viable treatments. For example, the programs we are considering relating to culture media and EggPCs banking may not reach commercialization or, if commercialized, may not be successful. If we do not accurately evaluate the commercial potential or target market for a particular potential fertility treatment, we may relinquish valuable rights to potential fertility treatments through collaboration, licensing or other royalty arrangements when it would have been more advantageous for us to retain sole development and commercialization rights to such potential fertility treatment.

Table of Contents

***We may not be successful in obtaining necessary rights to additional technologies or potential fertility treatments, including from our scientific founders, for our development pipeline through acquisitions and in-licenses.***

We may be unable to acquire or in-license additional technologies or potential fertility treatments from third parties, including our scientific founders, in order to grow our business. A number of more established companies may also pursue strategies to license or acquire potential fertility treatments that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we continue to work collaboratively with our scientific founders. These scientists continue to be active in the field of infertility and may develop new potential fertility treatments or intellectual property based on their continued research relating to infertility. The rights to new inventions by our scientific founders generally belong to the hospitals and academic institutions at which they are employed and are not subject to license or other rights in our favor. In the event that our scientific founders, or other third party scientists or entities, develop potential fertility treatments or intellectual property that we wish to acquire or in-license, we may be unable to negotiate such acquisition or in-license. Our failure to reach an agreement for any applicable potential fertility treatment or intellectual property could result in a third party acquiring the related rights and thereby harm our business.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire relevant potential fertility treatments on terms that would allow us to make an appropriate return on our investment.

We expect competition for acquiring and in-licensing potential fertility treatments that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. If we are unable to successfully obtain rights to suitable potential fertility treatments on reasonable terms, or at all, our business, financial condition and prospects for growth could suffer.

***We face substantial competition, including from more established infertility treatments, such as traditional IVF, as well as advances in new artificial reproductive technologies, which may result in others discovering, developing or commercializing potential fertility treatments before or more successfully than we do.***

There are a number of fertility treatments that are generally accepted in the medical and patient communities, including fertility drugs, IUI and IVF. Competition in the infertility market is largely based on pregnancy and live birth rates and side effects of treatment on patients. Accordingly, our success is highly dependent on our ability to develop potential fertility treatments that improve pregnancy and live birth rates and reduce risks and side effects, as compared to existing treatments. The ability of any potential fertility treatment that we successfully develop to reduce the overall costs associated with IVF also will be an important competitive factor.

Competitors may develop new infertility drugs, ART therapies, devices and techniques that could render obsolete our potential fertility treatments. There are a number of pharmaceutical companies, biotechnology companies, universities and research organizations actively engaged in research and development of potential fertility treatments. Like AUGMENT, OvaPrime and OvaTure, some of these potential fertility treatments are designed to address the shortcomings of IVF. In particular, we are aware of a number of companies and laboratories that are currently developing potential fertility treatments intended to identify high quality embryos for use in IVF, a university study of the transfer of granulosa cell mitochondria into eggs and a university study of induced pluriopotent stem cells, or iPS, shows that iPS cells can be generated from somatic cells and programmed to become differentiated cells, which can include germ line cells such as oocytes. Novocellus Ltd. is developing an embryo viability test, using culture media, to aid in the selection of embryos used in IVF. FertiliTech and

Table of Contents

Auxogyn, Inc. are developing hardware and software that analyzes embryo development against cell division timing parameters to help identify the highest quality embryo within a group of embryos. If successfully developed, these potential fertility treatments could improve outcomes and alleviate some of the other shortcomings of traditional IVF, thereby decreasing the need for our potential fertility treatments. Fertility Focus, along with its strategic partner Norgenix, are developing a fertiloscope for the early diagnosis of, and immediate corrective surgery for, the physical causes of infertility. Molecular diagnostic companies like Reprogenetics are developing novel preimplantation genetic diagnosis and screening methods to detect chromosomal and genetic disorders of embryos prior to transfer back to the women. Testing embryos in this manner may increase the likelihood of pregnancy, reduce the chances of pregnancy loss, and improve the odds of delivery. At this time, we cannot evaluate how our potential fertility treatments, if successfully developed and commercialized, would compare technologically, clinically or commercially to any other potential fertility treatments being developed or to be marketed by competitors. There can be no assurance that we will be able to compete effectively. OvaXon, our joint venture with Intrexon, is engaged in gene editing, which is a rapidly evolving field. OvaXon could potentially have competitors in both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Some of the pharmaceutical and biotechnology companies we expect OvaXon to compete with include GlaxoSmithKline plc, Sangamo BioSciences Inc., HemaQuest Pharmaceuticals, Inc., Merck & Co., Inc., and Novartis AG.

Our competitors may develop and commercialize new technologies before we do, allowing them to offer potential fertility treatments, services or solutions that are superior to those that we may offer or which establish market positions before the time, if any, at which we are able to bring potential fertility treatments to the market. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of potential fertility treatments, obtaining FDA and other regulatory approvals of potential fertility treatments and the commercialization of those treatments. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. Our competitors' potential fertility treatments may be safer, more effective or more effectively marketed and sold than any treatment we may commercialize and may render our potential fertility treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our potential fertility treatments. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

***We could be subject to negative publicity, political action and additional regulation because of the nature of our potential fertility treatments. These factors could increase our development and commercialization costs.***

Our potential fertility treatments are based on innovative science regarding eggs, embryos and fertilization, and in the case of our OvaXon joint venture, gene editing. These can be controversial subjects and, as a result, we could be subject to adverse publicity, political reaction and regulation, as well as changes to the laws and regulations affecting our potential fertility treatments. This may result in our incurring costs beyond what we anticipate in order to develop and commercialize our potential fertility treatments or may make it impossible to develop our potential fertility treatments at all. In addition, some states are considering adopting legislation defining when personhood begins. To the extent adopted, this legislation could limit, restrict or prohibit the use of IVF, which would have a negative effect on our ability to develop and sell our potential fertility treatments and, as a result, on our business.

Table of Contents

***Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any potential fertility treatments that we may develop.***

We face an inherent risk of product liability exposure related to the testing of our potential fertility treatments in human studies and clinical trials and will face an even greater risk if we commercialize AUGMENT, OvaPrime or any other potential fertility treatment that we may develop, including potential fertility treatments developed by OvaXon. Product liability claims involving our activities may be made for significant amounts because our potential fertility treatments involve mothers and children. For example, it is possible that we will be subject to product liability claims that assert that our potential fertility treatments have caused birth defects in children or that such defects are inheritable. In light of the nature of our planned activities, these claims could be made many years into the future based on effects that were not observed or observable at the time of birth. If we cannot successfully defend ourselves against claims that our potential fertility treatments caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

decreased demand for any potential fertility treatment that we may develop;

injury to our reputation and significant negative media attention;

withdrawal of clinical trial participants;

significant costs to defend the related litigation;

substantial monetary awards or payments to trial participants or patients;

loss of revenue;

the diversion of management's resources; and

the inability to commercialize any potential fertility treatments that we may develop.

We obtained product liability insurance coverage when we initiated our AUGMENT study in the United States. We will need to maintain product liability insurance coverage for introducing our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT and to generate data, conducting any clinical studies for AUGMENT, launching OvaPrime, or conducting clinical trials for our other potential fertility treatments. Such insurance is increasingly expensive and difficult to procure. In the future, such insurance may not be available to us at all, may only be available at a very high cost and, if available, may not be adequate to cover all liabilities that we may incur. In addition, we may need to increase our insurance coverage in connection with the commercialization of AUGMENT, OvaPrime or other potential fertility treatments. If we are not able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, our business could be harmed, possibly materially.

***Procedures such as IVF, as well as companies that manufacture and store cells and tissues, are the subject of standards and recommendations by national non-governmental bodies. Failure to comply with these standards could harm our commercial prospects or subject us to negative media attention or government sanctions.***

Some national organizations set voluntary guidelines for procedures like IVF and for the manufacture and storage of human cells and tissues. The American Society for Reproductive Medicine, or ASRM, for example, has issued recommendations on the minimum standards that ART practices should employ, including minimum qualifications of personnel and record keeping and informed consent practices. ASRM also has issued guidelines on the number of embryos that should be transferred at a single time through IVF. Similarly, the American Congress of Obstetricians and Gynecologists sets forth guidelines on numerous topics such as the circumstances in which embryos can be used for research purposes and the use of innovative medical procedures in clinical practice. Although voluntary, subject to exceptions discussed below, if we, or third parties that we work with,

Table of Contents

including IVF clinics, fail to comply with these standards, our commercial prospects could be harmed because patients may prefer to use the services and potential fertility treatments of companies that meet these voluntary standards. Similarly, physicians or IVF clinics may be less likely to endorse or use procedures or potential fertility treatments that fail to comply with such standards. In addition, failure to meet the standards could subject us to negative media attention. Moreover, noncompliance with these professional organization standards could subject us to compliance risks in states that have incorporated the standards into state law. For example, the State of Maryland has incorporated certain portions of the American Association of Tissue Banks' Standards for Tissue Banking into its regulations. Failure to comply with certain standards could, therefore, amount to a violation of state law to the extent we operate in a state that adopts a voluntary guideline into its regulations.

**Risks Related to Regulatory Approval of Our Potential Fertility Treatments and Other Regulatory Matters**

***Our plans to introduce AUGMENT and OvaPrime in selected regions outside of the United States depend upon AUGMENT and OvaPrime meeting the requirements of a class of products exempt from premarket review and approval in such regions. Failure to obtain required marketing approval in international regions would prevent our potential fertility treatments from being marketed in such regions.***

We believe that in certain regions outside of the United States, we will be able to introduce AUGMENT and OvaPrime into the market in the same way IVF and other assisted reproductive technologies are introduced without the need for pre-market review and approval by the relevant regulatory bodies. Our plans to introduce our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT and to generate data, and to transition ACE clinics to commercial centers, depend upon our being able to bring AUGMENT to the market without such pre-review and approval. Also, our plans for a commercial launch of OvaPrime outside of the United States in 2015 depend upon our being able to bring OvaPrime to the market without such pre-review and approval. There can be no assurance that foreign regulatory authorities will agree that AUGMENT or OvaPrime meet the requirements of a class of products exempt from premarket review and approval under applicable regulations. Additionally, foreign regulatory authorities may change their standards for products that are exempt from premarket review and approval. If a particular foreign regulatory authority does not agree that AUGMENT or OvaPrime does not meet the requirements for such an exemption, we may abandon the use of AUGMENT or OvaPrime in such regions, or suffer significant delays and expense seeking to obtain any necessary approval.

Further, in order to market and sell our potential fertility treatments in the EU and many other regions, we or our third party collaborators may need to obtain separate marketing approvals and will need to comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing. The time required to obtain approval in foreign regions may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally is subject to risks like those associated with obtaining FDA approval. In addition, in many countries outside the United States, a treatment must be approved for reimbursement before the treatment can be approved for sale in that country. Furthermore, some countries have restrictions particular to IVF, which may impose additional regulatory barriers for market entry for our potential fertility treatments. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA for marketing in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

In the EU, solely by way of example, our potential fertility treatments could be regulated as advanced therapy medicinal products, as medical devices or as human tissues and cells intended for human applications. Products regulated as advanced therapy medicinal products may only be placed on

Table of Contents

the market in the EU once they have been granted a marketing authorization by the European Commission. Securing a marketing authorization from the European Commission requires the submission of extensive preclinical and clinical data and supporting information, including information about the manufacturing process, to the EMA to establish the potential fertility treatment's safety, efficacy and quality. Following review of the marketing authorization application the EMA will issue an opinion, which the European Commission will take into account when deciding whether or not to grant a marketing authorization. Treatments regulated as medical devices in the EU are not subject to premarket review and approval by regulatory authorities. However, before placing the treatment on the market in the EU the manufacturer must demonstrate that the treatment meets certain essential requirements set out in applicable laws. For lower risk devices, the manufacturer may self-declare conformity to the essential requirements and apply the CE mark to the device. All other devices must undergo a conformity assessment procedure by a notified body, which is a third party licensed by regulatory authorities to perform such assessments. If the notified body agrees that the essential requirements have been met, it will issue a CE certificate, which allows the manufacturer to draw up a declaration of conformity and apply the CE mark to the device. Once a medical device has been CE marked it may be marketed throughout the EU.

Products regulated as human tissues and cells for human applications that do not fall within the definition of an advanced therapy medicinal product or a medical device are not generally subject to premarket review and approval by regulatory authorities. However, the establishments that process and use such human tissues and cells must be licensed and are subject to various quality system and adverse event reporting requirements. We believe that AUGMENT should be subject to this general regimen for human cells and tissues, but regulatory authorities in the EU could disagree with our conclusion and determine that the procedure involves sufficient manipulation of the cells to bring the potential fertility treatment within the scope of the rules governing advanced therapy medicinal products. The relevant criteria for determining which products qualify as advanced therapy medicinal products could also change. If, for example, the European Commission determines that AUGMENT is an advanced therapy medicinal product and, therefore, requires premarket review, we may be required to halt any on-going studies or other uses in humans and conduct a more time consuming and expensive clinical trial program for this potential fertility treatment and may be unable to file for or obtain the necessary approvals to commercialize AUGMENT.

While we believe EU marketing authorization is not required, medical treatments and processes, such as IVF, are regulated at the national level in the EU. Such national regulations may restrict the extent to which the eggs used in IVF treatments may be manipulated and so may prevent us from commercializing AUGMENT or OvaPrime in that country. In addition, certain other countries outside the EU and United States may have regulations that require us to obtain permission prior to commercializing AUGMENT or OvaPrime.

***It is unclear what regulatory pathway FDA will ultimately require AUGMENT or other of our potential fertility treatments to follow.***

We believe that AUGMENT meets the regulatory definition of a 361 HCT/P. AUGMENT involves mere isolation of mitochondria from egg precursor cells, and injection of those mitochondria into the same woman's egg, which we believe constitutes minimal manipulation of both the mitochondria and the egg. AUGMENT involves only homologous use, is not combined with any other article, and has a systemic effect, but is for reproductive use. If FDA ultimately agrees with our conclusions, AUGMENT will not be required to conduct clinical trials pursuant to an IND, nor will it be required to seek FDA pre-market review and approval through an NDA or BLA. However, both AUGMENT and our other potential fertility treatments constitute new technologies, the proper regulatory characterization of which will constitute matters of first impression for FDA. Particularly because AUGMENT and our other potential fertility treatments are potential fertility treatments that are intended to result in the

Table of Contents

creation of human life, there can be no assurance that FDA will agree with our views as to the proper regulatory characterization of AUGMENT or any of our other potential fertility treatments. FDA may conclude that AUGMENT and/or other potential fertility treatments constitute drugs, biologics, or medical devices. If FDA makes such a determination for any of our potential fertility treatments, we would be required to conduct clinical trials under an IND (or IDE for a medical device) and seek FDA pre-market review and approval pursuant to an NDA or BLA (or PMA for a medical device). In that event, we may abandon pursuing that potential fertility treatment in the United States, or suffer significant delays and expense seeking to approve any necessary approval.

***On September 6, 2013, we received an "untitled" letter from the FDA questioning the status of AUGMENT as a 361 HCT/P and advising us to file an IND application. We anticipate having further discussions with the FDA to present details on AUGMENT and its qualifications as a 361 HCT/P, and to determine the appropriate path forward. We continue to believe that AUGMENT qualifies as a 361 HCT/P. If the FDA disagrees with our interpretation of the relevant laws and regulations as they apply to AUGMENT, and requires an IND for the AUGMENT study, we may need to delay or abandon development of AUGMENT or other potential fertility treatments in the United States. The submission of an IND and a BLA or NDA would require us to compile significant amounts of data related to the AUGMENT process, as well as data from preclinical and clinical testing. We cannot guarantee that we would ever be able to secure such approval.***

The FDA regulates 361 HCT/Ps, such as AUGMENT, under a two-tiered framework. Certain higher risk HCT/Ps are regulated as new drugs, biologics or medical devices. Manufacturers of new drugs, biologics and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND or investigational device exemption. The FDA must review and approve a BLA or NDA before a new drug or biologic may be marketed, and in some cases must approve a premarket approval application for medical devices.

By contrast, the FDA exempts certain lower risk HCT/Ps from these requirements if they meet certain specified criteria. Such products frequently are referred to as "361 HCT/Ps," because the FDA regulates them under the authority given to it under section 361 of the PHSA to create regulations to control the spread of communicable diseases. We believe that AUGMENT meets the criteria for regulation as a 361 HCT/P rather than as a new drug or biologic and, therefore, that AUGMENT will not be subject to the requirement for an IND or FDA premarket review and approval. Thus, our current financial and business plans assume that we will not need to seek or obtain FDA approval for AUGMENT. Rather, we believe that we will have to comply with the requirements for 361 HCT/Ps set forth in FDA regulations and develop adequate substantiation to support marketing claims we make for the AUGMENT procedure.

The TRG is a body within the FDA designed to provide formal opinions regarding whether a particular product will be regulated as a 361 HCT/P. Product manufacturers are not required to consult with the TRG and instead can market their products based on their own conclusion that the product meets the 361 HCT/P criteria. We have not consulted the TRG.

The regulatory pathway for cell and tissue-based products is subject to significant uncertainty. The FDA's criteria for regulation as a 361 HCT/P are complex, and the FDA has provided little guidance on the meaning of terms used in the criteria, such as "minimal manipulation," "homologous," or "combination of the cells and tissues with another article." In addition, AUGMENT uses new technology that would present a matter of first impression for the FDA in determining whether to require premarket authorization. Further, AUGMENT may receive a high degree of scrutiny from the FDA due to its use as an aid to reproduction. The FDA or Congress could change the relevant criteria for determining which products qualify as 361 HCT/Ps or the regulatory requirements for HCT/Ps.

The courts may also interpret those criteria and requirements in unexpected ways. For example, in *United States v. Regenerative Sciences LLC*, the United States District Court for the District of Columbia

Table of Contents

recently rejected a company's argument that the Regenexx Procedure, which involves the use of stem cells for the treatment of various orthopedic conditions, was exempt from regulation by the FDA because the procedure constitutes the practice of medicine. The court also held that the procedure does not qualify for regulation as a 361 HCT/P because it involves more than "minimal manipulation" of the cells. The court's finding turned on the fact that the Regenexx Procedure involves cell culture and expansion, which changes the biological characteristics of the cells. In February 2014, the United States Court of Appeals for the D.C. Circuit affirmed the lower court's opinion. We think the AUGMENT procedure is distinguishable from the Regenexx Procedure because AUGMENT does not involve cell cultures or cell expansion. Nonetheless, this case suggests that courts may take a narrow view of what constitutes minimal manipulation.

Importantly, the court also noted the longstanding principle that the FDA's decisions on scientific matters, including the agency's conclusion that the procedure involves more than minimal manipulation, are entitled to substantial deference. This means that if the FDA disagrees with our conclusion that AUGMENT should be regulated as a 361 HCT/P, and not as a new biologic or drug, it may be very difficult to challenge the agency's position in court. If the FDA disagrees with our interpretation of the relevant laws and regulations as they apply to AUGMENT, and requires an IND for the AUGMENT study, we may need to delay or abandon development of AUGMENT or other potential fertility treatments in the United States.

***Even if the FDA regulates AUGMENT as a 361 HCT/P, we must still generate adequate substantiation for any claims made in our marketing of AUGMENT. Failure to establish such adequate substantiation in the opinion of federal or state authorities or equivalent authorities outside of the United States could substantially impair our ability to generate revenue.***

Even if we ultimately do not need to submit AUGMENT to the FDA for preapproval, we still must generate adequate substantiation for claims we make in our marketing materials. Both the FTC and the states retain jurisdiction over the marketing of products in commerce and require a reasonable basis for claims made in marketing materials. Many countries outside of the U.S. have similar regulatory authorities that regulate the marketing of products. We intend to generate such adequate substantiation for any claims we make about the AUGMENT procedure. If, however, after we commence marketing of AUGMENT, the FTC or one or more states or foreign authorities conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties or may be forced to alter or cease our marketing of AUGMENT in one or more jurisdictions. Any of this could materially harm our business. In addition, if our promotion of AUGMENT suggests that AUGMENT is not a 361 HCT/P, the FDA or equivalent foreign regulatory authorities might consider the potential fertility treatment to be a new drug or biologic. We will therefore be limited in the promotional claims that we could make about AUGMENT.

