OvaScience, Inc.
Form 10-K
February 25, 2013

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, 2012**

**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: 000-54647**

# 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**<br>**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: **None**

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

**Title of each class**
Common Stock, par value $0.001 per share

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

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 30, 2012: $9,013,186.

As of January 31, 2013, there were 14,268,068 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 2013 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, prospectus, plans and objections 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.

Table of Contents

## PART I

### Item 1. *Business.*

***Overview***

We are a life science company developing proprietary products to improve the treatment of female infertility based on recent scientific discoveries about the existence of 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 egg precursor cells within the ovaries of adult mice. Subsequent research by Dr. Tilly demonstrated that these egg precursor cells also exist in human ovaries and have the potential to mature into eggs and, therefore, to replenish a woman's egg supply. These discoveries put into question the long held belief that a woman is born with a finite number of eggs. This research also demonstrated that these egg precursor cells might provide a source of fresh cellular components, such as mitochondria, that could potentially be used to enhance the quality of existing eggs.

We hold an exclusive license from MGH to an issued patent and various patent applications directed to methods of identifying and purifying egg precursor cells, compositions comprising egg precursor cells and methods of using egg precursor cells to treat infertility and related disorders. We are working to develop product candidates based on these egg precursor cell discoveries, with the goal of improving the success of *in vitro* fertilization, or IVF. In an IVF procedure, a woman's own eggs, or the eggs of a donor, are fertilized outside of the woman's body and the resulting embryos are transferred back into the woman's uterus.

Dr. Tilly discovered the existence of mouse egg precursor cells by staining the outer cell layer of the ovary using an antibody that binds specifically to a protein found on egg precursor cells 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 egg precursor cells 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 egg precursor cells. Dr. Tilly also conducted an experiment in which human egg precursor cells 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 egg precursor cells were published in the March 2012 issue of *Nature Medicine*.

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

Our first product candidate is AUGMENT, which stands for autologous germline mitochondria energy transfer. We are designing AUGMENT to increase the success of IVF by isolating fresh mitochondria from a woman's own egg precursor cells and then adding the mitochondria into the woman's egg during IVF. Mitochondria are the structures within cells responsible for energy production. As a result of the passage of time and other factors, the eggs of women of advanced reproductive age often contain mitochondria that produce inadequate amounts of energy. We believe that by supplementing preexisting egg mitochondria with fresh mitochondria from egg precursor cells we will improve the likelihood that, after fertilization, the egg will develop into a viable embryo and thereby reduce the number of IVF cycles as well as the number of embryos transferred per cycle required to achieve a live birth. In late 2012, we initiated a study of AUGMENT in the United States

Table of Contents

in up to 40 women aged 38 to 42 who have failed two to five IVF cycles to assess both safety and effectiveness. We refer to this study as our AUGMENT Study. We have initiated commercial preparations for AUGMENT and, assuming the final results of the AUGMENT Study are positive, plan to begin generating revenues from AUGMENT in the second half of 2014. As initial data from the AUGMENT Study in humans in the United States becomes available, we will seek to commercialize AUGMENT in certain other markets in the second half of 2014. We currently expect we would commercialize AUGMENT on our own in select countries and consider potential partnerships for other countries. In support of our commercial strategy, we also plan to conduct a study of AUGMENT in humans outside of the United States beginning in the first half of 2014. We do not believe we will be required to seek premarket approval or clearance of AUGMENT from regulatory authorities in the United States or certain other countries.

Our second product candidate is OvaTure. We have preliminarily designed and plan to continue to optimize the design for our OvaTure program as a potential next generation of IVF. OvaTure involves the creation of mature fertilizable eggs from a woman's own egg precursor cells. If successful, this would allow women with compromised eggs due to age or other factors to undergo IVF using their own higher quality eggs. In addition, we believe OvaTure would reduce or eliminate the need for hormonal hyperstimulation for egg retrieval in the IVF process. Hormonal hyperstimulation is used in IVF to cause the maturation of multiple eggs. It is associated with significant side effects and is not appropriate for use by all women, for example, women with hormone-dependent cancers. We initiated preclinical development of OvaTure in 2012. We expect we will need to obtain regulatory approval of OvaTure in both the United States and the EU prior to commercialization.