***Numerous states place restrictions on the operation of facilities and laboratories that recover, test, process, manufacture, store or dispose of certain cells and tissues. If we do not comply with such state regulations, as well as potential local regulations, we could be subject to significant sanctions.***

Various states, including New York, California, Florida, Illinois, Maryland, Texas, Massachusetts and others, impose requirements on facilities and laboratories that recover, test, process, manufacture, store or dispose of certain cells and tissues. These requirements can have significant geographic reach. In Maryland, for example, the permit requirements applicable to tissue banks, including reproductive tissue banks, apply not only to tissue banks located in Maryland, but also those tissue banks located outside of the state that are represented or serviced in Maryland. In some cases, the requirements imposed by states, such as record keeping and testing requirements, may be more stringent than those imposed by the FDA. Failure to comply with these state requirements could subject us to significant sanctions.

Table of Contents

***We will not be able to sell any potential fertility treatment that is regulated as a medical device without obtaining and maintaining necessary regulatory clearances or approvals.***

To market any potential fertility treatments that are regulated as medical devices, or that require the use of a new medical device, such as the innovative culture media solution that we are planning to develop, we will need to seek approval or clearance from the FDA, either through the premarket approval process or the 510(k) clearance process. We currently expect to be able to rely on the 510(k) clearance process, as opposed to the premarket approval process, for some of our medical device potential fertility treatments. However, it is difficult to predict whether the FDA will allow us to use the 510(k) pathway or require us to use the premarket approval process. We cannot guarantee that we will be able to obtain clearance or approval of these medical devices through either pathway. In addition, even if the FDA permits us to use the 510(k) pathway, the requirements to bring a product to market through this process may be significantly more resource intensive than we currently expect. The FDA has announced that it intends to make changes to the 510(k) process, and these changes, or any other changes related to FDA's regulation of medical devices, could have an adverse effect on our ability to gain regulatory clearance for, and to commercialize, our potential fertility treatments. In addition, any modifications to medical devices that we successfully bring to market, if any, may require new regulatory clearances or premarket approvals. Marketing a medical device without the necessary clearance or approval could result in a warning letter, fines, injunctions, product seizures or other civil or criminal penalties. Delays in our receipt of regulatory clearance or approval will cause delays in our ability to sell our potential fertility treatments, which will have a negative effect on our ability to generate and grow revenues.

***In addition to the challenges associated with obtaining any necessary marketing approvals in international jurisdictions, economic, political and other risks associated with foreign operations could adversely affect our international sales.***

If we succeed with our international commercialization strategy, then our business will be subject to risks associated with doing business internationally. For example, our future results of operations could be harmed by a variety of factors, including:

changes in foreign currency exchange rates;

changes in a country's or region's political or economic conditions, particularly in developing or emerging markets;

trade protection measures and import or export licensing requirements;

differing business practices associated with foreign operations;

difficulty in staffing and managing widespread operations, including compliance with labor laws and changes in those laws;

differing protection of intellectual property and changes in that protection; and

differing regulatory requirements and changes in those requirements.

We do not currently have an international infrastructure including, without limitation, sales, manufacturing and distribution capabilities and have no experience in conducting foreign operations. Establishing commercial activities and complying with laws in foreign jurisdictions may be costly and could disrupt our operations.

Table of Contents

***Even if we successfully launch AUGMENT, it will be subject to ongoing regulation. We could be subject to significant civil or criminal penalties if we fail to comply with these requirements, and we may be unable to commercialize our potential fertility treatments.***

Even if the FDA allows AUGMENT or any other potential fertility treatment of ours to be marketed as a 361 HCT/P and, therefore, without an NDA or BLA, we will still be subject to numerous post-market requirements, including those related to registration and listing, record keeping, labeling, current good tissue practices, or cGTPs, donor eligibility and other activities. HCT/Ps that do not meet the definition of a 361 HCT/P and, therefore, are approved via an NDA or BLA, are also subject to these and additional ongoing obligations. If we fail to comply with these requirements, we could be subject to warning letters, product seizures, injunctions or civil and criminal penalties. We are currently relying on a third party cGTP-compliant facility to conduct the various steps involved in the AUGMENT process, including the purification of the woman's mitochondria from the ovarian tissue biopsy. In the future, we may establish our own processing facility, which would need to be cGTP compliant. Any failure by us or the third party facility on which we rely to maintain cGTP compliance could require remedial action, such as product recalls and delays in distribution and sales of AUGMENT and any other potential fertility treatments that we develop, as well as enforcement actions.

Moreover, even if the FDA or equivalent foreign regulatory authorities allow AUGMENT or any other potential fertility treatment to be marketed without premarket approval, the regulatory authorities could still seek to withdraw the potential fertility treatment from the market for a variety of reasons, including if the agency develops concerns regarding the safety or efficacy of the potential fertility treatment or its manufacturing process.

***OvaTure and any other potential fertility treatment for which we obtain marketing approval are subject to continuing regulation after approval. We may be subject to significant penalties if we fail to comply with these requirements.***

Any potential fertility treatment, including any potential fertility treatment developed by our OvaXon joint venture, for which we obtain marketing approval or clearance will be subject to continuing regulation by the FDA or equivalent foreign regulatory authorities. For example, such potential fertility treatments will be subject to requirements relating to submission of safety and other post-marketing information and reports, registration and listing, manufacturing, packaging, quality control, storage, distribution, quality assurance and corresponding maintenance of records and documents, labeling, advertising and promotional activities, distribution of samples to physicians and recordkeeping. Even if marketing approval or clearance of a potential fertility treatment is granted, the approval or clearance may be subject to limitations on the uses for which the potential fertility treatment may be marketed, be subject to restrictions on distribution or use through a risk evaluation and mitigation strategy, or contain requirements for costly post-marketing testing to further evaluate the safety or efficacy of the potential fertility treatment. The FDA and equivalent foreign regulation authority closely regulate the post-approval marketing and promotion of drugs, biologics and medical devices to ensure such products are marketed only for the approved indications or cleared uses and in accordance with the provisions of the approved labeling. The FDA and equivalent foreign regulation authority impose stringent restrictions on manufacturers' communications regarding off-label use and if we market our potential fertility treatments other than for their approved indications, we may be subject to enforcement action for off-label marketing.

In addition, later discovery of previously unknown problems with our potential fertility treatments, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the labeling or marketing of potential fertility treatments;

Table of Contents

restrictions on distribution or use of potential fertility treatments;

requirements to conduct post-marketing clinical trials;

warning or untitled letters from the FDA or equivalent foreign regulatory authorities;

withdrawal of potential fertility treatments from the market;

refusal to approve pending applications or supplements to approved applications;

recall of potential fertility treatments;

fines, restitution or disgorgement of profits or revenue;

suspension or withdrawal of marketing approvals;

refusal to permit the import or export of our potential fertility treatments;

product seizure;

injunctions; or

the imposition of civil or criminal penalties.

***It is unlikely that third party payors will cover or reimburse for AUGMENT, OvaPrime or other, future potential fertility treatments and services, and many patients may be unable to afford them.***

Many third party payors, both in the United States and other foreign countries, including national health services or government funded insurance programs as well as private payors, place significant restrictions on coverage and reimbursement for IVF and other ART procedures. Those restrictions may include limits on the types of procedures covered, limits on the number of procedures covered and overall annual or lifetime dollar limits on reimbursement for IVF and other ART procedures. As a result, we believe very few third party payors, either in the United States or outside the United States, will reimburse for AUGMENT, OvaPrime or our other potential fertility treatments and services. Thus, it is likely that IVF clinics and physicians will be able to use AUGMENT, OvaPrime and our other potential fertility treatments and services only if the patient can afford and is willing to pay out-of-pocket. The cost of AUGMENT, OvaPrime and our other potential fertility treatments and services may be beyond the means of many patients. This may limit the size of the market and prices charged for AUGMENT, OvaPrime or our potential fertility treatments and services and, thereby, limit our future revenues.

Even in those limited situations in which government or private payors may cover AUGMENT, OvaPrime or other potential fertility treatments and services, cost containment pressures may later cause these third party payors to adopt strategies designed to limit the amount of reimbursement paid to IVF clinics and physicians, including but not limited to the following:

reducing reimbursement rates;

challenging the prices charged for medical potential fertility treatments or services;

further limiting potential fertility treatments and services covered;

challenging whether potential fertility treatments or services are medically necessary;

taking measures to limit utilization of potential fertility treatments and services;

negotiating prospective or discounted contract pricing;

adopting capitation strategies; and

seeking competitive bids.

Table of Contents

Additionally, in those limited situations where ART procedures such as IVF are available to disabled patients of childbearing age enrolled in federal healthcare programs, such as Medicare, the covered services and potential fertility treatments may be subject to changes in coverage and reimbursement rules and procedures, including retroactive rate adjustments. These contingencies could even further decrease the range of potential fertility treatments and services covered by such programs or the reimbursement rates paid directly or indirectly for such potential fertility treatments and services. Such changes could further limit our ability to sell our potential fertility treatments, which may have a material adverse effect on our revenues.

In March 2010, Congress enacted sweeping healthcare reform legislation known as the Affordable Care Act. The Affordable Care Act will substantially change the way that healthcare is financed by both governmental and private insurers and significantly affect the delivery and financing of healthcare in the United States. The Affordable Care Act contains provisions that, among other things, govern enrollment in federal healthcare programs, effect reimbursement changes, encourage use of comparative effectiveness research in healthcare decision making and enhance fraud and abuse requirements and enforcement. The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products, which could include potential fertility treatments such as OvaTure, if the FDA regulates it as a biologic. The fee, which is not deductible for federal income tax purposes, is based on the manufacturer's market share of sales of branded drugs and biologics, excluding orphan drugs, to, or pursuant to coverage under, specified U.S. government programs. In addition, the law subjects most medical devices to a 2.3% excise tax, beginning on January 1, 2013. The implementation of the Affordable Care Act may have a material adverse effect on our results of operations and financial condition.

The reimbursement process for products and procedures outside the United States generally is subject to risks, like those associated with reimbursement in the United States, including the risk that it is unlikely that third party payors will cover or reimburse AUGMENT, OvaPrime or other, future potential fertility treatments and services. Many national health services and third party payors in the EU already place coverage and reimbursement limits on ART procedures, including IVF, and may impose even greater limits in the future. In many EU member states medicinal products and medical devices are subject to formal pricing and reimbursement approvals before they can be reimbursed by national health services or government-funded insurance schemes. Reimbursement may be conditional on the agreement by the seller not to sell the product above a fixed price in that country, or the national authority may unilaterally establish a reimbursement price in connection with the inclusion of the product on a list of reimbursable products.

The likelihood that many third party payors will refuse to cover and reimburse for AUGMENT, OvaPrime and our future potential fertility treatments and services and that many patients will be unable to afford to pay for them out of pocket may reduce the demand for, or the price of, AUGMENT, OvaPrime and other future potential fertility treatments and services, which would have a material adverse effect on our revenues. Additional legislation or regulation relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future, and could adversely affect the revenues generated from the sale of our potential fertility treatments.

***Several states and certain foreign countries have enacted legislation that may hamper the ability of IVF clinics and physicians to pass through the cost of our potential fertility treatments to patients or third party payors.***

Several states, including California and New York, and certain foreign countries require direct billing of laboratory or pathology services, prohibit physicians from marking up the cost of laboratory or pathology services when they pass these costs on to patients or other payors or require that physicians disclose to patients what they actually paid to obtain laboratory or pathology services. Additionally, the federal government has enacted regulations limiting the Medicare reimbursement

Table of Contents

available to physicians who contract out the technical component of certain laboratory and pathology procedures.

To the extent that AUGMENT, OvaPrime or possibly other, future potential fertility treatments or services are treated as laboratory or pathology services for purposes of reimbursement, these laws may make it difficult for us to market those potential fertility treatments and services to IVF clinics and physicians in some states and may also require us to restructure our business model before we can expand into certain markets. To the extent that our IVF clinic and physician customer base anticipates seeking Medicare reimbursement, these laws may require a comprehensive restructuring of our business model, and therefore adversely impact our ability to market our potential fertility treatments. Any additional legislation or regulation in this area could also adversely affect our ability to market our potential fertility treatments.

***Even though we anticipate very limited third party coverage and reimbursement for AUGMENT, OvaPrime and our future potential fertility treatments and services, our future arrangements with third party payors and IVF clinics and physicians may be subject to foreign, federal and state fraud and abuse laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

Even though we anticipate very limited third party coverage and reimbursement, including from federal healthcare programs, for AUGMENT, OvaPrime and possibly other, future potential fertility treatments and services, our future arrangements with third party payors and IVF clinics and physicians may expose us to broadly applicable fraud and abuse laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute AUGMENT, OvaPrime and possibly other, future potential fertility treatments and services for which we obtain marketing approval. Restrictions under federal and state fraud and abuse laws and regulations that may be applicable to our business include the following:

the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

the federal Stark law prohibits physicians from referring patients to hospitals, laboratories, and other types of entities in which they or their immediate family members have a financial interest, if the referral is for a select list of Medicare or Medicaid-covered services, including most clinical laboratory services, and also prohibits entities that furnish the covered services subsequent to a prohibited referral from billing Medicare or Medicaid for the services provided and from receiving payment from a federal healthcare program for those services;

the federal False Claims Act imposes civil penalties, often through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for failure to safeguard the privacy, security and transmission of individually identifiable health information and for executing a scheme to defraud any federal healthcare program;

the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in any matter within the jurisdiction of the executive, legislative, or judicial branch of the U.S. government, including in

Table of Contents

connection with the delivery of or payment for federally reimbursed healthcare benefits, items or services;

the federal transparency requirements under the "sunshine" provisions of the Affordable Care Act require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and

analogous foreign laws and regulations, such as anti-bribery laws and laws governing the promotion of medicinal potential fertility treatments or medical devices, as well as the Foreign Corrupt Practices Act, may apply to sales or marketing arrangements and interactions with physicians in countries outside the United States.

Efforts to ensure that our business arrangements with third parties will comply with applicable fraud and abuse laws and regulations will involve substantial costs. It is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the IVF clinics or physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Even the assertion of a violation under any of these provisions could have a material adverse effect on our financial condition and results of operations. Any such assertion would likely trigger an investigation of our business or executives that could cause us to incur substantial costs and result in significant liabilities or penalties, as well as damage to our reputation.

***Laws and regulations governing international operations, including the Foreign Corrupt Practices Act, may preclude us from developing, manufacturing and selling certain potential fertility treatments outside of the United States and require us to develop and implement costly compliance programs.***

We have begun to expand our operations outside of the United States, and we must comply with numerous laws and regulations relating to our business operations in each jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

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 certain accounting provisions requiring the company to maintain books and records that accurately and fairly

Table of Contents

reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biotechnology industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical studies and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

The failure to comply with laws governing international business practices may result in substantial penalties. Violation of the FCPA can result in significant civil and criminal penalties. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA's accounting provisions.

***We may have obligations under our contracts with IVF clinics and physicians or other healthcare providers to protect the privacy of patient health information.***

In the course of performing our business, we will obtain, from time to time, confidential patient health information. For example, we may learn patient names and be exposed to confidential patient health information when we provide training on AUGMENT, OvaPrime and possibly other, future potential fertility treatments and services to the staff at IVF clinics and physicians' offices. United States federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information and privacy and security rules under HIPAA. At this time, we are not a HIPAA covered entity. However, our current and future business associate or other confidentiality agreements with covered entities contain commitments to protect the privacy and security of patients' health information and, in some instances, may require us to indemnify the covered entity for any claim, liability, damage, cost or expense arising out of or in connection with a breach of the agreement by us. If we were to violate one of these agreements, we could lose customers and be exposed to liability or our reputation and business could be harmed. In addition, the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted in February 2009, expands the HIPAA privacy and security rules, including imposing many of the requirements of those rules directly on business associates and making business associates directly subject to HIPAA civil and criminal enforcement provisions and associated penalties. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements. Our failure to comply may result in criminal and civil liability.

Other federal and state laws apply to the use and disclosure of health information, as well as certain financial information, which could affect the manner in which we conduct our business. Such laws are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA or cover different subject matter. Such state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

In the member states of the EU and many other countries, we will be subject to similar or more stringent data privacy laws, such as those implementing the European Data Protection Directive 95/46/EC, that require us to protect all individually identifiable information and restrict the use, disclosure and onward transfer of that information. Such national laws typically have their own civil or criminal enforcement provisions and associated penalties. We may incur costs in complying with the applicable privacy and security requirements, which may include registration with the national data protection authorities.

Table of Contents

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

**Risks Related to the Manufacturing of Our Potential Fertility Treatments**

***We have entered into an agreement with a third party for the manufacture of AUGMENT and expect to rely on third parties for the manufacture of our other potential fertility treatments for preclinical testing, clinical trials and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our potential fertility treatments or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts because we have limited control of third parties' activities, including manufacturing capacity and costs and regulatory compliance.***

We do not own a manufacturing facility. In July 2013, we entered into a master services agreement with a global third party manufacturer to provide services for the manufacture of AUGMENT to perform the identification and isolation of EggPCs and the preparation of mitochondria steps in the AUGMENT process for our ACE program and early commercial activities. In our anticipated launch of AUGMENT and OvaPrime outside the United States, we may use our existing global cGTP-compliant manufacturer, contract with in-country manufacturers or manufacture on-site in clinics using our own equipment and employees. While we believe that our third party manufacturer has the capability to undertake the manufacture of AUGMENT in accordance with all applicable rules and regulations, there can be no assurance that it will be able to do so successfully. There can be no assurance that our global contract manufacturer, or any in-country manufacturer that we contract with, will maintain consistent quality standards with respect to any in-house manufacturing we do at individual IVF clinics. While we will seek to maintain high standards by working with high quality clinics, providing our own manufacturing equipment and personnel, and conducting regular training and quality audits, there can be no assurance that such clinics will maintain consistent quality standards. We do not have internal capabilities to manufacture AUGMENT, or internal or external capabilities to manufacture OvaPrime, OvaTure or any other potential fertility treatment.

Reliance on third party manufacturers and laboratories entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing or service agreement by the third party; and

Table of Contents

the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We expect to rely on third party manufacturers or third party collaborators for the manufacture of our other potential fertility treatments for preclinical testing, clinical trials and for commercial supply. We may be unable to establish any agreements with third party manufacturers or to do so on acceptable terms.

Third party manufacturers and laboratories may not be able to comply with cGTP or current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Any performance failure on the part of our existing or future manufacturers and service providers could delay clinical development or marketing approval or adversely affect or impede commercial sales. Our failure, or the failure of our third party manufacturers and service providers, to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our potential fertility treatments and harm our business and results of operations.

We may compete with other companies for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGTP and cGMP regulations and that might be capable of manufacturing for us. It is possible that some of these manufacturers have agreements with our competitors that limit or restrict their ability to contract with us, further narrowing the number of manufacturers that are available to us.

We do not currently have arrangements in place for redundant supply or a second manufacturing source for AUGMENT. Although we believe that there are other potential alternative manufacturers who could manufacture our potential fertility treatments, we may incur added costs and delays in identifying and qualifying any such replacement. We are pursuing a second manufacturing source for AUGMENT.

Our current and anticipated future dependence upon others for the manufacture of our potential fertility treatments may adversely affect our future profit margins and our ability to commercialize AUGMENT or any future potential fertility treatments that we seek to market on a timely and competitive basis.

We do not currently manufacture AUGMENT outside of the United States. If our current third party manufacturer is unable to supply AUGMENT for certain countries outside the United States, we will need to contract with third party manufacturers that comply with cGTP regulations to supply AUGMENT in other jurisdictions in which we decide to commercialize AUGMENT, if any. Although we believe there are other manufacturers who could manufacture our potential fertility treatments outside the United States, we may incur added costs and delays in identifying and qualifying a non-United States manufacturer.