We also plan to develop and acquire additional product offerings related to the treatment of female infertility. We are currently considering two opportunities:

development of IVF culture media, which is the solution used to provide nutrients for eggs and embryos in the IVF process, that can increase the activity of mitochondria; and

cryopreservation, or banking, of egg precursor cells for future fertility treatments.

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. 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.

***Background***

Infertility is a widespread problem in the United States and worldwide. 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. According to the 2005 *Fertility, Family Planning and Reproductive Health of U.S. Women Report* prepared by the CDC, approximately 7.3 million women in the United States aged 15 to 44 had used infertility services at some point in their lives. 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%.

Table of Contents

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 on the surface 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.

In the United States and elsewhere in the world, women are choosing to have children later in life. 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. Furthermore, 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. 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

Table of Contents

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 2011 involved IVF. 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 66% of all IVF procedures performed in the United States in 2011. 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 the CDC, the percentages of ART cycles performed in the United States in 2009 in these categories were as follows:

| Type of ART Cycle | % of Total ART Cycles |
|---|---|
| Fresh Nondonor | 70.1% |
| Frozen Nondonor | 17.8 |
| Fresh Donor | 7.5 |
| Frozen Donor | 4.6 |

Although ART success rates have increased modestly over the last decade, these rates remain relatively low. According to the CDC, of the 147,260 ART cycles performed in the United States in 2010, only 47,090, or 32%, resulted in live births. Couples seeking to preserve a genetic match must use nondonor egg and sperm for treatments. However, these patients generally have lower success rates than patients using donor eggs, which typically come from women in their 20s or early 30s. According to the CDC, in 2010, 100,824 fresh nondonor ART cycles were started in the United States, of which 37,191, or 37%, led to a pregnancy and 30,425, or 30%, resulted in a live birth. In contrast, the CDC found that in 2010, 56% 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.

Table of Contents

***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 *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.

Table of Contents

*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***

According to ESHRE, approximately 1.5 million ART cycles are performed each year worldwide. ESHRE estimates that, in 2009, over 537,000 ART cycles were performed in Europe. According to SART, approximately 154,000 IVF cycles were performed in the United States in 2011. Examples of other countries in which a large number of IVF cycles are performed include Japan, Australia and Brazil.

Despite the 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. According to SART, in the United States, there were approximately 113,000 ART cycles performed in 2003, as compared to the approximately 154,000 ART cycles performed in 2011. SART and CDC figures indicate that approximately 60% of ART cycles were performed in women aged 35 and older.

According to SART, fewer than 35,000 of the 154,000 total ART cycles performed in 2011 were thawed (not fresh) cycles. Of the fresh cycles where age information is available (all of which are nondonor), approximately 60% were performed in women aged 35 and older.

Marketdata Enterprises, Inc. reported in *Fertility Clinics & Infertility Services: An Industry Analysis* (2009) that the estimated gross revenues reported by IVF clinics in the United States were $1.7 billion in 2008, as compared to $250 million in 1990. Despite this growth, we believe IVF continues to be underutilized. According to the CDC, approximately 1.2 million women sought fertility treatment in the United States in 2002. However, we estimate that fewer than 100,000 women are treated with IVF annually.

Many third party payors, both in the EU and in the United States, 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. Thus, it is likely that IVF clinics and physicians will be able to use AUGMENT and other, future products and services of ours in the treatment of a patient only if the patient can afford and is willing to pay out of pocket.