Providing AUGMENT to patients in regions outside the United States requires coordination internally among our employees and externally with physicians, IVF clinics, regulatory authorities and third party manufacturers, suppliers and carriers. For example, a patient's physician or clinical site will need to coordinate with us to ship a patient's ovarian tissue biopsy to the cGTP-compliant facility responsible for the next steps in the AUGMENT process, and we will need to coordinate with them to ship isolated cellular components from the patient's processed tissue back to them. Such coordination involves a number of risks that may lead to failures or delays in processing our AUGMENT potential fertility treatment. If we are unable to coordinate appropriately, we may encounter delays, incur additional costs or adversely affect our ability to commercialize AUGMENT.

Table of Contents

***We intend to improve the efficiency and reduce the cost of our current AUGMENT process prior to commercialization. If we fail to do so, we may not continue commercial activities or generate significant revenues, and the profitability of our planned operations could be adversely affected.***

We continue to enhance the process for AUGMENT. As a result, while we are not able to project the likely AUGMENT costs, we believe that we will need to significantly reduce AUGMENT costs in order to achieve commercial success. We are actively working on initiatives that we have identified which we believe will enable us to achieve these cost savings. However, there can be no assurance that these initiatives will be successful. If we are not successful in reducing AUGMENT costs, we may not be able to continue commercial activities on schedule, if at all, and AUGMENT revenues may be lower than we expect and the profitability of AUGMENT sales could be adversely affected, possibly materially.

***In the future, we may build and equip a cGTP-compliant facility for the processing of AUGMENT. Constructing and equipping such a facility in compliance with regulatory requirements will be time consuming and expensive.***

In the future, we may lease, build and equip a cGTP-compliant facility for the processing of AUGMENT. We believe that such a facility may be important to our ability to meet demand for AUGMENT and to process AUGMENT on a cost-effective basis. The leasing, build-out and equipping of this facility will require substantial capital expenditures. In addition, it will be costly and time consuming to recruit necessary additional personnel for the operation of the facility. Furthermore, we do not have experience running a manufacturing facility. Nor do we currently have funding available for any of these purposes. If we are unable to successfully construct and equip a commercial manufacturing facility in compliance with regulatory requirements, or hire additional necessary personnel appropriately, our revenues from AUGMENT, and the profitability of such revenues, may be adversely affected.

***Lack of coordination internally among our employees and externally with physicians, IVF clinics and third party suppliers and carriers could result in processing and manufacturing difficulties, regulatory enforcement actions, disruptions or delays and cause us to have insufficient resources to meet any AUGMENT site's requirements or potential commercial requirements.***

Providing AUGMENT to patients requires coordination internally among our employees and externally with physicians, IVF clinics and third party suppliers and carriers. For example, a patient's physician or clinical site will need to coordinate with us to ship a patient's ovarian tissue biopsy to the cGTP-compliant facility responsible for the next steps in the AUGMENT process, and we will need to coordinate with them to ship the patient's egg precursor cells, or the patient's mitochondria from the egg precursor cells, to them. Such coordination involves a number of risks that may lead to failures or delays in processing our AUGMENT potential fertility treatment, including:

- difficulties in the timely shipping of patient-specific materials to us or in the shipping of our potential fertility treatments to the treating physicians due to errors by third party carriers, transportation restrictions or delays or other reasons;

- destruction of, or damage to, patient-specific materials or our potential fertility treatments during the shipping process due to improper handling by third party carriers, hospitals, physicians or us;

- destruction of, or damage to, patient-specific materials during any of the tissue or cell processing steps required for egg precursor cell isolation and selection of the patient-specific mitochondria;

- destruction of, or damage to, patient-specific materials or our potential fertility treatments during storage at our facilities;

Table of Contents

failure to maintain precise patient records sufficient to ensure the chain of custody procedures are followed;

destruction of, or damage to, patient-specific materials or our potential fertility treatments stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians;

failure to ensure adequate quality control and assurances in the AUGMENT process as we increase production quantities; and

failure to establish or maintain sufficient manufacturing capacity, whether through third party manufacturers or internally.

If we are unable to coordinate appropriately, we may encounter delays or additional costs in achieving our clinical and commercialization objectives. We, or third parties, could face regulatory action as a result of the failure to comply with cGTPs or other applicable rules. Some or all of these risks may also be applicable to OvaTure and any other future potential fertility treatments.

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

***We will rely on selected international IVF clinics to gain experience and generate data on AUGMENT through our ACE access program and to introduce, as well as to launch OvaPrime if our preclinical studies and potential fertility treatment optimization efforts are successful. We will also rely on third parties to conduct any clinical trials for other potential fertility treatments. Such third parties may not perform satisfactorily, including failing to meet volume expectations, quality standards or deadlines for the completion of such studies or trials.***

Our reliance on these third parties for providing our potential fertility treatments and for clinical development activities will reduce our control over these activities.

We will remain responsible for ensuring that AUGMENT and OvaPrime, when and if introduced to international IVF clinics, are introduced with consistent and high quality standards. Moreover, the FDA and equivalent foreign regulatory authorities will require us to comply with GCPs with respect to any clinical trials for any of our potential fertility conducted in connection with a submission to the FDA or foreign regulatory authorities, including an IND or equivalent application, and will require that we record and report clinical trial results to assure that data and reported results are credible and accurate and that the rights and safety are protected. We will also be required to register ongoing FDA-regulated clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Our reliance on these third parties for providing AUGMENT to IVF clinics and conducting clinical development activities will reduce our control over these activities. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, provide our potential fertility treatments, conduct our clinical trials in accordance with regulatory requirements or our stated protocols or maintain consistent quality standards, in the case of contract manufacturing and clinics manufacturing our treatments on site, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our potential fertility treatments and will not be able to, or may be delayed in our efforts to, successfully commercialize our potential fertility treatments. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, and could devote more of their resources to such other entities at the expense of expending sufficient resources on our clinical development activities.

Table of Contents

***We expect to depend on collaborations with third parties, particularly Intrexon, for the development and commercialization of our potential fertility treatments. If those collaborations are not successful, we may not be able to capitalize on the market potential of these potential fertility treatments.***

In December 2013, we established a collaboration with Intrexon to accelerate development of OvaTure, and entered into the OvaXon joint venture with Intrexon to create new applications to prevent inherited diseases for human and animal health. Further, we currently intend to commercialize AUGMENT and OvaPrime ourselves in some markets and to collaborate with third parties to commercialize AUGMENT, OvaPrime and any future potential fertility treatments in other markets. In addition, we may seek partners for further development and commercialization of our other potential fertility treatments. These collaborations could take the form of license, distribution, sales representative, joint venture, sponsored research, co-promotion or other arrangements with pharmaceutical and biotechnology companies, other commercial entities and academic and other institutions.

In any such arrangements with third parties, we will likely have limited control over the amount and timing of resources that such collaborators dedicate to the development or commercialization of our potential fertility treatments. Collaboration agreements may not lead to development or commercialization of potential fertility treatments in the most efficient manner, or at all. Our ability to generate revenues from these arrangements will depend on, among other things, our collaborators' successful performance of the functions assigned to them in these arrangements.

Collaborations involving our potential fertility treatments would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and could devote fewer resources to our potential fertility treatments than we expect them to;
- a collaborator with marketing and distribution rights to one or more other potential fertility treatments may not commit sufficient resources to the marketing and distribution of our potential fertility treatments;
- collaborators may not pursue development and commercialization of our potential fertility treatments or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a potential fertility treatment or repeat or conduct new clinical trials;
- collaborators could independently develop, or develop with third parties, potential fertility treatments that compete directly or indirectly with our potential fertility treatments;
- collaborators may create intellectual property that we need to in-license, may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our potential fertility treatments or that result in costly litigation or arbitration that diverts management's attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable potential fertility treatments.

Table of Contents

***If we are not able to establish collaborations, we may have to alter our development and commercialization plans.***

Our potential fertility treatment development programs and the potential commercialization of such treatments will require substantial additional cash to fund expenses. We may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of some of our potential fertility treatments. For example, we currently intend to seek to collaborate with third parties to commercialize AUGMENT, OvaPrime and other potential fertility treatments we successfully develop in certain EU member states and other parts of the world.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States of our potential fertility treatment, the potential market for such potential fertility treatment, the costs and complexities of manufacturing and delivering the potential fertility treatment to patients, the potential and relative cost of competing fertility treatments, uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative potential fertility treatments or technologies for similar indications or conditions that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our potential fertility treatment. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators. Collaborations are complex and time consuming to negotiate, document and manage. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we are not able to obtain a collaborator for a particular program, we may have to curtail the development of such program or of one or more of our other development programs, delay the potential commercialization of such program, reduce the scope of any sales or marketing activities for the program or increase our expenditures and undertake development or commercialization activities for the program at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our potential fertility treatments or bring these potential fertility treatments to market and generate revenue.

**Risks Related to Our Intellectual Property**

***If we fail to comply with our obligations under our intellectual property licenses, we could lose license rights that are important to our business.***

We have an exclusive license from MGH with respect to the intellectual property that forms the basis of our business. The license under MGH-owned patent rights and know-how is for human female fertility, the treatment or prevention of inherited (including mitochondrial) diseases or defects in all animals, including humans, assisted and/or artificial reproductive technology in all non-human animals, and the artificial creation of food, research animals and/or animal products; and the license under the MGH and Harvard co-owned patent right is for *ex-vivo* human female fertility treatments. Our existing MGH license agreement and another agreement granting rights impose, and we expect that future license agreements will impose, various obligations on us, including diligence, milestone payments,

Table of Contents

royalty payments, insurance and other obligations. For example, under our license agreement with MGH, we are required to use commercially reasonable efforts to develop and make available to the public licensed fertility treatments and to satisfy specified diligence milestones within specified timeframes. If we fail to comply with our obligations under this or other of our license agreements, our licensors may have the right to terminate our licenses, in which event we might not be able to market potential fertility treatments that are covered by these agreements, or to convert our licenses to non-exclusive licenses, which could materially adversely affect the value of the potential fertility treatments we developed under the license agreements. Termination of these license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, or to cease commercialization of licensed technology and potential fertility treatments. This could materially adversely affect our business, particularly in the case of our license from MGH.

***If we are unable to obtain and maintain patent protection for our technology and potential fertility treatments, or if our licensors are unable to obtain and maintain patent protection for the technology or potential fertility treatments that we license from them, our competitors could develop and commercialize technology and potential fertility treatments similar or identical to ours, and our ability to successfully commercialize our technology and potential fertility treatments may be adversely affected.***

Our success depends in large part on our and our licensors' ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and potential fertility treatments. We and our licensors have sought to protect our proprietary position by filing patent applications within the United States and abroad related to our novel technologies and potential fertility treatments that are important to our business. The process of obtaining patent protection is uncertain, and we and our licensors may not succeed in obtaining the patent protection for our novel technologies and potential fertility treatments that we seek. If we and our licensors are unable to obtain and maintain patent protection of sufficient scope for our technology and potential fertility treatments, our competitors could develop and commercialize technology and potential fertility treatments similar or identical to ours, and in that case our ability to successfully commercialize our technology and potential fertility treatments may be adversely affected. This risk is greater outside the United States where some aspects of our in-licensed intellectual property are not protected by patents. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Moreover, under our license agreement with MGH, we do not have the right to control the preparation, filing and prosecution of the licensed patent applications, to defend the validity and enforceability of the licensed patents against challenges by third parties, or to maintain the licensed patents covering our technology or potential fertility treatments. This could also be the case under any other license agreements we enter into in the future. Therefore, we rely on MGH, and may rely on other licensors in the future, to file, defend and maintain patents that are important to our business. The failure of MGH or other licensors to successfully prosecute, defend and maintain these patents and patent applications in a manner consistent with the best interests of our business could adversely affect our ability to successfully commercialize our technology and potential fertility treatments.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or potential fertility treatments or that effectively prevent others from commercializing competitive technologies and potential fertility treatments. Changes in either the patent laws or interpretation of the patent laws in the United States

Table of Contents

and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Under the America Invents Act enacted in September 2011, the United States moved to a first inventor to file system in March 2013. Outside the United States, the first to file a patent application is generally entitled to the patent. We may become involved in patent litigation or reexamination, post-grant review, opposition, derivation or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such litigation or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or potential fertility treatments and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize potential fertility treatments without infringing third party patent rights.

***If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and potential fertility treatments similar or identical to ours.***

Our owned and licensed patents and any owned or licensed patent applications that issue as patents may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or potential fertility treatments in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to use and commercialize, or to stop or prevent others from using or commercializing, similar or identical technology and potential fertility treatments, or limit the duration of the patent protection of our technology and potential fertility treatments. Given the amount of time required for the development, testing and regulatory review of new potential fertility treatments, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, certain of the U.S. patents and patent applications that we exclusively license from MGH will expire in May 2025. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing potential fertility treatments similar or identical to ours.

***We may initiate lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Table of Contents

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

Our commercial success depends upon our ability and the ability of our current and future collaborators to develop, manufacture, market and sell our potential fertility treatments and use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our potential fertility treatments and technology, including interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our potential fertility treatments and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or treatment. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our potential fertility treatments or force us to cease some of our business operations, which could materially harm our business. Claims that we have wrongfully appropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

***We may be subject to claims that our employees have wrongfully appropriated, used or disclosed intellectual property of their former employers.***

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not appropriate or use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have appropriated, used or disclosed intellectual property, including information forming the basis of patents and patent applications, trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and our reputation may be harmed.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, such developments could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses, reduce the resources available for development activities and adversely affect our ability to raise additional funds. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Table of Contents

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and potential fertility treatments, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. The protection available for trade secrets is particularly important with respect to our process for manufacturing AUGMENT, to OvaPrime and to our other potential fertility treatments, which will involve significant unpatented know-how. Any appropriation of our know-how, by competing contract manufacturers, collaborators or otherwise, could harm our business and we could suffer financial loss. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such trade secrets, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

**Risks Related to Employee Matters and Managing Growth**

***Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on Dr. Dipp, our chief executive officer, Arthur Tzianabos, our chief scientific officer, Mr. Stern, our executive vice president, global commercial operations and Mr. Bleck, our principal financial officer, as well as the other principal members of our management and scientific teams and our scientific co-founders, Drs. Tilly and Sinclair. Although we have entered into employment agreements with Dr. Dipp, Dr. Tzianabos, Mr. Stern and Mr. Bleck providing for certain benefits, including severance in the event of a termination without cause, these agreements do not prevent them from terminating their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

In addition to her role as chief executive officer of our company, Dr. Dipp also serves as a general partner of Longwood Fund, LP, a venture capital investment fund and one of our principal stockholders. It is possible that Dr. Dipp may transition to an executive chairman role at our company at some point in the future, once we have meaningfully advanced our development efforts, grown our company overall and identified and hired a suitable successor. In such event, we will need to recruit and hire a new principal executive officer. Our inability to hire a suitable executive to assume this position in a timely fashion could delay the execution of our business plans or disrupt our operations.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and

Table of Contents

commercialization strategy. Our consultants and advisors, including our scientific co-founders, may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

***We expect to expand our research and development and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research and development and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

The physical expansion of our operations may also lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

***A breakdown or breach of our information technology systems could subject us to liability or interrupt the operation of our business.***

Many of our key business processes are facilitated by information technology systems. Information technology systems are potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, individuals authorized to access our information technology systems may pose a risk by exposing private or confidential data to unauthorized persons or to the public. While we believe that we have taken appropriate security measures to minimize these risks to our data and information technology systems, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business.

**Risks Associated with Our Capital Stock**

***The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.***

Even if an active trading market develops for our common stock, our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our common stock;
- the delay or failure to execute our plans for AUGMENT or OvaPrime;
- results of preclinical testing or clinical trials of our potential fertility treatments, including OvaTure, or those of our competitors;
- the cost of our development programs;
- the success of competitive potential fertility treatments or technologies;
- the success of our OvaXon joint venture with Intrexon;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals, new potential fertility treatment introductions and commercial results;
- the recruitment or departure of key personnel;

developments concerning our licensors or manufacturers;

Table of Contents

the results of our efforts to discover, acquire or in-license additional potential fertility treatments;

litigation and other developments relating to our issued patents or patent applications or other proprietary rights or those of our competitors or other material litigation;

disagreement by the FDA or equivalent foreign regulatory authorities regarding the regulatory pathway applicable to AUGMENT or OvaPrime;

regulatory or legal developments in the United States or other countries, particularly with respect to IVF procedures;

conditions in the pharmaceutical or biotechnology industries;

changes in the structure of healthcare payment systems;

actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;

variations in our financial results or those of companies that are perceived to be similar to us; and

general economic, industry and market conditions.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

***We expect a substantial number of shares will become available for resale in the near future, which may adversely impact any trading market that may develop for our common stock.***

As of December 31, 2013, we had 18,528,215 shares of common stock outstanding, including the unvested Founders' Stock. Of these, 7,630,683 shares may be immediately sold pursuant to one registration statement on Form S-3 (some of which may also be sold pursuant to Rule 144), 3,888,880 shares may be immediately sold pursuant to another registration statement on Form S-3 and 37,434 shares may be sold exclusively pursuant to Rule 144.

We have also filed Form S-8 registration statements under the Securities Act to register all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and lock-up agreements.

The availability of a substantial number of shares for resale under registration statements or pursuant to Rule 144 promulgated under the Securities Act may adversely impact any trading market that may develop for our common stock or reduce the price at which such shares may be sold.

***We have never paid and do not intend to pay cash dividends.***

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our common stockholders' sole source of gain for the foreseeable future.

63

Table of Contents

***Our executive officers, directors and principal stockholders have the ability to control all matters submitted to stockholders for approval.***

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock beneficially own shares, in the aggregate, representing approximately 57% of our outstanding capital stock as of December 31, 2013. As a result, if these stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act collectively, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

***Provisions in our certificate of incorporation and by-laws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;
- limit who may call stockholder meetings;
- prohibit actions by our stockholders by written consent;
- require that stockholder actions be effected at a duly called stockholders meeting;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a manner prescribed by the statute.

Table of Contents

***We are an "emerging growth company" and have elected to comply with certain reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.***

We are an "emerging growth company," as defined in the JOBS Act enacted in April 2012. We have chosen and may continue to choose to take advantage of exemptions from various public company reporting requirements for as long as we continue to be an emerging growth company.

These exemptions include, but are not limited to, (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements, and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. However, if certain events occur prior to the end of such five year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1 billion or we issue more than $1 billion of non-convertible debt in any three year period, we would cease to be an emerging growth company prior to the end of such five year period. We have taken advantage of certain of the reduced disclosure obligations regarding executive compensation in the filings we have made with the SEC and may elect to take advantage of other reduced burdens in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

***We will incur increased costs as a result of operating as a public company, particularly once we cease to be an emerging growth company, and our management will be required to devote substantial time to new compliance initiatives.***

As a public reporting company, we have incurred significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel have devoted a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantial costs to maintain the same or similar coverage.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and, once we cease to be an emerging growth company, will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed time period we have documented and evaluated our internal

Table of Contents

control over financial reporting, which may be costly. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting.

**Item 1B.** ***Unresolved Staff Comments***

None.

**Item 2.** ***Properties***

We currently occupy approximately 7,900 square feet of office and laboratory space in Cambridge, Massachusetts. 6,000 square feet are under a lease that expires in August 2017 and the remaining 1,900 square feet are under a sublease that expires in August 2015. We believe our facility is sufficient to meet our current needs and that suitable additional space will be available if and when needed.

**Item 3.** ***Legal Proceedings***

On September 16, 2013, a purported shareholder class action, styled *Meriam Ratner v. OvaScience, Inc., et al.,* was filed in the United States District Court for the District of Massachusetts, naming us and certain of our officers as defendants. The lawsuit alleges that we made material misrepresentations and/or omissions of material fact relating to the qualification of AUGMENT as a 361 HCT/P in our public disclosures during the period from February 25, 2013 through September 10, 2013, in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 promulgated thereunder. On February 2, 2014, we and certain of our officers, as defendants, filed a motion to dismiss with the District Court. On February 3, 2014, plaintiff Meriam Ratner voluntarily dismissed the suit without prejudice.

We are not party to any other litigation in any court and management is not aware of any contemplated proceeding by any governmental authority against the Company.

**Item 4.** ***Mine Safety Disclosures***

Not Applicable.

Table of Contents

## PART II

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

**Market Information**

Our common stock began trading on the NASDAQ Global Market ("NASDAQ") on April 30, 2013 under the symbol "OVAS". Our common stock was first traded on the OTC Bulletin Board on November 9, 2012 under the symbol "OVSC." Prior to that date, there was no public market for our common stock.

The following table sets forth, for the periods indicated, the high and low sales prices and the high and low bid information of our common stock as reported by NASDAQ and the OTC Bulletin Board, as applicable, for the periods indicated:

| **Year Ended December 31, 2013** | **High** | **Low** |
|---|---|---|
| Fourth Quarter 2013 | $ 10.30 | $ 8.14 |
| Third Quarter 2013 | $ 15.75 | $ 9.06 |
| Second Quarter 2013 (beginning April 30, 2013) | $ 16.00 | $ 10.50 |

| | **High Closing Price** | **Low Closing Price** | **High Bid Price** | **Low Bid Price** |
|---|---|---|---|---|
| Second Quarter 2013(through April 29, 2013) | $ 12.50 | $ 9.00 | $ 13.50 | $ 9.00 |
| First Quarter 2013 | $ 14.00 | $ 8.15 | $ 15.00 | $ 8.15 |
| **Year Ended December 31, 2012** | | | | |
| Fourth Quarter 2012 (beginning November 14, 2012) | $ 9.30 | $ 7.50 | $ 10.00 | $ 7.50 |

The over-the-counter market quotations from November 14, 2012 to April 29, 2013 reflect inter-dealer prices, without retail mark-up, mark-down or commission. The high and low bid prices do not necessarily represent actual transactions.

On February 25, 2014, the closing price of a share of our common stock on NASDAQ was $10.18.

**Holders**

As of January 31, 2014, there were 18,563,215 shares of common stock outstanding, which were held by approximately 250 record holders.

**Dividends**

We have never paid cash dividends on any of our capital stock and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends to holders of our common stock in the foreseeable future.

**Recent Sales of Unregistered Securities**

Set forth below is information regarding shares of common stock issued by us between January 1, 2013 and December 31, 2013 that were not registered under the Securities Act. Also included is the consideration, if any, received by us, for such shares and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(1) In March 2013, we issued and sold an aggregate of 3,888,880 shares of our common stock to investors for an aggregate purchase price of approximately $35.0 million. Leerink Swann LLC

Table of Contents

acted as lead placement agent and Ladenburg Thalmann & Co. Inc., Oppenheimer & Co. Inc., Roth Capital Partners, LLC and Wedbush Securities Inc. acted as co-agents in connection with such private placement of common stock.

(2) In December 2013, we issued 273,224 shares of our common stock to Intrexon Corporation upon the execution of a collaboration agreement as partial consideration for the use of Intrexon's synthetic biology technology platform for the accelerated development of our OvaTure platform.

No underwriters were involved in the foregoing issuances of securities.

The offers, sales and issuances of the securities described in paragraph (1) and (2) were deemed to be exempt from registration under the Securities Act in reliance on the exemption from the registration requirements of the Securities Act pursuant to Regulation D promulgated under Section 4(2) of the Securities Act relative to transactions by an issuer not involving a public offering. The recipients in each of these transactions represented to us in connection with their purchase that they were accredited investors and were acquiring the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.

**Item 6.** ***Selected Financial Data***

The selected financial data set forth below is derived from our audited consolidated financial statements and may not be indicative of future operating results. The following selected consolidated financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the notes thereto included elsewhere in this report. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

| | Year Ended, December 31, | | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2013 |
|---|---|---|---|---|
| | 2013 | 2012 | | |
| | (in thousands, except per share amounts) | | | |
| **Consolidated Statements of Operations Data:** | | | | |
| Total operating expenses(1) | $ 29,134 | $ 13,529 | $ 2,624 | $ 45,287 |
| Loss from operations | (29,134) | (13,529) | (2,624) | (45,287) |
| Net loss | (29,044) | (13,510) | (2,624) | (45,178) |
| Accretion of convertible preferred stock to redemption value | | | (101) | (101) |
| Net loss applicable to common stockholders | $ (29,044) | $ (13,510) | $ (2,725) | $ (45,279) |
| Net loss per share applicable to common stockholders basic and diluted | $ (1.80) | $ (2.33) | $ (3.00) | $ (5.42) |
| Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted | 16,160 | 5,810 | 909 | 8,350 |

Table of Contents

| | As of December 31, | | |
|---|---|---|---|
| | 2013 | 2012 | 2011 |
| | (in thousands) | | |
| **Consolidated Balance Sheet Data:** | | | |
| Cash, cash equivalents and short-term investments | $ 44,427 | $ 31,391 | $ 4,541 |
| Total assets | 47,545 | 32,814 | 4,585 |
| Total current liabilities | 5,774 | 2,086 | 675 |
| Total long-term liabilities | 70 | 7 | 87 |

(1) In 2013 the loss from operations includes $4.7 million related to the technology access fee to Intrexon related to the OvaTure Collaboration.

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

The following discussion should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements. Actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those discussed in "Risk Factors" and elsewhere in this Annual Report on Form 10-K. See also "Cautionary Note Regarding Forward-Looking Statements."

**Overview**

OvaScience is a global life science company focused on the discovery, development, and commercialization of new fertility treatments. Our patented technology is based on egg precursor cells ("EggPC[SM]"), which are found in the outer layer of a woman's own ovaries. The recent discovery of EggPCs countered a long-held medical belief that women are born with a set number of eggs, thereby enabling new possibilities in the treatment of female infertility.

Our portfolio of fertility treatment options takes advantage of proprietary methods to identify, isolate and concentrate EggPCs from the patient's ovarian tissue. By applying our EggPC technology platform in unique ways, we are developing new fertility treatment options that are designed to improve egg quality and in vitro fertilization ("IVF"). These treatment options under development include the following:

AUGMENT[SM] aims to improve egg quality and potentially increase the success of IVF by transferring mitochondria from a woman's EggPCs to her mature egg during IVF. We plan to introduce AUGMENT in 2014 in at least four international regions.

OvaPrime[SM] is designed to boost a woman's egg reserve by transferring the EggPCs from the outer layer of her ovary (outer cortex) back into the ovary prior to IVF. We expect to introduce OvaPrime outside of the United States in 2015.

OvaTure[SM] seeks to mature a woman's own EggPCs into fertilizable eggs without the need for hormone hyperstimulation.

OvaXon[SM] is a joint venture with Intrexon Corporation, which is focused on developing new applications to prevent inherited diseases by gene editing EggPCs for applications in human and animal health.

Table of Contents

We believe our EggPC technology has the potential to make significant advances in the field of fertility because it may enable us to address poor egg and embryo quality due to age and other causes. We believe our EggPC technology could improve IVF by:

*Increasing live birth rates and reducing the number of IVF cycles.* By improving egg quality, we believe we may be able to increase the percentage of IVF treatments which result in live births and, in so doing, reduce the number of IVF cycles required.

*Reducing the incidence of multiple births.* By generating higher quality eggs, we believe our EggPC technology may allow for the transfer of fewer embryos per IVF cycle and, as a result, lower the incidence of multiple births and the associated complications for the mother and baby.

*Lowering the overall cost of IVF.* If we reduce the number of IVF cycles required for a live birth and the incidence of multiple births, we believe our fertility treatment options may also lower the overall costs associated with IVF.

*Reducing the need for hormonal hyperstimulation.* We are designing our OvaTure technology to mature EggPCs into fertilizable eggs *in vitro*. If successful, OvaTure could reduce, or possibly eliminate, the need for hormonal hyperstimulation for the maturation of multiple oocytes prior to egg retrieval in the IVF process.

*Prevent inherited diseases.* By applying gene editing techniques to EggPCs, we believe we may be able to prevent the transmission of inherited diseases, such as Huntington's Disease, in future generations.

**AUGMENT**

The Company's first fertility treatment is AUGMENT[SM], which we plan to introduce to international IVF clinics in 2014 through our AUGMENT Centers of Excellence ("ACE") access program. The goal is for physicians to gain experience using AUGMENT and to generate data. In 2014, we expect to establish ACE clinics in at least four international regions, which we anticipate will result in 40 to 60 AUGMENT cycles this year. By year end 2014, we expect to transition these ACE clinics to commercial centers. We are targeting international regions that combine elements of the following key criteria:

Key opinion leaders / high volume IVF clinics

High quality IVF labs

Out-of-pocket pay and high average cost per cycle

Donor egg restrictions

As part of AUGMENT, a woman's eggs may be rejuvenated by injecting mitochondria prepared from her own EggPCs into her egg during IVF. This has the potential to improve egg quality and thereby increase the success of IVF. With higher quality eggs, there is also the potential to reduce the need for multiple embryo transfers, which can result in a lower incidence of conceiving multiples (twins or triplets) and resulting complications.

AUGMENT complements the existing standard of practice for an IVF cycle. Prior to hormone hyperstimulation, a small tissue biopsy is taken from the outer layer of the ovary, where the EggPCs reside. Our proprietary process identifies and isolates the patient's own EggPCs followed next by the removal of her own mitochondria within the EggPCs. The women's own mitochondria are then injected into her egg at the time of intracytoplasmic sperm injection ("ICSI").

The development of assisted reproductive technologies has a long history of innovation based on techniques and tools developed in IVF clinics around the world. In fact, all of the major innovations in

Table of Contents

fertility treatment have been developed in countries outside of the United States, including IVF and ICSI, and more recently, time-lapse imaging, oocyte vitrification and in vitro maturation of oocytes. This is a main reason why the IVF market is predominantly located outside of the United States where 90% of the 1.6 million IVF cycles are performed. Given the market size, as well as the innovative history and acceptance of new fertility methods and technologies internationally, we have always had a strategy to make our fertility treatments available to patients worldwide. We plan to introduce our first fertility treatment, AUGMENT, through a limited commercial launch in international IVF clinics in 2014, and we are preparing to launch a second fertility treatment using this approach in 2015. We believe that we will be able to introduce AUGMENT into these regions without pre-market review and approval, but if applicable regulatory bodies disagree, we may abandon AUGMENT in that region or suffer significant delay or expense in seeking necessary approvals to gain clinical experience with AUGMENT in the United States ahead of a commercial launch. In December 2012, we initiated a study of AUGMENT in the United States. In September 2013, we received an "untitled" letter from the FDA advising us to file an Investigational New Drug (IND) application for AUGMENT. Following the receipt of the FDA letter, we chose to suspend enrollment in the U.S. study. We anticipate having further discussions in 2014 with the FDA to present details on AUGMENT and to determine the appropriate path forward.

**Strategic Alliances**

Strategic alliances are integral to our growth. These alliances provide access to breakthrough science, potential funding and innovative drug development programs, all intended to help us realize the full potential of our potential fertility treatment pipeline while at the same time allowing us to retain significant downstream value in our programs through commercialization rights.

***Collaboration with Intrexon to Accelerate Development of OvaTure***

***Scope***

In December 2013, we entered into a collaboration agreement (the "OvaTure Collaboration") with Intrexon governing the use of Intrexon's synthetic biology technology platform for the accelerated development of our OvaTure platform. The OvaTure Collaboration provides that Intrexon will deliver laboratory and animal data to support the successful filing of an IND for OvaTure.

Although we have not discussed OvaTure with the FDA, we expect we will need to obtain regulatory approval of OvaTure in both the United States prior to commercialization. OvaScience owns exclusive human commercial rights for OvaTure.

We will participate as an equal member on the Joint Steering Committee ("JSC") and Intellectual Property Committee ("IPC"). The JSC shall agree upon the services and the activities to be included in the work plan, and IPC has authority over intellectual property matters. We have the tie-breaking vote if there are any disputes with the JSC.

***Technology Access Fee Payable to Intrexon***

The technology access fee payable to Intrexon is comprised of (1) the issuance of 273,224 shares or $2.5 million of our newly issued common stock, to Intrexon, upon the execution of the OvaTure Collaboration in December 2013, and (2) a $2.5 million cash payment due December 2014, which is payable solely upon the passage of time.

The technology access fee does not give us the right to any research and development services, and the technology access has no alternative future use to us. We therefore recorded $4.7 million in research and development expense in the year ended December 31, 2013 with $2.5 million recorded to

Table of Contents

additional paid-in capital and common stock and $2.2 million recorded in accrued liabilities, which represents the present value of the $2.5 million technology access fee due in December 2014.

The shares issued to Intrexon are subject to "piggy-back" registration rights that entitle Intrexon to have the shares included in any new registration statement filed in connection with an underwritten public offering, subject to underwriter cutback. The piggy-back registration rights will not be triggered by any offering subject to a previously filed registration statement, including our current universal shelf registration statement.

***Research and Development Funding and Potential Commercial Milestone***

The JSC will also approve a budget under the work plan. We will reimburse Intrexon for research and development services performed, subject to budget caps. If applicable, OvaScience will also make a commercial milestone payment three months after the first commercial sale of OvaTure.

***Termination Rights***

The collaboration has an indefinite term, with OvaScience having the right to terminate the collaboration after 90 days' prior written notice, and either OvaScience or Intrexon may terminate after a material breach by the other party that is not cured within 60 days. We may assign the collaboration in the event of a change of control transaction.

***Royalties***

Upon the delivery of laboratory and animal data necessary to support the successful filing of an IND application, we will incur an obligation to pay Intrexon a mid-single digit royalty on net sales of any OvaTure fertility treatments, and the exact royalty will depend upon whether Intrexon completes the milestone by the targeted deadline of two years after technology transfer.

***Joint Venture***

In December 2013, we also entered into a joint venture with Intrexon to leverage Intrexon's synthetic biology technology platform and OvaScience's technology relating to egg precursor cells to pursue the prevention of genetic disease and animal health. We and Intrexon formed OvaXon, LLC ("OvaXon") to conduct the joint venture. Each party contributed $1.5 million to OvaXon and each has a 50% equity interest, and research and development costs and profits will be split accordingly. Each party will also have 50% control over OvaXon with disputes resolved through arbitration, if necessary.

We recorded $1.5 million as an equity method investment in OvaXon LLC in December 2013.

**Financial Operations Overview**

***Revenue***

To date, we have not generated any revenue. Our ability to generate revenue, if ever, will depend heavily on the successful development and eventual commercialization of AUGMENT, OvaPrime, OvaTure and our other future treatments.

***Research and Development Expenses***

Research and development expenses consist of costs associated with our research activities, discovery efforts and the development of our treatments. Our research and development expenses consist of:

employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;

Table of Contents

Fees for acquired technologies which have not yet reached technological feasibility and have no alternative use;

external research and development expenses incurred under arrangements with third parties, such as contract research organizations, manufacturing organizations and consultants, including our scientific advisory board;

license fees; and

facilities, laboratory supplies and other allocated expenses.

We expense research and development cost to operations as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

We use our employee and infrastructure resources across multiple research and development projects. We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. We do not have actual external or total expenses by project for the inception to date period or for the years ended December 31, 2013, December 31, 2012 and the period from April 5, 2011 through December 31, 2011. Research and development expenses to date have primarily related to the development of AUGMENT.

We expect our expenses to increase over time for our OvaPrime and OvaTure programs.

The successful development of our treatments is highly uncertain. As this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our treatments or the period, if any, in which material net cash inflows from our treatments may commence. This is due to the numerous risks and uncertainties associated with developing treatments, including the uncertainty of:

the scope, rate of progress and expense of our discovery efforts and other research and development activities;

the safety, efficacy and potential advantages of our treatments as compared to traditional IVF or other therapies;

our ability to market, commercialize and achieve market acceptance for AUGMENT, OvaPrime, OvaTure and other potential fertility treatments that we are developing or may develop in the future;

the results of introducing our ACE access program into international IVF clinics to gain clinical experience using AUGMENT and to generate data outside the United States;

the results of our efforts to study, optimize and ultimately launch OvaPrime outside of the United States;

the terms and timing of potential regulatory approvals, if any; and

the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights.

A change in the outcome of any of these variables with respect to the development of a treatment could mean a significant change in the costs and timing associated with the development of that potential fertility treatment.

Table of Contents

***General and Administrative Expenses***

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation expense, in our executive, finance, accounting, legal, corporate communications, corporate development, human resources and commercial functions. Other costs include facilities costs not otherwise included in research and development expense, and professional fees for legal and accounting services. General and administrative costs also consist of the costs of maintaining our intellectual property portfolio.

***Interest Income***

Interest income typically consists of interest earned on cash, cash equivalents and short-term investments.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation described in greater detail below. We base our estimates on our limited historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report. However, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

***Accrued Research and Development Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include fees paid to contract research organizations in connection with research and development activities for which we have not yet been invoiced.

Table of Contents

We base our expenses related to contract research organizations on our estimates of the services received and efforts expended pursuant to quotes and contracts with the contract research organizations that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepayment accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period.

***Stock-Based Compensation***

As we continue to grow, we expect to make additional stock option and restricted stock grants, which will result in additional stock-based compensation expense. Accordingly, we describe below the methodology we have employed to date in measuring such expenses.

Since our inception in April 2011, we have applied the fair value recognition provisions of Financial Accounting Standards Board Accounting Standards Codification Topic 718, *Compensation Stock Compensation*, which we refer to as ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. Stock-based compensation expense is recognized ratably over the requisite service period, which in most cases is the vesting period of the award. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance criteria, which affects the awards expected to vest and the period over which the expense is recognized, and recognize the expense using the accelerated attribution model to the extent the condition is deemed probable. Calculating the fair value of stock-based awards requires that we make highly subjective assumptions. We used the Black-Scholes option pricing model to value our stock option awards.

The valuation assumptions were determined as follows:

*Risk-free interest rate:* The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term of the awards.

*Expected annual dividend yield:* The estimate for annual dividends is zero, because we have not historically paid a dividend and do not intend to do so in the foreseeable future.

*Expected stock price volatility:* We determine the expected volatility by using a weighted average of selected peer companies.

*Expected term of options:* We have used the simplified method to calculate the expected term in fiscal 2013 as we have not had significant historical exercise and post-vest termination data to provide a reasonable basis upon which to estimate the expected term for the options granted to employees. The contractual term will be used for option awards granted to non-employees. Historical data will be incorporated into our assumption as it becomes available.

Under ASC 718, we are required to estimate the level of forfeitures expected to occur and record compensation expense only for those awards that we ultimately expect will vest. We evaluate our estimated forfeiture rate at the end of each reporting period. We estimate forfeitures based upon historical data, adjusted for known trends and anticipated future actual results, and we will adjust the estimate of forfeitures if actual forfeitures differ or are expected to differ from such estimates. Subsequent changes in estimated forfeitures are recognized through a cumulative adjustment in the period of change and will also impact the amount of stock-based compensation expense in future periods.

Table of Contents

We began trading on the NASDAQ Global Market on April 30, 2013.

Prior to April 30, 2013, we have historically granted stock options at exercise prices not less than the fair market value of our common stock as determined by our board of directors, with input from management. Our board of directors has historically determined the estimated fair value of our common stock on the date of grant based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which we sold shares of our preferred stock, the superior rights and preferences of securities senior to our common stock at the time of each grant and the likelihood of achieving a liquidity event such as an IPO, the listing of our common stock on a securities exchange, which we refer to as public trading, or sale of our company.

At the time of each of these stock option grants made prior to November 14, 2012, the exercise price was determined by our board of directors, with input from management, based on the various objective and subjective factors noted below. As of November 14, 2012, the date our common stock first became publicly traded, the fair value at the grant date was determined using the closing price of a share of our common stock, as listed on the OTC Bulletin Board on the grant date. As there was no public market for our common stock prior to November 14, 2012, our board of directors determined the estimated fair value of our common stock on the grant dates, taking into consideration various objective and subjective factors, including:

- external market conditions affecting the biopharmaceutical industry;
- prices at which we sold shares of preferred stock to third party investors;
- the superior rights and preferences of securities senior to our common stock at the time of each grant;
- our historical operating and financial performance;
- the timing of hiring key members of our management team including the nature and timing of regulatory requirements for our potential fertility treatments;
- the status of our research and development efforts;
- the likelihood of achieving a liquidity event, such as an IPO, public trading or sale of our company; and
- estimates, contemporaneous valuations and analysis provided by management.