***The OvaScience Solution***

Our solution is to build on the discovery of egg precursor cells by Dr. Tilly, one of our scientific founders, by using these cells as a source of fresh eggs or cellular components to provide treatments for infertility. We believe this approach provides the potential for significant advances in the field of infertility because it may enable us to address poor egg and embryo quality due to age and other causes. Most other treatments do not address this fundamental cause of infertility. As a first step, we are working to develop and commercialize innovative products to improve IVF, an area with limited

Table of Contents

innovative advances since its introduction in the late 1970s. We believe our technology, including our first two product candidates, AUGMENT and OvaTure, may improve IVF by:

*Increasing live birth rates and reducing the number of IVF cycles.* If we improve the quality of the egg used in the IVF process, we believe we may be able to increase the percentage of IVF treatments resulting in live births and, in so doing, reduce the number of IVF cycles required to achieve a successful birth.

*Reducing the incidence of multiple births.* If we provide higher quality eggs, we believe our egg precursor cell solutions may allow for the transfer of fewer embryos per IVF cycle and, as 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 treatments may also lower the overall costs associated with IVF.

*Reducing the need for hormonal hyperstimulation.* We are designing OvaTure to use egg precursor cells to generate mature fertilizable eggs *in vitro* that can be used in IVF. If successful, OvaTure might reduce or possibly eliminate the need for hormonal hyperstimulation for egg retrieval in the IVF process.

If we are successful in achieving these goals, we believe more women may choose to use IVF, which would increase the market for our products.

***Strategy***

Our goal is to become a leading female fertility company by bringing medical innovation to female infertility and commercializing products that we believe will increase pregnancy and live birth rates for women unable to conceive naturally. Key elements of our strategy are to:

*Commercialize AUGMENT ourselves in the United States.* We plan to commercialize AUGMENT ourselves in the United States. We have initiated commercial preparations for AUGMENT and, assuming the final results of the AUGMENT Study are positive, plan to begin generating revenues from AUGMENT in the second half of 2014. To launch AUGMENT in the United States, we plan to recruit a dedicated sales and marketing team sufficient for us to call on the approximately 100 clinics with the highest IVF volumes. These clinics are responsible for the majority of the IVF cycles performed in the United States annually.

*Expand AUGMENT to international markets.* As initial data from the AUGMENT Study in humans in the United States becomes available, we will seek to commercialize AUGMENT in certain other markets outside of the United States in the second half of 2014. We currently expect we would commercialize AUGMENT on our own in select countries and consider potential partnerships for other countries. In support of our commercial strategy, we also plan to conduct a study of AUGMENT in humans outside of the United States beginning in the first half of 2014.

*Advance development of OvaTure.* Our goal for OvaTure in 2013 is to continue conducting preclinical studies necessary to initiate a human proof of concept study.

*Develop and acquire additional infertility products.* Over time, our plan is to expand our product offerings for the treatment of female infertility using our egg precursor cell and other technologies. We are initially focusing on opportunities to develop innovative culture media for use in IVF procedures and to establish egg precursor cell banking capabilities.

Table of Contents

***Our Product Candidates***

Our key current product candidates are AUGMENT and OvaTure. We are also considering developing innovative culture media and establishing egg precursor cell banking capabilities.

***AUGMENT***

We are designing our first product candidate, AUGMENT, to treat infertility due to poor egg quality. AUGMENT will involve first isolating mitochondria from a woman's own egg precursor cells and then injecting the fresh mitochondria back into the woman's own egg with the sperm as part of ICSI. In late 2012, we initiated our AUGMENT Study in humans to determine AUGMENT's safety and effectiveness. We have initiated commercial preparations for AUGMENT and, assuming the final results of the AUGMENT Study are positive, plan to begin generating revenues from AUGMENT in the second half of 2014. We do not believe that human testing or commercialization of AUGMENT will require premarket approval of the U.S. Food and Drug Administration, or FDA, or the equivalent regulatory authorities in certain other countries.