There were significant judgments and estimates inherent in the determination of these valuations.

**Results of Operations**

We were incorporated on April 5, 2011. As a result, the following table summarizes our results of operations for the years ended December 31, 2013 and 2012 and the period from April 5, 2011 (inception) to December 31, 2011. There is no comparable period for 2011 (in thousands).

| | Year Ended, December 31, | | Period from April 5, 2011 (inception) to December 31, | 2013 / 2012 Comparison | | 2012 / 2011 Comparison | |
|---|---|---|---|---|---|---|---|
| | 2013 | 2012 | | Increase / (Decrease) $ | % | Increase / (Decrease) $ | % |

| | 2011 | | | | | |
|---|---|---|---|---|---|---|
| Research and development | $ 15,802 | $ 6,323 | $ 1,170 | $ 9,479 | 150% | $ 5,153 | 440% |
| General and administrative | 13,332 | 7,206 | 1,454 | 6,126 | 85% | 5,752 | 396% |
| Interest income | 90 | 19 | | 71 | 374% | 19 | 100% |
| Net loss | $ (29,044) | $ (13,510) | $ (2,624) | $ (15,534) | 115% | $ (10,886) | 415% |

Table of Contents

**Revenue**

To date, we have not generated any revenues. Our ability to generate revenues, which we do not expect will occur prior to the second half of 2014, if ever, will depend heavily on the successful development and eventual commercialization of AUGMENT, OvaPrime, OvaTure, and our other potential fertility treatments.

**Research and Development Expenses**

The increase in research and development expense for the year ended December 31, 2013 compared to the year ended December 31, 2012 was primarily attributable to:

- an expense of $4.7 million for a technology access fee in connection with a collaboration agreement with Intrexon, Inc. for our OvaTure program;
- an increase of $1.9 million in stock-based compensation for employees and non-employees (including a modification of options that resulted in incremental stock-based compensation expense of $0.4 million) and salaries, bonus, payroll taxes and benefits, which were driven primarily by the hiring of new research and development personnel;
- an increase of $1.6 million in contract research organization expenses and consulting fees primarily related to AUGMENT; and
- an increase of $0.4 million resulting from the impairment of laboratory equipment;

The increase in research and development expense for the year ended December 31, 2012 compared to the period from April 5, 2011 to December 31, 2011 was primarily attributable to:

- an increase in contract research organization expenses of $2.3 million comprised of expenses for outsourced biology, chemistry, clinical and development services; and
- an increase in compensation and benefits, including stock-based compensation, of $2.0 million primarily due to the hiring of research and development employees.

Research and development expenses from April 1, 2011 to December 31, 2013 primarily related to the development of AUGMENT. During the year ended December 31, 2013, we recorded a research and development expense of $4.7 million for a technology access fee associated with a collaboration agreement with Intrexon for the OvaTure program.

We expect research and development expense to increase if our programs successfully advance. We do not believe that the historical costs are indicative of the future costs associated with these programs nor represent what any other future treatment program we initiate may cost. Due to the variability in the length of time and scope of activities necessary to develop a treatment and uncertainties related to cost estimates and our ability to commercialize and/or obtain marketing approval for our treatments, accurate and meaningful estimates of the total costs required to bring our treatments to market are not available.

Because of the risks inherent in drug discovery and development, we cannot reasonably estimate or know:

- the nature, timing and estimated costs of the efforts necessary to complete the development of our programs;
- the anticipated completion dates of these programs; or

the period in which material net cash inflows are expected to commence, if at all, from the programs described above and any potential future treatments.

Table of Contents

There is significant uncertainty regarding our ability to successfully develop any treatments. These risks include the uncertainty of:

- introducing our ACE access program into international IVF clinics for physicians using AUGMENT and to generate data;
- the scope and rate of progress of our preclinical studies and other research and development activities from OvaPrime, OvaTure and our other potential fertility treatments;
- the scope, rate of progress and cost of any clinical trials that we may commence in the future;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our programs under development;
- the cost and timing of regulatory approvals;
- the cost of establishing clinical supplies of any treatments; and
- the effect of competing technological and market developments.

**General and Administrative Expenses**

The increase in general and administrative expense for the year ended December 31, 2013 compared to the year ended December 31, 2012 was primarily attributable to:

- an increase of $4.2 million in both stock-based compensation and salaries, bonus, payroll taxes and benefits. Stock-based compensation for the year ended December 31, 2013 included expense related to December 2012 restricted stock units and stock options granted to the Chief Executive Officer. Increases in salaries, bonus, payroll taxes and benefits were primarily driven by the hiring of new general and administrative personnel; and
- an increase of $1.2 million in consulting and commercial preparation expenses.

The increase in general and administrative expense for the year ended December 31, 2012 compared to the period from April 5, 2011 to December 31, 2011 was primarily attributable to:

- an increase of $2.6 million in professional fees, comprised of fees for audit, tax and legal services, corporate filing fees and investor relation fees primarily related to activities associated with becoming a publicly traded company;
- an increase of $1.0 million for higher salaries, bonus, payroll taxes and benefits primarily due to the hiring of general and administrative employees;

an increase of $0.5 million in consulting expenses primarily for business planning and strategy; and

an increase of $0.5 million in market research analysis and public relations expense.

**Interest Income**

Interest income for the years ended December 31, 2013 and 2012 increased as compared to the period from April 5, 2011 through December 31, 2011 primarily as a result of higher average balances on our cash equivalents and short-term investments.

Table of Contents

**Liquidity and Capital Resources**

We have not generated any commercial sales to date. We have instead relied on the proceeds from sales of equity securities to fund our operations. Our short-term investments primarily trade in liquid markets, and the average days to maturity of our portfolio as of December 31, 2013 are less than six months. Because our treatments are in various stages of development and the outcome of these efforts in uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our treatments or whether or when we may achieve profitability.

Our significant capital resources are as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2013 | 2012 |
| Cash, cash equivalents and short-term investments | $ 44,427 | $ 31,391 |
| Working capital | 39,303 | 29,879 |

| | Year Ended December 31, | | Period from April 5, 2011 (inception) to December 31, 2011 |
|---|---|---|---|
| | 2013 | 2012 | |
| Cash (used in) provided by: | | | |
| Operating activities | $ (18,094) | $ (11,156) | $ (1,560) |
| Investing activities | (11,018) | (17,640) | |
| Capital expenditures (included in investing activities above) | (719) | (849) | |
| Financing activities | 32,414 | 39,031 | 6,101 |

***Cash Flows***

Cash used in operating activities in all of the periods presented was primarily attributed to the funding of our net loss. Cash flows from operations can vary significantly due to various factors, including changes in the net loss and the timing of disbursements made for accounts payable and accruals.

Cash used in investing activities for the years ended December 31, 2013 and 2012 included the purchase of and proceeds from maturities of short-term investments. Our investing activities for the years ended December 31, 2013 and 2012 included the purchases of property and equipment. Capital expenditures for the year ended December 31, 2013 consisted primarily of laboratory equipment. There were no investing activities for the period from April 5, 2011 (inception) to December 31, 2011.

Cash provided by financing activities for the year ended December 31, 2013 was primarily the result of the private placement of an aggregate of 3,888,880 shares of common stock at a price per share of $9.00 resulting in net proceeds of $32.7 million. Cash provided by financing activities for the year ended December 31, 2012 was primarily the result of the sale and issuance of 6,770,563 shares of our Series B preferred stock for net proceeds of approximately $35.0 million and private placement sale of an aggregate of 897,554 shares of common stock at a price per share of $5.50 resulting in net proceeds of $4.0 million.

We will need substantial additional funds to support our planned operations. In the absence of additional funding, business development activities, and treatment sales, we expect our existing cash, cash equivalents and marketable securities of $44.4 million at December 31, 2013 will enable us to fund our current operating plan into 2015. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our

Table of Contents

treatments, and the extent to which we may enter into collaborations with third parties for development and commercialization of our treatments, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current treatments. Our future capital requirements will depend on many factors, including:

- introducing our ACE access program into international IVF clinics for physicians to gain experience using AUGMENT and to generate data;
- educating physicians and embryologists the use of AUGMENT;
- conducting any AUGMENT studies;
- incurring the costs associated with expansion of foreign operations;
- establishing a domestic and international sales, marketing, manufacturing and distribution infrastructure to commercialize AUGMENT and any other potential fertility treatment, we successfully develop;
- conducting further studies of, continuing optimization of and ultimately commercially launching OvaPrime;
- receiving revenue, if any, from commercial activities of AUGMENT, OvaPrime or any other potential fertility treatments;
- continuing research and preclinical development of OvaTure, both internally and in collaboration with Intrexon, and other potential fertility treatments;
- initiating any clinical trials of OvaTure and other potential fertility treatments;
- collaborating with Intrexon through the OvaXon joint venture to create new applications to prevent inherited diseases for human and animal health;
- following the regulatory process in the United States and abroad, including the premarketing and marketing approval requirements, to which some of our potential fertility treatments may be subject;
- following the regulatory or institutional review board review of our potential fertility treatments that are subject to such review;
- preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- establishing collaborations and partnerships on favorable terms, if at all; and
- developing, acquiring or in-licensing other potential fertility treatments and technologies.

Until such time, if ever, as we can generate substantial treatment revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. 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 additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or treatments or 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 fertility treatment development or future

Table of Contents

commercialization efforts or grant rights to develop and market treatments that we would otherwise prefer to develop and market ourselves.

**Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

**Contractual Obligations**

| | | Payments Due by Period | | | |
|---|---|---|---|---|---|
| **Contractual Obligations** | **Total** | **Less than 1 Year** | **1 - 3 Years** | **3 - 5 Years** | **More than 5 Years** |
| License obligations(1) | $ 3,060 | $ 2,612 | $ 224 | $ 224 | * |
| Long-term liabilities(2) | 130 | 10 | 30 | 30 | 60 |
| Operating leases | 1,103 | 323 | 607 | 173 | |
| Purchase obligations(3) | 727 | 727 | | | |
| | $ 5,020 | $ 3,672 | $ 861 | $ 427 | $ 60 |

(1) Amount includes $2.5 million payment due to Intrexon in December 2014 for the second installment of the technology access fee. We have agreed to pay license fees and maintenance fees totaling $0.1 million annually (*). The agreement is cancellable by us. As we are unable to reasonably predict the likelihood, timing or amount of any such milestone, royalty or sublicense income payments, we have excluded them from the table above. This excludes a milestone that may reach $1.0 million in 2014 based on certain criteria.

(2) Long-term liabilities include current maturities.

(3) At December 31, 2013 we have non-cancellable payments that become due in January 2014 for research services and a research grant of approximately $0.1 million. Additionally, we have certain minimum purchase requirements with our contract manufacturer of $0.6 million.

**Recently Adopted Accounting Standards**

We have not recently adopted any new accounting standards. There are no recently issued accounting standards that have a material impact on us.

**Item 7A.** ***Quantitative and Qualitative Disclosures about Market Risk***

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and marketable securities of $44.4 million as of December 31, 2013 and $31.4 million as of December 31, 2012. The cash and cash equivalents as of December 31, 2013 consist of cash in bank deposits, money market funds and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investment strategy is primarily in short term securities. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase.

A hypothetical 100 basis point increase in interest rates would result in an approximate $0.1 million decrease in the fair value of our investments as of December 31, 2013, as compared to an approximate $0.2 million decrease as of December 31, 2012. We have the ability to hold our fixed income investments until maturity and, therefore, we do not expect our operating results to be affected to any significant degree by the effect of a change in market interest rates on our investments.

81

Table of Contents

We contract with third party research and development organizations and contract manufacturers globally. We may be subject to fluctuations in foreign currency rates in connection with any such agreements. Transactions denominated in currencies other than the functional currency are recorded based on exchange rates at the time such transactions arise. As of December 31, 2013, all of our liabilities were denominated in our functional currency.

**Item 8.** ***Consolidated Financial Statements and Supplementary Data***

Our consolidated financial statements, together with the independent registered public accounting firm report thereon, appear at pages F-1 through F-30 of this Annual Report on Form 10-K.

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

None.

**Item 9A.** ***Controls and Procedures***

**Evaluation of Disclosure Controls and Procedures.**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2013. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2013, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

The management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. The Company's internal control system was designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2013. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control  Integrated Framework. Based on our assessment we believe that, as of December 31, 2013, the Company's internal control over financial reporting is effective based on those criteria.

Table of Contents

This annual report does not include an attestation report of the company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit emerging growth companies, which we are, to provide only management's report in this annual report.

**Changes in Internal Controls.**

No change in our internal control over financial reporting, identified in connection with the evaluation of such internal control, that occurred during the fiscal quarter ended December 31, 2013 has materially affected, or is reasonably likely to materially affect, the our internal control over financial reporting.

**Item 9B.** ***Other Information***

On January 10, 2014, we announced the appointment of Marc Kozin, former President of L.E.K. Consulting's North American practice, to our Board of Directors. Mr. Marc Kozin will replace Jonathan Tilly, Ph.D., a scientific co-founder of OvaScience who was recently appointed as Chair of the Department of Biology at Northeastern University. Dr. Tilly will continue to serve as a member of OvaScience's Scientific Advisory Board.

Table of Contents

## PART III

**Item 10.** ***Directors, Executive Officers and Corporate Governance***

The information required by Item 10 of Form 10-K may be found under the captions "Employees," "Directors," "Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the definitive proxy statement to be delivered to stockholders in connection with our 2014 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We make available our code of business conduct and ethics free of charge through our website which is located at www.ovascience.com. We intend to disclose any amendment to, or waiver from, our code of business conduct and ethics that is required to be publicly disclosed pursuant to SEC rules.

**Item 11.** ***Executive Compensation***

The information required by Item 11 of Form 10-K may be found in the definitive proxy statement to be delivered to stockholders in connection with our 2014 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

The information required by Item 12 of Form 10-K may be found under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under our Equity Compensation Plans" in the definitive proxy statement to be delivered to stockholders in connection with our 2014 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

The information required by Item 13 of Form 10-K may be found under the captions "Certain Relationships and Related Transactions" and "Corporate Governance" in the definitive proxy statement to be delivered to stockholders in connection with our 2014 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

**Item 14.** ***Principal Accounting Fees and Services***

The information required by Item 14 of Form 10-K may be found in the definitive proxy statement to be delivered to stockholders in connection with our 2014 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Table of Contents

## PART IV

**Item 15.** ***Exhibits and Financial Statement Schedules***

(a)

List of documents filed as part of this report:

(1)

Consolidated Financial Statements listed under Part II, Item 8 and included herein by reference.

(2)

Consolidated Financial Statement Schedules:

No schedules are submitted because they are not applicable, not required or because the information is included in the Consolidated Financial Statements or Notes to Consolidated Financial Statements.

(3)

Exhibits.

Table of Contents

**Signatures**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized, on February 27, 2014.

OVASCIENCE, INC.

By: /s/ MICHELLE DIPP

Michelle Dipp, M.D., Ph.D.
*President and Chief Executive Officer*

**SIGNATURES**

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

| Signature | Title | Date |
|---|---|---|
| /s/ MICHELLE DIPP<br>Michelle Dipp, M.D., Ph.D. | President and Chief Executive Officer and Director (Principal executive officer) | February 27, 2014 |
| /s/ CHRISTOPHER BLECK<br>Christopher Bleck | Principal financial and accounting officer | February 27, 2014 |
| /s/ RICHARD ALDRICH<br>Richard Aldrich | Director | February 27, 2014 |
| /s/ JEFFREY D. CAPELLO<br>Jeffrey D. Capello | Director | February 27, 2014 |
| /s/ MARY FISHER<br>Mary Fisher | Director | February 27, 2014 |
| /s/ MARC KOZIN<br>Marc Kozin | Director | February 27, 2014 |
| /s/ STEPHEN KRAUS<br>Stephen Kraus | Director | February 27, 2014 |
| /s/ THOMAS MALLEY<br>Thomas Malley | Director | February 27, 2014 |

Table of Contents

| Signature | Title | Date |
|---|---|---|
| /s/ HARALD STOCK<br>Harald Stock, Ph.D. | Director | February 27, 2014 |
| /s/ CHRISTOPH WESTPHAL<br>Christoph Westphal, M.D., Ph.D. | Director | February 27, 2014 |

Table of Contents

**Index to Consolidated Financial Statements of**
**OvaScience, Inc.**

Table of Contents

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Stockholders of
OvaScience, Inc.

We have audited the accompanying consolidated balance sheets of OvaScience, Inc. (a development stage company) (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years ended December 31, 2013 and 2012, the period from April 5, 2011 (inception) to December 31, 2011 and the period from April 5, 2011 (inception) to December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of OvaScience, Inc. as of December 31, 2013 and 2012 and the consolidated results of its operations and its cash flows for the years ended December 31, 2013 and 2012, the period from April 5, 2011 (inception) to December 31, 2011 and the period from April 5, 2011 (inception) to December 31, 2013, in conformity with U.S. generally accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 27, 2014

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Consolidated Balance Sheets**

**(In thousands, except share and per share data)**

| | As of December 31, 2013 | As of December 31, 2012 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 18,078 | $ 14,776 |
| Short-term investments | 26,349 | 16,615 |
| Prepaid expenses and other current assets | 650 | 574 |
| Total current assets | 45,077 | 31,965 |
| Property and equipment, net | 880 | 756 |
| Investment in OvaXon | 1,500 | |
| Restricted cash | 88 | 93 |
| Total assets | $ 47,545 | $ 32,814 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,654 | $ 875 |
| Accrued expenses | 4,120 | 1,211 |
| Total current liabilities | 5,774 | 2,086 |
| Other non-current liabilities | 70 | 7 |
| Total liabilities | 5,844 | 2,093 |
| Commitments and contingencies (Note 11) | | |
| Stockholder's equity: | | |
| Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding | | |
| Common stock, $0.001 par value per share; 100,000,000 shares authorized; 18,528,215 and 14,268,068 shares issued at December 31, 2013 and December 31, 2012, respectively; 17,541,126 and 12,622,919 shares outstanding at December 31, 2013 and December 31, 2012, respectively | 18 | 13 |
| Additional paid-in capital | 86,851 | 46,848 |
| Accumulated other comprehensive income/(loss) | 10 | (6) |
| Deficit accumulated during the development stage | (45,178) | (16,134) |
| Total stockholders' equity | 41,701 | 30,721 |

| | | |
|---|---|---|
| Total liabilities and stockholders' equity | $ 47,545 | $ 32,814 |

See accompanying notes.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Consolidated Statements of Operations and Comprehensive Loss**

**(In thousands, except per share data)**

| | Year Ended, December 31, | | Period from April 5, 2011 (inception) to December 31, | Period from April 5, 2011 (inception) to December 31, |
|---|---|---|---|---|
| | 2013 | 2012 | 2011 | 2013 |
| Operating expenses: | | | | |
| Research and development | $ 15,802 | $ 6,323 | $ 1,170 | $ 23,295 |
| General and administrative | 13,332 | 7,206 | 1,454 | 21,992 |
| Total operating expenses | 29,134 | 13,529 | 2,624 | 45,287 |
| Loss from operations | (29,134) | (13,529) | (2,624) | (45,287) |
| Interest income | 90 | 19 | | 109 |
| Net loss | $ (29,044) | $ (13,510) | $ (2,624) | $ (45,178) |
| Accretion of convertible preferred stock to redemption value | | | (101) | (101) |
| Net loss applicable to common stockholders | $ (29,044) | $ (13,510) | $ (2,725) | $ (45,279) |
| Net loss per share applicable to common stockholders basic and diluted | $ (1.80) | $ (2.33) | $ (3.00) | $ (5.42) |
| Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted | 16,160 | 5,810 | 909 | 8,350 |
| Net loss | (29,044) | $ (13,510) | (2,624) | $ (45,178) |
| Other comprehensive loss: | | | | |
| Unrealized gains / (losses) on available-for-sale securities | 16 | (6) | | 10 |

| | | | | |
|---|---|---|---|---|
| Comprehensive loss | $ (29,028) | $ (13,516) | $ (2,624) | $ (45,168) |
| Non-cash stock-based compensation expenses included in operating expenses are as follows: | | | | |
| Research and development | $ 2,361 | $ 1,143 | $ 269 | $ 3,773 |
| General and administrative | 2,733 | 239 | 77 | 3,049 |

See accompanying notes.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Consolidated Statements of Stockholders' Equity / (Deficit)**

**(In thousands, except share data)**

| | Series A convertible preferred stock | | Series B convertible preferred stock | | Common stock | | Additional paid-in capital | Accumulated other comprehensive income (loss) | Deficit accumulated during the development stage | Total stockholders' equity (deficit) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| Balance at April 5, 2011 (inception) | | $ | | $ | | $ | $ | $ | $ | $ |
| Sale of common stock to founders | | | | | 526,443 | | | | | |
| Vesting of restricted stock | | | | | 683,309 | 1 | | | | 1 |
| Issuance of Series A convertible preferred stock, net of issuance costs of $101 | 6,200,000 | 6,200 | | | | | (101) | | | (101) |
| Stock-based compensation expense | | | | | | | 347 | | | 347 |
| Net loss | | | | | | | | | (2,624) | (2,624) |
| Balance at December 31, 2011 | 6,200,000 | 6,200 | | | 1,209,752 | 1 | 246 | | (2,624) | (2,377) |
| Vesting of Founders Stock | | | | | 674,505 | 1 | | | | 1 |
| Issuance of Series B convertible preferred stock, net of issuance costs of $2,246 | | | 6,770,563 | 34,992 | | | | | | |
| Conversion of Series A convertible preferred stock to common stock on a one-for-2.023 basis | (6,200,000) | (6,200) | | | 3,064,753 | 3 | 6,197 | | | 6,200 |
| Conversion of Series B convertible preferred stock to common stock on a one-for-one basis | | | (6,770,563) | (34,992) | 6,770,563 | 7 | 34,985 | | | 34,992 |
| Common stock issued as part of the private placement, net of issuance costs of $898 | | | | | 897,554 | 1 | 4,038 | | | 4,039 |
| Exercise of stock options | | | | | 5,792 | | | | | |
| Stock-based compensation expense | | | | | | | 1,382 | | | 1,382 |
| Unrealized loss on investments | | | | | | | | (6) | | (6) |
| Net loss | | | | | | | | | (13,510) | (13,510) |
| Balance at December 31, 2012 | | | | | 12,622,919 | 13 | 46,848 | (6) | (16,134) | 30,721 |
| Common stock issued as part of the private placement, net of issuance costs of $2,348 | | | | | 3,888,880 | 4 | 32,652 | | | 32,656 |
| Issuance of shares to Intrexon | | | | | 273,224 | | 2,500 | | | 2,500 |
| Vesting of Founders Stock | | | | | 658,060 | 1 | | | | 1 |
| Exercise of stock options | | | | | 42,799 | | 42 | | | 42 |
| Stock-based compensation expense | | | | | | | 5,094 | | | 5,094 |
| Vesting of restricted stock, net of shares withheld for taxes | | | | | 55,244 | | (285) | | | (285) |
| Unrealized gain on investments | | | | | | | | 16 | | 16 |
| Net loss | | | | | | | | | (29,044) | (29,044) |
| Balance at December 31, 2013 | | | | | 17,541,126 | $ 18 | $ 86,851 | $ 10 | $ (45,178) | $ 41,701 |

See accompanying notes.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Consolidated Statements of Cash Flows**

**(In thousands)**

| | Year Ended December 31, | | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2013 |
|---|---|---|---|---|
| | 2013 | 2012 | | |
| **Cash flows from operating activities:** | | | | |
| Net loss | $ (29,044) | $ (13,510) | $ (2,624) | $ (45,178) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation and amortization | 231 | 93 | | 324 |
| Impairment of property and equipment | 364 | | | 364 |
| Amortization of premium | 586 | 77 | | 663 |
| Stock-based compensation expense | 5,094 | 1,382 | 346 | 6,822 |
| Issuance of common stock for technology access fee | 2,500 | | | 2,500 |
| Changes in operating assets and liabilities: | | | | |
| Prepaid expenses and other assets | (76) | (530) | (44) | (650) |
| Accounts payable | (721) | 599 | 276 | 154 |
| Accrued expenses and other non-current liabilities | 2,972 | 733 | 486 | 4,191 |
| Net cash used in operating activities | (18,094) | (11,156) | (1,560) | (30,810) |
| **Cash flows from investing activities:** | | | | |
| Purchases of property, plant and equipment | (719) | (849) | | (1,568) |
| Maturities of short-term investments | 5,670 | | | 5,670 |
| Purchases of short-term investments | (15,974) | (16,698) | | (32,672) |
| Decrease / (increase) in restricted cash | 5 | (93) | | (88) |
| Net cash used in investing activities | (11,018) | (17,640) | | (28,658) |
| **Cash flows from financing activities:** | | | | |
| Proceeds from issuance of preferred stock, net of issuance costs | | 34,992 | 6,099 | 41,091 |
| Net proceeds from the issuance of common stock | 32,414 | 4,039 | 2 | 36,455 |
| Net cash provided by financing activities | 32,414 | 39,031 | 6,101 | 77,546 |
| Net increase in cash and cash equivalents | 3,302 | 10,235 | 4,541 | 18,078 |
| Cash and cash equivalents at beginning of period | 14,776 | 4,541 | | |
| Cash and cash equivalents at end of period | $ 18,078 | $ 14,776 | $ 4,541 | $ 18,078 |

| | | | | |
|---|---|---|---|---|
| Supplemental disclosure of non-cash investing and financing activity | | | | |
| Investment in OvaXon | $ 1,500 | $ | $ | $ 1,500 |
| Accretion of convertible preferred stock to redemption value | $ | $ | $ (101) | $ (101) |
| Conversion of convertible preferred stock to common stock | $ | $ 41,192 | $ | $ 41,192 |

See accompanying notes.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements**

**1. Organization**

OvaScience, Inc., incorporated on April 5, 2011 as a Delaware corporation, is a life science company developing proprietary potential treatments for female infertility based on recent scientific discoveries about the existence of egg precursor cells. As used through these consolidated financial statements, the terms "OvaScience," "we," "us," and "our" refer to the business of OvaScience, Inc. and its wholly owned subsidiary. Our operations to date have been limited to organizing and staffing , business planning, raising capital, acquiring and developing our technology, identifying potential treatments, planning and conducting a study in humans for our most advanced treatment and undertaking preclinical studies of certain potential fertility treatments. We have commenced our planned principal operations but have not generated any significant revenues to date. Accordingly, we are considered to be in the development stage.

We are subject to a number of risks similar to other life science companies in the development stage, including, but not limited to, the need to obtain adequate additional funding, possible failure to provide our treatments to IVF clinics to gain clinical experience in select countries outside of the United States, the need to obtain marketing approval for certain of our treatments, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's treatments and protection of proprietary technology. If we do not successfully commercialize any of treatments, we will be unable to generate treatment revenue or achieve profitability. As of December 31, 2013 we had a deficit accumulated during the development stage of approximately $45.2 million.

Unless otherwise indicated, all information in these financial statements gives retrospective effect to the one-for-2.023 reverse stock split of our common stock (the "Reverse Stock Split") that was effected on March 28, 2012 (see Note 7).

***Liquidity***

We have incurred annual net operating losses in each year since our inception. We have not generated any treatment revenues related to our primary business purpose and have financed our operations primarily through private placements of our preferred stock and common stock. We have not completed development of any treatment and have devoted substantially all of our financial resources and efforts to raising capital and research and development. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We believe that our cash and investments of approximately $44.4 million at December 31, 2013 will be sufficient to fund our current operating plan and continue as a going concern into 2015. We will be required to obtain additional funding in order to continue to fund our operations for 2015 and beyond. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

Our consolidated financial statements include the accounts of OvaScience and our wholly-owned subsidiary, OvaScience Securities Corporation. We have eliminated all significant intercompany accounts and transactions in consolidation.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

The preparation of consolidated financial statements in accordance with generally accepted accounting principles requires our management to make estimates and judgments that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments. We based on our estimates of historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

**Cash Equivalents and Short-Term Investments**

Cash equivalents and short-term investments primarily consist of money market funds and corporate debt securities. Corporate debt securities include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist of money market funds, are stated at fair value. They are also readily convertible to known amounts of cash and have such short-term maturities that each presents insignificant risk of change in value due to changes in interest rates.

The appropriate classification of marketable securities is determined at the time of purchase and reevaluated at each balance sheet date. We have classified all of our short-term investments at December 31, 2013 and December 31, 2012 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income / (loss), which is a separate component of stockholders' equity.

The cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest income. The cost of securities sold or the amount reclassified out of accumulated other comprehensive income into earnings is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in interest income.

We conduct periodic reviews to identify and evaluate each investment that is in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income / (loss). For available-for-sale debt securities in an unrealized loss position, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within the statement of operations as an impairment loss.

Regardless of our intent to sell a security, we perform an additional analysis on all securities in an unrealized loss position to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security and are recorded within earnings as an impairment loss.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Fair Value Measurements**

We define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

We value our short-term investments utilizing third party pricing services. The pricing services use observable market inputs to determine value, including benchmark yields, reportable trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, reference data, new issue data, and monthly payment information. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and confirming that those securities trade in active markets. We valued the balance of the technology access fee payable to Intrexon Inc. for $2.5 million in cash in December 2014 based on a discounted cash flow model. We used a 15% discount rate, which we believe approximates our one year unsecured borrowing rate.

**Restricted Cash**

Restricted cash consists of balances held in deposit with major financial institutions to collateralize letters of credit in the names of our landlords pursuant to certain operating lease agreements. We disclose these amounts separately on our consolidated balance sheet as Restricted cash.

**Concentrations of Risk**

We have no significant off-balance sheet risk.

Cash, cash equivalents and marketable securities are the only financial instruments we have that are subject to concentration of credit risk. Cash and cash equivalents are primarily maintained with two major financial institutions in the United States. Deposits at banks may exceed the insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk. Short-term investments consistent of investment grade corporate debt securities. Our investment policy, which has been approved by our board of directors, limits the amount we may invest in any one issuer of investments, thereby reducing credit risk concentrations.

**Segment Information**

We make operating decisions based upon the performance of the enterprise as a whole and utilize our consolidated financial statements for decision making. We operate in one segment, which focuses on developing treatments dedicated to the treatment of female infertility.

**Research and Development Costs**

We expense research and development costs to operations as incurred. Research and development expenses consist of costs associated with research activities, including license payments paid to third parties for rights to intellectual property, the costs of development of treatments and advances in the field of infertility. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

when the service has been performed rather than when the payment is made. We also include as research and development expense access fees for technologies which have not yet reached technological feasibility and have no alternative use. Research and development expenses consist of:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, contract manufacturing organizations and consultants;
- license fees; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies.

We are a party to a collaboration agreement with Intrexon Corporation in which we will reimburse the collaborator for work it has performed. If the arrangement provides for us to reimburse the collaborator for research and development expenses or achieving a development milestone for which a payment is due, as is the case with Intrexon Corporation in future periods, we record the reimbursement or the achievement of the development milestone as research and development expense.

**Stock-based Compensation**

For stock options granted to employees and directors with only service-based vesting conditions, we measure stock-based compensation cost at the grant date based on the estimated fair value of the award, and recognize it as expense over the requisite service period on a straight-line basis. We record the expense of services rendered by non-employees based on the estimated fair value of the stock option as of the respective vesting date. Further, we expense the fair value of non-employee stock options that contain only service-based vesting conditions over the requisite service period of the underlying stock options. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance criteria, which affects the awards expected to vest and the period over which the expense is recognized, and recognize the expense using the accelerated attribution model, to the extent achievement of the performance condition is deemed probable. We use the Black-Scholes valuation model in determining the fair value of equity awards

Stock-based compensation expense is determined based on the fair value of the award at the grant date, including estimated forfeitures, and is adjusted each period to reflect actual forfeitures and the outcomes of certain performance conditions.

**Income Taxes**

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss and tax credit carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect of a change in tax rate on deferred taxes is recognized in income or loss in the period that includes the enactment date.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

We apply judgment in the determination of the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. We recognize any material interest and penalties related to unrecognized tax benefits in income tax expense.

Due to the uncertainty surrounding the realization of the net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of December 31, 2013 and 2012.

**Property and Equipment**

Property and equipment is stated at cost. Depreciation is recorded using the straight-line method over the estimated useful lives of the applicable assets. Upon sale or retirement, the cost and related accumulated depreciation are eliminated from the respective account and resulting gain or loss, if any, is included in current operations. Amortization of leasehold improvements is included in depreciation expense. Repairs and maintenance charges that do not increase the useful life of the assets are charged to operations as incurred. Property and equipment are depreciated over the following periods:

| | |
|---|---|
| Laboratory equipment | 3 - 5 years |
| Furniture | 5 years |
| Computer equipment | 3 years |
| Leasehold improvements | Shorter of asset life or lease term |

**Impairment of Long-Lived Assets**

We evaluate our long-lived assets for potential impairment. Potential impairment is assessed when there is evidence that events or changes in circumstances have occurred that indicate that the carrying amount of a long-lived asset may not be recovered. Recoverability of these assets is assessed based on undiscounted expected future cash flows from the assets, considering a number of factors, including past operating results, budgets and economic projections, market trends, and potential fertility treatment development cycles. An impairment in the carrying value of each asset is assessed when the undiscounted expected future cash flows, including its eventual residual value, derived from the asset are less than its carrying value. Impairments, if any, are recognized in earnings. An impairment loss would be recognized in an amount equal to the excess of the carrying amount over the undiscounted expected future cash flows. See Note 6 for discussion on impairment charges recognized during the periods presented.

**Net Loss per Share**

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period, without consideration for common stock equivalents. Our potentially dilutive shares, which include preferred stock, outstanding stock options, restricted stock units and unvested Founders' shares, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**2. Summary of Significant Accounting Policies (Continued)**

**Consolidation of Variable Interest Entities**

We use a qualitative approach in assessing the consolidation requirement for variable interest entities. The approach focuses on identifying which enterprise has the power to direct the activities that most significantly impact the variable interest entity's economic performance and which enterprise has the obligation to absorb losses or the right to receive benefits from the variable interest entity. In the event that we are the primary beneficiary of a variable interest entity, the assets, liabilities, and results of operations of the variable interest entity are included in our consolidated financial statements.

**3. Collaboration with Intrexon and OvaXon Joint Venture**

***Scope***

On December 18, 2013, we entered into a collaboration agreement (the "OvaTure Collaboration") with Intrexon governing the use of Intrexon's synthetic biology technology platform for the accelerated development of our OvaTure platform. The OvaTure Collaboration provides that Intrexon will deliver laboratory and animal data to support the successful filing of an investigational new drug application ("IND") for OvaTure.

Although we have not discussed OvaTure with the FDA, we expect we will need to obtain regulatory approval of OvaTure in the United States prior to commercialization. OvaScience owns exclusive human commercial rights for OvaTure.

We will participate as an equal member on the Joint Steering Committee ("JSC") and Intellectual Property Committee ("IPC"). The JSC shall agree upon the services and the activities to be included in the work plan, and IPC has authority over intellectual property matters. We have the tie-breaking vote if there are any disputes with the JSC.

***Technology Access Fee Payable to Intrexon***

The technology access fee payable to Intrexon is comprised of (1) the issuance of 273,224 shares, or $2.5 million of our newly issued common stock, to Intrexon, upon the execution of the OvaTure Collaboration in December 2013, and (2) a $2.5 million cash payment due December 2014, which is payable solely upon the passage of time.

The technology access fee does not give OvaScience the right to any research and development services, and the technology access has no alternative future use to OvaScience. We therefore recorded $4.7 million in research and development expense in the year ended December 31, 2013 with $2.5 million recorded to additional paid-in capital and common stock and $2.2 million recorded in accrued liabilities, which represents the present value of the remaining $2.5 million technology access fee due in December 2014.

The shares issued to Intrexon are subject to "piggy-back" registration rights that entitle Intrexon to have the shares included in any new registration statement filed in connection with an underwritten public offering, subject to underwriter cutback. The piggy-back registration rights will not be triggered by any offering subject to a previously filed registration statement, including our current universal shelf registration statement.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**3. Collaboration with Intrexon and OvaXon Joint Venture (Continued)**

***Research and Development Funding and Potential Commercial Milestone***

The JSC will also approve a budget for services to be performed under the work plan. We will reimburse Intrexon for research and development services performed, as dictated by the approved budget. If applicable, OvaScience will also make a commercial milestone payment three months after the first commercial sale of OvaTure.

***Termination Rights***

The collaboration has an indefinite term, with OvaScience having the right to terminate the collaboration after 90 days' prior written notice, and either OvaScience or Intrexon may terminate after a material breach by the other party that is not cured within 60 days. We may assign the collaboration in the event of a change of control transaction.

***Royalties***

Upon the delivery of laboratory and animal data necessary to support the successful filing of an IND application, we will pay Intrexon a mid-single digit royalty on net sales of OvaTure potential fertility treatments, and the exact royalty will depend upon whether Intrexon completes the Milestone by the targeted deadline of two years after technology transfer.

***Joint Venture***

On December 18, 2013, we also entered into a joint venture with Intrexon to leverage Intrexon's synthetic biology technology platform and OvaScience's technology relating to egg precursor cells to pursue the prevention of genetic disease and animal health. We and Intrexon formed OvaXon, LLC ("OvaXon") to conduct the joint venture. Each party contributed $1.5 million to OvaXon and each has a 50% equity interest, and research and development costs and profits will be split accordingly. Each party will also have 50% control over OvaXon with disputes resolved through arbitration, if necessary.

As of December 31, 2013, we recorded a $1.5 million investment in OvaXon, an equity method investment, with the offset recorded to Accounts Payable. This was paid in January 2014.

We consider OvaXon a variable interest entity. OvaXon does not have a primary beneficiary as both OvaScience and Intrexon have equal ability to direct the activities of OvaXon through JSC and IPC membership and 50% voting rights. OvaXon has been accounted for under the equity method and is not consolidated. This analysis and conclusion will be updated annually to reflect any changes in ownership or power over OvaXon.

**4. Fair Value Measurements**

The fair value of our financial assets and liabilities reflects our estimate of amounts that we would have received in connection with the sale of the assets or paid in connection with the transfer of the liabilities in an orderly transaction between market participants at the measurement date. In connection with measuring the fair value of our assets and liabilities, we seek to maximize the use of observable inputs (market data obtained from independent sources) and to minimize the use of unobservable inputs (our assumptions about how market participants would price assets and liabilities). The following

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**4. Fair Value Measurements (Continued)**

fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used in order to value our assets and liabilities:

Level 1 quoted prices (unadjusted) in active markets for identical assets or liabilities.

Level 2 quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.

Level 3 unobservable inputs based on our assumptions used to measure assets and liabilities at fair value.

For fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. The prices provided by third party pricing services are validated by reviewing their pricing methods and obtaining market values from other pricing sources. After completing these validation procedures, we did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2013 or December 31, 2012.

We review investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, we consider the intent to sell, or whether it is more likely than not that we will be required to sell, the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity and the duration of the impairment and changes in value subsequent to year end. As of December 31, 2013 and December 31, 2012, there were no investments with a fair value that was significantly lower than the amortized cost basis or any investments that had been in an unrealized loss position for a significant period.