**Initiated AUGMENT Study**

An institutional review board, or IRB, has approved the protocol for our AUGMENT Study and, as of February 1, 2013, we have initiated this study in two IVF clinics. The protocol for the study calls for the enrollment of up to 40 premenopausal female patients between the ages of 38 and 42 who have failed at least two but not more than five previous IVF attempts. The IVF clinic will take an ovarian biopsy from each patient, from which we will obtain mitochondria from the patient's own egg precursor cells. We will then add the patient's mitochondria to her own egg during the ICSI fertilization process.

The patients will be divided into four cohorts of 10 patients each. Following treatment of each cohort and through the duration of each patient's pregnancy, we plan to review the relevant safety and efficacy data of all patients who have been treated, including adverse events, miscarriages, premature births and congenital malformations, if any, as well as fertilization rates, progression to blastocyst, chemical pregnancy, gestational sacs, and live births. We will determine whether to adjust the amount of mitochondria given to the patients in subsequent cohorts. Depending on the pace at which we enroll the study, we expect to be able to analyze preliminary pregnancy rate data in late 2013. We expect to make our decision as to whether to proceed with commercialization activities for AUGMENT based on these preliminary data.

The primary objective of the study will be to evaluate the safety of AUGMENT in women undergoing IVF who have had a history of IVF failure. The secondary objectives of the study will be to evaluate egg and embryo quality, fertilization, implantation, pregnancy and live birth rates. The study will be open label and will not have a formal control arm. However, each IVF clinic that we expect to participate in the AUGMENT Study maintains its own database that tracks the clinic's success rates. As a result, we expect to be able to compare the data generated from the AUGMENT Study with the data from comparable patient populations who received IVF without AUGMENT at the clinics at which our marketing study is conducted. For this comparison, we plan to use site specific data from patients treated prior to our study as well as from patients who are treated during, but not as part of, our study. Based on a study by Stern *et al*. published in *Fertility and Sterility* (2010), which reported data on the average live birth rate for women in the United States aged 38 to 42 who failed two to three previous cycles, we expect this IVF clinic specific data for a patient population that is comparable to the women whom we enroll in our AUGMENT Study will show a live birth rate of approximately 13%.

Following completion of treatment of the 40 patients we plan to enroll in our AUGMENT Study, we expect to consider extending the study, or initiating a new study, to include additional sites and patients, such as women who are over 38 years of age but have not yet failed an IVF cycle or women who are under 38 years of age.

Table of Contents

**Scientific Rationale and Supporting Studies**

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 isolated from the woman's own egg precursor cells 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 ATP 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), third party researchers transfused cytoplasm from the eggs of younger women donors into the eggs of older women whose eggs were prone to abnormal development. 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.

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. Mitochondrial DNA is contained in cytoplasm and it is the mitochondria that is responsible for the production of energy in all cells of the body. Unlike nuclear DNA, 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 to improve her fertility instead of 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 only mitochondria appropriate 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 egg precursor cells to improve the quality of the patient's eggs. By using mitochondria from the woman's own egg precursor cells, instead of from a third party donor, AUGMENT does not involve the transfer of third party genetic material.

Table of Contents

**AUGMENT Steps**

We are designing AUGMENT to use mitochondria from a woman's own egg precursor cells in IVF procedures to improve the energy and quality of the woman's eggs. Although we are continuing to refine the steps that will comprise the AUGMENT process, the following is a summary of the process that we are using for purposes of our AUGMENT Study to isolate the patient's own mitochondria for insertion into one of her own mature eggs during IVF:

*Collection of ovarian tissue:* At least one month prior to the start of the ovarian hyperstimulation procedure to obtain mature eggs, the IVF clinic will surgically obtain up to three small pieces (approximately 3x3x1 mm each) of ovarian surface tissue from the patient. We will then register the tissue from the ovarian biopsy with a patient identification number and freeze the tissue.