The following tables provide the Company's assets and liabilities that are measured at fair value on a recurring basis as of December 31, 2013 and December 31, 2012 (in thousands).

| Description | Balance as of December 31, 2013 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| *Assets:* | | | | |
| Cash and money market funds | $ 18,078 | $ 18,078 | $ | $ |
| Corporate debt securities (including commercial paper) | 26,349 | | 26,349 | |
| Total assets | $ 44,427 | $ 18,078 | $ 26,349 | $ |
| *Liabilities:* | | | | |
| Technology access fee due to Intrexon | $ 2,186 | $ | $ | $ 2,186 |
| Total liabilities | $ 2,186 | $ | $ | $ 2,186 |

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**4. Fair Value Measurements (Continued)**

| Description | Balance as of December 31, 2012 | Level 1 | Level 2 |
|---|---|---|---|
| *Assets:* | | | |
| Cash and money market funds | $ 14,776 | $ 14,776 | |
| Corporate debt securities (including commercial paper) | 16,615 | | 16,615 |
| Total assets | $ 31,391 | $ 14,776 | $ 16,615 |

Changes in the fair value of the Level 3 technology access fee due to Intrexon for the year ended December 31, 2013 were as follows:

| | Technology access fee (in thousands) |
|---|---|
| Balance at December 31, 2012 | $ |
| Collaboration with Intrexon | 2,174 |
| Fair value adjustment(1) | 12 |
| Balance at December 31, 2013 | $ 2,186 |

(1) Fair value adjustments consist of interest recorded.

There have been no changes to the valuation methods during the years ended December 31, 2013 and 2012. There were no transfers of assets or liabilities between Level 1 and Level 2 during the years ended December 31, 2013 and 2012. We had no short-term investments that were classified as Level 3 during the years ended December 31, 2013 or 2012.

Cash and cash equivalents, prepaid expenses, accounts payable and accrued expenses are carried at amount that approximate fair value due to their short-term maturities.

**5. Cash, Cash Equivalents and Marketable Securities**

The following tables summarize the Company's cash, cash equivalents and marketable securities as of December 31, 2013 and December 31, 2012 (in thousands):

| December 31, 2013 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Cash and money market funds | $ 18,078 | $ | $ | $ 18,078 |
| Corporate debt securities | | | | |
| Due in one year or less | 22,631 | 11 | (2) | 22,640 |
| Due in two years or less | 3,708 | 2 | (1) | 3,709 |
| Total | $ 44,417 | $ 13 | $ (3) | $ 44,427 |
| Reported as: | | | | |
| Cash and cash equivalents | $ 18,078 | $ | $ | $ 18,078 |
| Short-term investments | 26,339 | 13 | (3) | 26,349 |
| Total | $ 44,417 | $ 13 | $ (3) | $ 44,427 |

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**5. Cash, Cash Equivalents and Marketable Securities (Continued)**

| December 31, 2012 | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
|---|---|---|---|---|
| Cash and money market funds | $ 14,776 | $ | $ | $ 14,776 |
| Corporate debt securities | | | | |
| Due in one year or less | 5,754 | 2 | (1) | 5,755 |
| Due in two years or less | 10,867 | 3 | (10) | 10,860 |
| Total | $ 31,397 | $ 5 | $ (11) | $ 31,391 |
| Reported as: | | | | |
| Cash and cash equivalents | $ 14,776 | $ | $ | $ 14,776 |
| Short-term investments | 16,621 | 5 | (11) | 16,615 |
| Total | $ 31,397 | $ 5 | $ (11) | $ 31,391 |

At December 31, 2013 and 2012 we held eight and fifteen debt securities that had been in an unrealized loss position for less than 12 months, respectively. We held no investments that have been in a continuous unrealized loss position for 12 months or longer. The aggregate fair value of these securities was $9.5 million and $11.6 million at December 31, 2013 and 2012, respectively. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for the eight securities as of December 31, 2013 to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities. Three of these securities were sold in January 2014 for an immaterial realized gain, the remaining five securities we do not intend to sell before the recovery of their amortized cost bases, which recovery is expected within the next 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2013 or 2012.

As of December 31, 2013, we held $11.7 million in financial institution debt securities and other corporate debt securities located in Canada, the United Kingdom, the Netherlands, Australia, and Norway. As of December 31, 2012, we held $7.6 million in financial institution debt securities and other corporate debt securities located in Canada, the United Kingdom, the Netherlands, and Australia. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of December 31, 2013 or 2012.

We had no realized gains or losses or other-than-temporary impairments on our short-term investments for the years ended December 31, 2013 and 2012, the period from April 5, 2011 (inception) through December 31, 2011 and the period from April 5, 2011 (inception) through December 31, 2013.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**6. Property and Equipment**

Property and equipment and related accumulated depreciation are as follows (in thousands):

| | December 31, 2013 | December 31, 2012 |
|---|---|---|
| Laboratory equipment | $ 1,377 | $ 663 |
| Furniture | 106 | 101 |
| Computer equipment | 7 | 7 |
| Leasehold improvements | 78 | 78 |
| Less: accumulated depreciation | (688) | (93) |
| | $ 880 | $ 756 |

We recorded depreciation and amortization expense of $0.2 million, $0.1 million, zero, and $0.3 million for the years ended December 31, 2013 and 2012, the period from April 5, 2011 (inception) through December 31, 2011, and the period from April 5, 2011 (inception) through December 31, 2013, respectively. In July 2013, we entered into a master services agreement with a new global third party manufacturer to provide services for the manufacture of AUGMENT to replace our existing contract manufacturer. As a consequence of the contract manufacturer transition, we determined that we would no longer use certain laboratory equipment, and as such, recorded an impairment loss of $0.4 million. The loss is included within research and development expense.

**7. Convertible Preferred Stock**

In July 2011, we sold 6,200,000 shares of Series A Preferred Stock at a price of $1.00 per share for gross proceeds of $6.2 million. We incurred approximately $0.1 million of issuance costs in connection with the sale of the Series A Preferred Stock, which were recorded to additional paid-in capital.

On March 29, 2012, we sold 6,770,563 shares of Series B Preferred Stock at a price of $5.50 per share for gross proceeds of approximately $37.2 million. We incurred approximately $2.2 million of issuance costs in connection with the sale of the Series B Preferred Stock, which were recorded as a reduction of the proceeds received.

On August 13, 2012, as a result of the completion of the private placement of our common stock (see Note 8), our Series A and Series B Preferred Stock automatically converted into shares of common stock. Each share of Series A Preferred Stock converted into common stock on a one-for-2.023 basis, into a total of 3,064,753 shares of common stock, and each share of Series B Preferred Stock converted into common stock on a one-for-one basis, into a total of 6,770,563 shares of common stock.

We assessed the Series A Preferred Stock and the Series B Preferred Stock for any beneficial conversion features or embedded derivatives, including the conversion option, that would require bifurcation from the Series A Preferred Stock and/or the Series B Preferred Stock and receive separate accounting treatment. On the date of the issuance, the fair value of the common stock into which the Series A Preferred Stock and the Series B Preferred Stock, respectively, was convertible was less than the effective conversion price of the Series A Preferred Stock and the Series B Preferred Stock, respectively, and, as such, there was no intrinsic value of the conversion option on the commitment date. In addition, no embedded derivatives were identified that would require bifurcation.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**7. Convertible Preferred Stock (Continued)**

The rights, preferences and privileges of the Series A Preferred Stock and the Series B Preferred Stock were as set forth below until the Series A Preferred Stock and the Series B Preferred Stock converted into common stock on August 13, 2012 (see Note 8).

**Conversion**

Shares of Series A Preferred Stock were convertible into common stock based on a defined conversion ratio, which was originally set at one-for-one and following the Reverse Stock Split was one-for-2.023, adjustable for certain dilutive events. Shares of Series B Preferred Stock were convertible into common stock based on a defined conversion ratio, which was one-for-one, adjustable for certain dilutive events. The conversion ratios for the Series A Preferred Stock and the Series B Preferred Stock were subject to change in accordance with anti-dilution provisions contained in our restated certificate of incorporation. More specifically, the applicable conversion ratio was subject to adjustment to prevent dilution on a weighted-average basis in the event that we issued additional shares of common stock or securities convertible or exercisable for common stock at a purchase price less than the then effective applicable conversion ratio. We evaluated this feature and concluded it did not require bifurcation as a derivative because the Series A Preferred Stock and the Series B Preferred Stock were each concluded to have the characteristics of an equity-host and the feature was clearly and closely related to the Series A Preferred Stock and the Series B Preferred Stock, respectively.

The Series A Preferred Stock and the Series B Preferred Stock were convertible at the option of the holder at any time without any additional consideration. In addition, the Series A Preferred Stock and the Series B Preferred Stock would automatically convert into shares of common stock at the then effective applicable conversion rate, upon the earliest to occur of (a) the closing of the sale of shares of common stock to the public at a price of at least $16.50 per share in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"), provided that such offering results in at least $35.0 million of gross proceeds to us and the our common stock is listed for trading on a national securities exchange, (b) the closing of certain private placement or registered offerings of our equity securities or (c) the effectiveness of a registration statement under the Securities Act covering the re-sale of privately placed securities. In addition, all outstanding shares of Series A Preferred Stock and Series B Preferred Stock would convert into common stock upon the vote or written consent of the holders of 70% of the outstanding Series A Preferred Stock and Series B Preferred Stock, voting as a single class (subject to certain limitations).

**Dividends**

Prior to the payment of any dividend, except a common stock dividend, to the common stockholders, the holders of Series A Preferred Stock and Series B Preferred Stock were entitled to receive an amount at least equal to the amount that would have been received by the holders of Series A Preferred Stock and Series B Preferred Stock had all shares of Series A Preferred Stock and Series B Preferred Stock been converted to common stock immediately prior to issuance of the dividend. There were no guaranteed dividends that accrue.

**Liquidation preference**

In the event of any liquidation, dissolution or winding up of the Company, including a deemed liquidation event, such as certain mergers or a disposition of substantially all the assets of the

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**7. Convertible Preferred Stock (Continued)**

Company, unless holders of at least 70% of the outstanding shares of Series A Preferred Stock and Series B Preferred Stock, including certain of our major investors, elected otherwise, the holders of Series A Preferred Stock and Series B Preferred Stock were entitled to receive, in preference to common stockholders, an amount equal to $1.00 per share, in the case of the Series A Preferred Stock, and $5.50 per share, in the case of the Series B Preferred Stock, in each case adjustable for certain dilutive events, plus all declared but unpaid dividends. If we had insufficient assets to pay the holders of Series A Preferred Stock and Series B Preferred Stock the full amount to which they were entitled, the holders of the Series A Preferred Stock and Series B Preferred Stock would share ratably in any distribution in proportion to the respective amounts which would otherwise be payable.

After payment of such preferential amounts, the remaining assets of the Company, if any, would be distributed ratably to the holders of common stock, Series A Preferred Stock and Series B Preferred Stock on an as-converted to common stock basis. However, the holders of Series A Preferred Stock and Series B Preferred Stock were limited to the receipt of an aggregate amount (including through payment of the preferential amounts described above) equal to the greater of:

(1) $2.00 per share, in the case of the Series A Preferred Stock, and $11.00 per share, in the case of the Series B Preferred Stock, in each case adjustable for certain dilutive events, and

(2) the amount such holders would have received if all Series A Preferred Stock or Series B Preferred Stock, as the case may be, had been converted to common stock immediately prior to the liquidation event.

**Voting rights**

Holders of Series A Preferred Stock and Series B Preferred Stock were entitled to vote as a single class with the holders of common stock, and had one vote for each equivalent common share into which the Series A Preferred Stock and the Series B Preferred Stock was convertible. In addition, the affirmative vote of the holders of at least 70% of the outstanding Series A Preferred Stock and Series B Preferred Stock, including certain of our major investors, voting together on an as-converted to common stock basis, was required to amend our organizational documents, declare or pay dividends, subject to limited exceptions, create certain new series or classes of stock or reclassify existing series or classes, exclusively license our material intellectual property, effect a significant change in our business, create indebtedness in excess of $0.25 million, increase the number of shares of common stock reserved for equity compensation, or undertake change of control transactions. Furthermore, the affirmative vote of the holders of at least 60% of the outstanding Series B Preferred Stock was required to amend or repeal our organizational documents, increase the number of shares of Series B Preferred Stock, undertake change of control transactions or exclusively license any of our material intellectual property. The holders of Series A Preferred Stock were entitled to elect two directors and the holders of Series B Preferred Stock were entitled to elect one director. The holders of our common stock, Series A Preferred Stock and Series B Preferred Stock, voting together on an as converted to common stock basis, had the right to elect the remaining directors.

**8. Common Stock**

On March 28, 2012, our board of directors and stockholders approved, and we filed, a restated certificate of incorporation effecting a Reverse Stock Split of the outstanding shares of our common

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**8. Common Stock (Continued)**

stock at a ratio of one share for every 2.023 shares outstanding, so that every 2.023 outstanding shares of common stock before the Reverse Stock Split represented one share of common stock after the Reverse Stock Split. Each stockholder's percentage ownership interest in the Company and proportional voting power remains unchanged after the Reverse Stock Split, except for minor changes and adjustments resulting from rounding of fractional interests. The rights and privileges of the holders of capital stock were unaffected by the Reverse Stock Split. All information in these financial statements has, unless otherwise indicated, been retroactively adjusted for all periods presented to give effect to the Reverse Stock Split.

On August 13, 2012, we issued and sold in a private placement an aggregate of 897,554 shares of common stock at a price per share of $5.50 resulting in net proceeds of $4.0 million. As a result of the completion of the private placement, on August 13, 2012, our Series A Preferred Stock and Series B Preferred Stock automatically converted into shares of common stock. Each share of Series A Preferred Stock converted into common stock on a one-for-2.023 basis, into a total of 3,064,753 shares of common stock, and each share of Series B Preferred Stock converted into common stock on a one-for-one basis, into a total of 6,770,563 shares of common stock.

In connection with the private placement, we agreed to file a registration statement (the "Resale S-1") covering the resale of the 6,770,563 shares of common stock issued upon conversion of Series B Preferred Stock and the 897,554 shares of common stock issued and sold in the private placement. We filed the resale S-1 covering the resale of the 7,630,683 shares of common stock on August 29, 2012 and it was declared effective on September 13, 2012.

On August 13, 2012, we amended our certificate of incorporation and by-laws to divide our board of directors into three classes with staggered three year terms. In addition, our restated certificate of incorporation and amended and restated by-laws provide that directors may be removed only for cause and only by the affirmative vote of the holders of 75% of the shares of capital stock present in person or by proxy and entitled to vote. Under our restated certificate of incorporation and amended and restated by-laws, any vacancy on the board of directors, including a vacancy resulting from an enlargement of the board of directors, may be filled only by vote of a majority of directors then in office. Furthermore, the restated certificate of incorporation provides that the authorized number of directors may be changed only by the board of directors.

In March 2013, we issued and sold in a private placement an aggregate of 3,888,880 shares of our common stock to investors at $9.00 per share. The private placement resulted in $32.7 million of net proceeds. We filed a registration statement covering the resale of all such shares.

In December 2013, we issued 273,224 shares of our common stock to Intrexon Corporation at $9.15 per share. The shares were issued in conjunction with a research and development agreement as the first installment of technology access fee (see Note 3).

We have reserved the following shares of common stock for the potential exercise of stock options and issuance of shares upon vesting of restricted stock units:

| | December 31, 2013 | December 31, 2012 |
|---|---|---|
| Outstanding stock options | 2,413,237 | 1,218,153 |
| Outstanding restricted stock units | 96,155 | 192,308 |

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**9. Stock-Based Compensation**

In March 2012, our board of directors and stockholders approved the 2012 Stock Incentive Plan (the "2012 Plan"). The 2012 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock units and other stock-based or cash awards to purchase shares of common stock to eligible employees, officers, directors and consultants. The number of shares of our common stock that are reserved for issuance under the 2012 Plan is equal to the sum of (1) 1,453,253 shares of common stock issuable under the 2012 Plan plus the number of shares of our common stock subject to outstanding awards under the 2011 Plan, described below, that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right (up to 679,622 shares) plus (2) an annual increase, to be added on the first day of each year beginning in 2013 and each subsequent anniversary until the expiration of the 2012 Plan, equal to the lowest of 975,000 shares of its common stock, 4.0% of the number of shares of our common stock outstanding on the first day of the year and an amount determined by our board of directors. We began making grants under the 2012 Plan following June 11, 2012, the effective date of our registration of securities on Form 10. Shares issued under the 2012 Plan are funded through the issuance of new shares. We ceased granting options under the 2011 Plan following the effective date of our registration of securities on Form 10.

**Founders' stock**

In April 2011, we issued 3,509,634 shares of its common stock to founders at a purchase price of $0.002 per share, which was determined by the board of directors to be the fair value of the common stock on the date of issuance. The shares were issued under restricted stock purchase agreements and not pursuant to the 2011 Plan. These restricted stock purchase agreements allow us, at our discretion, to repurchase unvested shares if the founder's relationship with us is terminated. The shares issued to three of the co-founders vested with respect to 25% of the shares on the grant date and with respect to the remaining shares in approximately equal quarterly installments through the fourth anniversary of the grant date. The shares issued to the remaining two co-founders vest in approximately equal quarterly installments from and after the grant date. Additionally, 25% of the then-unvested shares issued to the remaining two co-founders vested in July 2011 in connection with the Series A Preferred Stock financing.

A summary of our Founders' stock activity and related information is as follows:

| | Shares |
|---|---|
| Unvested at December 31, 2011 | 2,319,646 |
| Granted | |
| Vested | (674,505) |
| Unvested at December 31, 2012 | 1,645,141 |
| Granted | |
| Vested | (658,060) |
| Unvested at December 31, 2013 | 987,081 |

We record stock-based compensation expense for the common stock subject to repurchase based on the grant date intrinsic value for employees and the vesting date intrinsic value for non-employees. All of the restricted shares were issued at fair value.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**9. Stock-Based Compensation (Continued)**

**Stock options and restricted stock**

A summary of the Company's stock option activity and related information is as follows (in thousands, except share and per share data):

| | Shares | Weighted average exercise price per share | Weighted average remaining contractual term (years) | Aggregate intrinsic value |
|---|---|---|---|---|
| Outstanding at December 31, 2012 | 1,218,153 | 3.83 | 9.34 | 5,535 |
| Granted | 1,537,172 | 12.87 | | |
| Exercised | (42,799) | 0.99 | | |
| Forfeited | (278,158) | 7.07 | | |
| Cancelled | (21,131) | 4.01 | | |
| Outstanding at December 31, 2013 | 2,413,237 | 9.26 | 9.05 | 6,087 |
| Exercisable at December 31, 2013 | 468,710 | 3.46 | 8.28 | 3,112 |
| Vested and expected to vest at December 31, 2013 | 1,445,760 | 8.14 | 8.90 | 4,192 |

The total intrinsic value (the amount by which the fair market value exceeded the exercise price) of stock options exercised was $0.4 million, $48 thousand, zero and $0.4 million for the years ended December 31, 2013 and 2012, the period from April 5, 2011 (inception) to December 31, 2011 and the period from April 5, 2011 (inception) to December 31, 2013, respectively.

**Stock options**

The fair value of each employee stock-based award is estimated on the grant date using the Black-Scholes option pricing model.

We have used the simplified method to calculate the expected term in fiscal 2013 as we have not had significant historical exercise and post-vest termination data to provide a reasonable basis upon which to estimate the expected term for the options granted to employees. The contractual term will be used for option awards granted to non-employees. Historical data will be incorporated into our assumption as it becomes available.

The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to ours, including stage of potential fertility treatment development and life science industry focus. The representative group of companies consisted of ANI Pharmaceuticals, Inc., Corcept Therapeutics Inc., Neogenomics Inc., Sangamo Biosciences, Inc., and Stem Cells Inc. As a result of being a development stage company in a very early stage of potential fertility treatment development with no revenues, the representative group of companies has certain similar, but not all similar, characteristics to ours. We believe the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of ours.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**9. Stock-Based Compensation (Continued)**

The fair value of each stock-based award is estimated on the grant date using the Black-Scholes option pricing model using the following assumptions:

| | December 31, | | |
|---|---|---|---|
| | **2013** | **2012** | **2011** |
| Risk-free interest rate | 0.91% - 2.11% | 0.8% - 1.78% | 1.2% - 1.84% |
| Dividend yield | | | |
| Volatility | 83% - 91% | 79% - 89% | 79% - 82% |
| Expected term (years) | 5.1 - 9.93 | 5.1 - 9.93 | 6.0 - 9.75 |

During the year ended December 31, 2013, we granted 1,537,172 options to purchase common stock to employees with a weighted average exercise price of $12.87 per share at a weighted average grant date fair value of $9.34. During the year ended December 31, 2012, we granted 679,251 options to purchase common stock with a weighted average exercise price of $6.59 per share to employees at a weighted average grant date fair value of $4.82 per share.

We recognized total stock-based compensation expense for employee stock option grants of $2.3 million, $0.3 million and $26 thousand for the years ended December 31, 2013 and 2012 and for the period from April 5, 2011 (inception) to December 31, 2011, respectively.

During 2012, we granted 39,685 options to purchase common stock with a weighted average exercise price of $4.81 per share to non-employees. During 2011, we granted 165,339 options to purchase common stock with a weighted average exercise price of $0.04 per share to non-employees.

Stock-based awards issued to non-employees are accounted for using the fair value method. These stock-based option awards are revalued at each reporting date until vesting. We recognized total stock-based compensation of $2.2 million for the year ended December 31, 2013, $1.0 million for the year ended December 31, 2012 and $0.3 million for the period from April 5, 2011 (inception) to December 31, 2011 for these non-employee awards.

At December 31, 2013 there was $8.8 million of total unrecognized compensation cost related to non-vested stock options and restricted stock. We expect to recognize these costs over a remaining weighted average period of 2.7 years.

**Restricted Stock Units**

On December 5, 2012, we issued a total of 192,308 restricted stock units ("RSUs") to our Chief Executive Officer. This included a grant of 128,205 RSUs with service-based vesting as follows: 16,025 shares on March 31, 2013 and 16,025 shares each quarter thereafter until December 31, 2014. The fair value of the service-based RSUs is based on the closing price of our common stock on the award date, or $7.80 per share. The stock-based compensation expense for this grant will be recognized on a straight-line basis over the vesting period. We also granted 64,103 RSUs that will vest only upon the achievement of performance conditions as determined by the Company's board of directors. On March 20, 2013 the board of directors established the 2013 performance criteria for the first tranche of the award and communicated the performance criteria to the Chief Executive Officer. The grant date stock price of these performance-based RSUs was $10.00 per share. In December 2013, 19,230 performance-based RSUs vested out of a total of 32,051 performance-based RSUs granted. The total fair value of RSUs vested during 2013 (measured on the date of vesting) was $0.8 million. We

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**9. Stock-Based Compensation (Continued)**

recognized total stock-based compensation for the service-based awards and performance-based awards of $0.7 million and $36 thousand for the years ended December 31, 2013 and 2012, respectively.

The performance conditions for the 2014 tranche of the performance-based RSUs had not been established as of December 31, 2013. As a result, the measurement date and grant date have not occurred for accounting purposes and no expense has been taken related to these awards as of December 31, 2013. On February 7, 2014 the board of directors established the 2014 performance criteria for the second tranche of the performance-based RSUs and communicated the performance criteria to the Chief Executive Officer. The grant date stock price of these performance-based RSUs was $8.75 per share. Expense for these awards will only be recognized if and when it is deemed probable that the performance conditions will be met.

As of December 31, 2013, there was $0.5 million of total unrecognized compensation cost related to non-vested service-based RSUs granted under the 2012 Plan. The expense is expected to be recognized over a weighted average period of 1.0 years.

**10. Income Taxes**

We had no income tax expense or benefit for the years ended December 31, 2013, 2012 and 2011.

Subject to the limitations described below at December 31, 2013 and 2012, we had net operating loss carryforwards of approximately $33.0 million and approximately $14.1 million, respectively, to offset future federal taxable income, which expire beginning in 2031 continuing through 2033. The federal net operating loss carryforwards exclude approximately $0.4 million of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net operating losses. This amount will be recorded as an increase in additional paid in capital on the consolidated balance sheet once the excess benefits are "realized" in accordance with ASC 718. As of December 31, 2013 and 2012, we had net operating loss carryforwards of approximately $32.6 million and approximately $13.9 million, respectively, to offset future state taxable income, which expire beginning in 2031 continuing through 2033. We also had tax credit carryforwards of approximately $0.9 million and approximately $0.2 million as of December 31, 2013 and 2012, respectively, to offset future federal and state income taxes, which expire beginning in 2027 continuing through 2033.

The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**10. Income Taxes (Continued)**

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations follows:

| | Year Ended December 31, 2013 | Year Ended December 31, 2012 | Period from April 5, 2011 (inception) to December 31, 2011 |
|---|---|---|---|
| Income tax benefit using U.S. federal statutory rate | 34.00% | 34.00% | 34.00% |
| State income taxes, net of federal benefit | 5.28% | 5.42% | 5.47% |
| Research and development tax credits | 2.31% | 0.00% | 1.70% |
| Permanent items | (1.09)% | (2.78)% | (3.93)% |
| Change in the valuation allowance | (40.50)% | (36.64)% | (37.24)% |
| | % | % | % |

The principal components of our deferred tax assets are as follows (in thousands):

| | December 31, 2013 | December 31, 2012 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 12,939 | $ 5,527 |
| Research and development credits | 823 | 153 |
| Stock-based compensation | 1,602 | 142 |
| Patent and technology access fee | 1,954 | 129 |
| Other | 350 | (23) |
| Gross deferred tax assets | 17,668 | 5,928 |
| Valuation allowance | (17,668) | (5,928) |
| Net deferred tax asset | $ | $ |

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. We have considered our history of operating losses and concluded, in accordance with the applicable accounting standards, that it is more likely than not that we may not realize the benefit of our deferred tax assets. Accordingly, our deferred tax assets have been fully reserved at December 31, 2013 and 2012. We reevaluate the positive and negative evidence on a quarterly basis.

The valuation allowance increased approximately $11.7 million during the year ended December 31, 2013, due primarily to the increase in the net operating loss carryforwards and tax credits. The valuation allowance increased approximately $5.0 million during the year ended December 31, 2012, due primarily to the increase in the net operating loss carryforwards and tax credits.

We apply ASC 740, *Income Taxes*. ASC 740 provides guidance on the accounting for uncertainty in income taxes recognized in financial statements. At December 31, 2013 and 2012, we had no unrecognized tax benefits.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**10. Income Taxes (Continued)**

We will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2013, 2012 and 2011, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our consolidated statements of operations.

We file income tax returns in the U.S. Federal and Massachusetts jurisdictions. The statute of limitations for assessment by the Internal Revenue Service ("IRS") and state tax authorities is open for tax years ended December 31, 2012 and 2011. There are currently no federal or state income tax audits in progress.

We have not, as yet, conducted a study of research and development ("R&D") credit carryforwards. Such a study, once undertaken by us, may result in an adjustment to our R&D credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against our R&D credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment is required.

**11. Commitments and Contingencies**

On May 1, 2012, we entered into a commercial building lease agreement. The sixty month lease, which commenced on August 10, 2012, provides for the lease of approximately 6,000 square feet of space in Cambridge, Massachusetts. Base annual rent is initially set at approximately $22,000 per month with an annual increase of 3%. From April 2011 through April 2012, we leased office space from a significant stockholder. There was no formal lease arrangement with the stockholder. In May 2012 we entered into a commercial building sublease agreement. The 24 month sublease, which commenced on August 26, 2013, provides for the lease of 1,900 square feet of space also in Cambridge, Massachusetts. Base rent is approximately $4 thousand per month with an annual increase of 3%.

Future minimum lease payments as of December 31, 2013 are as follows (in thousands):

| Year | |
|---|---|
| 2014 | $ 323 |
| 2015 | 315 |
| 2016 | 292 |
| 2017 | 173 |
| 2018 | |
| | $ 1,103 |

Rent expense is recorded straight-line over the operating lease term, with deferred rent included on the balance sheet as an other liability. Rent expense for the years ended December 31, 2013 and 2012, for the period from April 5, 2011 (inception) through December 31, 2011 and for the period from April 5, 2011 (inception) through December 31, 2013 amounted to $0.4 million, $0.2 million, $41 thousand and $0.6 million, respectively.

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**12. Accrued Expenses**

Accrued expenses consist of the following (in thousands):

| | December 31, 2013 | December 31, 2012 |
|---|---|---|
| Technology access fee payable to Intrexon (present value) | $ 2,186 | $ |
| Compensation and related benefits | 719 | 471 |
| Legal, audit and tax services | 605 | 330 |
| Preclinical, clinical and contract manufacturing | 258 | 93 |
| Consulting | 174 | 139 |
| Other expenses | 178 | 178 |
| | $ 4,120 | $ 1,211 |

**13. Net Loss Per Share**

The following table sets forth the computation of basic and diluted loss per share applicable to common stockholders (in thousands, except per share data):

| | Year Ended, December 31, 2013 | Year Ended, December 31, 2012 | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2013 |
|---|---|---|---|---|
| Net loss applicable to common stockholders | $ (29,044) | $ (13,510) | $ (2,725) | $ (45,279) |
| Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted | 16,160 | 5,810 | 909 | 8,350 |
| Net loss per share applicable to common stockholders basic and diluted | $ (1.80) | $ (2.33) | $ (3.00) | $ (5.42) |

The amounts in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect (in thousands):

| | Year Ended, December 31, 2013 | 2012 | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2013 |
|---|---|---|---|---|
| | | | (in thousands) | |
| Series A Preferred Stock | | | 3,065 | |
| Series B Preferred Stock | | | | |
| Outstanding stock options and restricted stock units | 2,509 | 1,410 | 618 | 2,509 |
| Founders' stock | 987 | 1,645 | 2,319 | 987 |
| Total | 3,496 | 3,055 | 6,002 | 3,496 |

Table of Contents

**OvaScience, Inc.**
**(A development stage company)**

**Notes to Consolidated Financial Statements (Continued)**

**14. Related Party Transactions**

The Company's chief executive officer, Michelle Dipp, M.D., Ph.D., has not historically received any cash compensation for her service as chief executive officer because of her service as a general partner of one of the Company's principal stockholders. Pursuant to the terms of an employment agreement that the Company entered into with Dr. Dipp, in December 2012 the Company granted Dr. Dipp an option to purchase 339,313 shares of its common stock and restricted stock units in the aggregate amount of 192,308 shares of its common stock (see Note 9). In addition, the Company may in the future determine to compensate Dr. Dipp with cash or other compensation.

As discussed in Note 11, during 2011 and a portion of 2012, the Company leased office space from one of its principal stockholders.

**15. Employee Benefit Plan**

In January 2012, the Company adopted a 401(k) retirement and savings plan (the "401(k) Plan") covering all employees. The 401(k) Plan allows employees to make pre-tax contributions up to the maximum allowable amount set by the Internal Revenue Service. Under the 401(k) Plan, the Company may make discretionary contributions as approved by the board of directors. During the years ended December 31, 2013 and 2012, and for the period from April 5, 2011 (Inception) through December 31, 2013, the Company made contributions to the 401(k) Plan of $0.1 million, $0.1 million, and $0.2 million, respectively. No contributions were made during 2011.

Table of Contents

**SUPPLEMENTARY INFORMATION**
**(Unaudited)**

The following sets forth certain unaudited consolidated quarterly statements of operations data for each of our last eight quarters. In our opinion, this quarterly information reflects all adjustments consistency only of normal recurring adjustments, necessary for a fair statement for the periods presented. Such quarterly results are not necessarily indicative of future results of operations and should be read in conjunction with audited consolidated financial statements and the notes thereto included elsewhere herein.

| | Three Months Ended | | | |
|---|---|---|---|---|
| | March 31, 2013 | June 30, 2013 | September 30, 2013 | December 31, 2013 |
| | (in thousands, except per share amounts) | | | |
| Total operating expenses(1)(2) | $ 5,175 | $ 6,021 | $ 6,925 | $ 11,013 |
| Loss from operations | (5,175) | (6,021) | (6,925) | (11,013) |
| Net loss | (5,157) | (5,996) | (6,891) | (11,000) |
| Accretion of convertible preferred stock to redemption value | | | | |
| Net loss applicable to common stockholders | $ (5,157) | $ (5,996) | $ (6,891) | $ (11,000) |
| Net loss per share applicable to common stockholders basic and diluted | $ (0.39) | $ (0.36) | $ (0.40) | $ (0.64) |
| Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted | 13,345 | 16,869 | 17,048 | 17,270 |

(1) During the third quarter of 2013, we recorded an impairment of certain laboratory equipment of approximately $0.4 million (see Note 6).

(2) During the fourth quarter of 2013, we recorded research and development expense of approximately $4.7 million related to a technology access fee to Intrexon (see Note 3).

| | Three Months Ended | | | |
|---|---|---|---|---|
| | March 31, 2012 | June 30, 2012 | September 30, 2012 | December 31, 2012 |
| | (in thousands, except per share amounts) | | | |
| Total operating expenses | $ 2,966 | $ 3,234 | $ 3,120 | $ 4,209 |
| Loss from operations | (2,966) | (3,234) | (3,120) | (4,209) |
| Net loss | (2,966) | (3,234) | (3,118) | (4,192) |

| | | | | |
|---|---|---|---|---|
| Accretion of convertible preferred stock to redemption value | | | | |
| Net loss applicable to common stockholders | $ (2,966) | $ (3,234) | $ (3,118) | $ (4,192) |
| Net loss per share applicable to common stockholders basic and diluted | $ (2.14) | $ (2.09) | $ (0.42) | $ (0.33) |
| Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted | 1,383 | 1,548 | 7,438 | 12,612 |

Table of Contents

**Exhibit Index**

| Exhibit No. | Exhibit |
|---|---|
| 3.1 | Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-35890) filed by the Registrant on April 30, 2013) |
| 3.2 | Second Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K (File No. 001-35890) filed by the Registrant on April 30, 2013) |
| 4.1 | Specimen Stock Certificate evidencing the shares of Common Stock (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 (File No. 333-183602) filed by the Registrant on August 29, 2012) |
| 4.2 | Amended and Restated Investors' Rights Agreement, dated March 29, 2012, by and among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 4.3 | Registration Rights Agreement, dated August 13, 2012, by and among the Company and the persons party thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K (File No. 000-54647) filed by the Registrant on August 14, 2012) |
| 10.1# | 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.2# | Forms of Incentive Stock Option Agreement under the 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on May 17, 2012) |
| 10.3# | Forms of Nonstatutory Stock Option Agreement under the 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on May 17, 2012) |
| 10.4# | Form of Restricted Stock Agreement under the 2011 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.5# | 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.6# | Form of Incentive Stock Option Agreement under the 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on May 17, 2012) |
| 10.7# | Form of Nonstatutory Stock Option Agreement under the 2012 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on May 17, 2012) |
| 10.8# | Form of Amended and Restated Restricted Stock Agreement between the Registrant and each of Michelle Dipp and Christoph Westphal (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.9# | Amended and Restated Restricted Stock Agreement between the Registrant, Richard Aldrich and the Richard H. Aldrich Irrevocable Trust of 2011, dated March 29, 2012 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |

Table of Contents

| Exhibit No. | Exhibit |
|---|---|
| 10.10 | Exclusive License Agreement, dated June 27, 2011, between the Registrant and The General Hospital Corporation (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.11 | Amendment No. 1 to the Exclusive License Agreement, dated September 7, 2011, between the Registrant and The General Hospital Corporation (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.12 * | Amendment No. 2 to the Exclusive License Agreement, dated July 30, 2013, between the Registrant and The General Hospital Corporation |
| 10.13* | Amendment No. 3 to the Exclusive License Agreement, dated September 9, 2013, between the Registrant and The General Hospital Corporation |
| 10.14 * | Amendment No. 4 to the Exclusive License Agreement, dated November 14, 2013, between the Registrant and The General Hospital Corporation |
| 10.15 * | Amendment No. 5 to the Exclusive License Agreement, dated December 18, 2013, between the Registrant and The General Hospital Corporation |
| 10.16 | Amended and Restated Voting Agreement, dated March 29, 2012, between the Registrant and the other parties thereto (incorporated by reference to Exhibit 10.15 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.17# | Letter Agreement, dated November 14, 2011, between the Registrant and Christopher Bleck (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.18# | Letter Agreement, dated July 2011, between the Registrant and Scott Chappel (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.19 | Form of Indemnification Agreement between the Registrant and each of Richard Aldrich, Michelle Dipp, Stephen Kraus and Christoph Westphal (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.20 | Form of Indemnification Agreement between the Registrant and each of Jeffrey Capello, Mary Fisher, Marc Kozin, Thomas Malley, Jonathan Tilly and Harald Stock (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on April 11, 2012) |
| 10.21 | Lease Agreement, dated May 1, 2012, between the Registrant and ARE-MA Region No. 38, LLC, as amended (incorporated by reference to Exhibit 10.23 to Amendment No. 1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the Registrant on May 17, 2012) |
| 10.22 | Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (File No. 000-54647) filed by the Registrant on August 14, 2012) |
| 10.23# | Letter Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp (incorporated by reference to Exhibit 10.24 to the Annual Report on Form 10-K (File No. 000-54647) filed by the Registrant on February 25, 2013) |
| 10.24*# | Letter Agreement, dated December 19, 2012, between the Registrant and Alison Lawton |

Table of Contents

| Exhibit No. | | Exhibit |
|---|---|---|
| 10.25# | | Restricted Stock Unit Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp (incorporated by reference to Exhibit 10.26 to the Annual Report on Form 10-K (File No. 000-54647) filed by the Registrant on February 25, 2013) |
| 10.26# | | Restricted Stock Unit Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp (incorporated by reference to Exhibit 10.27 to the Annual Report on Form 10-K (File No. 000-54647) filed by the Registrant on February 25, 2013) |
| 10.27 | | Securities Purchase Agreement, dated March 12, 2013, among the Registrant and the persons party thereto (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (File No. 000-54647) filed by the Registrant on March 14, 2013) |
| 10.28 | | Registration Rights Agreement, dated March 12, 2013, among the Registrant and the persons party thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K (File No. 000-54647) filed by the Registrant on March 14, 2013) |
| 10.29# | | Letter Agreement, dated July 15, 2013, between the Registrant and Arthur Tzianabos (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-35890) filed by the Registrant on November 13, 2013) |
| 10.30# | | Stock Option Agreement, dated September 10, 2013, between the Registrant and Arthur Tzianabos (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (File No. 001-35890) filed by the Registrant on November 13, 2013) |
| 10.31# | | Separation Agreement, dated July 2, 2013, between the Registrant and Scott Chappel (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q (File No. 001-35890) filed by the Registrant on November 13, 2013) |
| 10.32# | | Non-Employee Director Compensation Policy of the Registrant (effective January 1, 2014) (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q (File No. 001-35890) filed by the Registrant on November 13, 2013) |
| 10.33# | | Form of Amendment to Employment Letter Agreements for Alison Lawton and Christopher Bleck relating to the definition of "good reason" termination (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q (File No. 001-35890) filed by the Registrant on November 13, 2013) |
| 10.34 | * | Intellectual Property License Agreement, dated December 18, 2013, between the Registrant and OvaXon, LLC |
| 10.35 | * | Exclusive Channel Collaboration Agreement, dated December 18, 2013, between the Registrant and Intrexon Corporation and OvaXon, LLC |
| 10.36 | * | Exclusive Channel Collaboration Agreement, dated December 18, 2013, between Intrexon Corporation and OvaXon, LLC |
| 21.1* | | List of Subsidiaries of the Registrant |
| 23.1* | | Consent of Ernst & Young |
| 31.1* | | Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2* | | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32.1* | | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Chief Executive Officer |
| 32.2* | | Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Principal Financial Officer |
| 101.INS** | | XBRL Instance Document |

Table of Contents

| Exhibit No. | Exhibit |
|---|---|
| 101.SCH** | XBRL Taxonomy Extension Schema Document |
| 101.CAL** | XBRL Taxonomy Extension Calculation Linkbase Document |
| 101.DEF** | XBRL Taxonomy Extension Definition |
| 101.LAB** | XBRL Taxonomy Extension Label Linkbase Document |

Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.

#
Indicates a management contract or compensatory plan.

*
Filed herewith.

**
Submitted electronically herewith. In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Annual Report on Form 10-K is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.