*Purification of egg precursor cells:* We will then thaw and wash the tissue from the ovarian biopsy. We will use an enzyme to digest the connective tissue and form a solution containing single cells. We will mix the solution of single cells with an antibody that has a fluorescent label in order to identify the egg precursor cells. We will then purify the egg precursor cells from the other cells in the single cell solution by a process known as fluorescence activated cell sorting, or FACS. We will then freeze and store the egg precursor cells in vials until the day of egg fertilization in the IVF process.

*Isolation of mitochondria from egg precursor cells:* On the day of the IVF procedure, we will thaw the purified egg precursor cells and isolate the mitochondria by a standard centrifugation procedure. Using a commercially available quantification method, we will assess the number of mitochondria.

*Dilution of mitochondria in ICSI buffer:* After determining the number of mitochondria, we will dilute the mitochondria in ICSI fertilization buffer. We will then transport the diluted mitochondria to the IVF facility 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 egg precursor cells will be performed with commercially available antibodies and enzymes and a standard FACS instrument that uses well described fluorescence sorting techniques.

We are working on an ongoing basis to reduce the anticipated cost of the AUGMENT procedure. For example, we plan to enhance our process of mitochondrial isolation and to optimize the freezing of the purified mitochondria. Under our currently planned process, we will isolate the mitochondria on the day of ICSI. In the future, we plan to freeze the purified preparation of mitochondria, which would allow more flexibility in the process and facilitate our ability to scale up for commercial use. We have successfully conducted initial experiments to determine the feasibility of this improvement.

We have contracted with a third party facility that is compliant with the current good tissue practices, or cGTPs, adopted by the FDA to perform the AUGMENT process from the step of purifying the egg precursor cells to the step of diluting the mitochondria in ICSI fertilization buffer. In 2012, we transferred our AUGMENT process technology to this third party. In the future, we may establish our own cGTP-compliant facility and perform these steps in the process ourselves, with the goals of maintaining better control of the process and reducing the cost of manufacturing.

***OvaTure***

Our second product candidate is OvaTure. We have preliminarily designed and plan to continue to optimize the design for our OvaTure program, the goal of which will be to use a woman's own egg precursor cells to generate her own mature, fertilizable eggs *in vitro* that can be used in IVF. If successful, this would allow women who have poor quality eggs to undergo IVF using higher quality

Table of Contents

non-donor eggs. Poor quality eggs can result from age and other factors, including diabetes, cancer and cancer treatments, such as chemotherapy. In addition, because we would generate the egg from the woman's own egg precursor cells, as opposed to retrieving it from the woman's body during a controlled ovarian stimulation procedure, we believe OvaTure would reduce or eliminate the need for much of the hormonal manipulations typically required in IVF.

**Development Plan**

We anticipate that the first step in developing OvaTure will be to optimize the culture conditions used *in vitro* to mature egg precursor cells into primary eggs and subsequently into mature, fertilizable eggs by tailoring the culture conditions to match the changing physiological needs of eggs *in vivo*. There are a number of specific proteins and growth factors, as well as cell-to-cell interactions, known to be involved in the maturation of an egg. We plan to test these proteins and growth factors alone and in combination with ovarian cells to determine the composition and sequence of stimuli that are necessary to induce the development of egg precursor cells into mature eggs that are capable of being fertilized.

We also plan to continue conducting preclinical mouse studies to confirm prior studies, described below, in which mouse egg precursor cells were first matured into primary eggs with a normal number of chromosomes, then into mature eggs capable of being fertilized and then into fertilized embryos that resulted in live births. We plan to monitor fertilization rates, pregnancy rates, litter size, percentage of congenital malformations and possibly the reproductive ability of offspring. Following these mouse studies, we expect to initiate preclinical studies in which we mature human egg precursor cells *ex vivo*, or outside of the body, into fertilizable eggs using our defined culture conditions.

If these preclinical studies are successful, we plan to submit an IND to the FDA to conduct human clinical trials of OvaTure. The goal of these clinical trials would be to generate data to support the filing and approval of a biologics license application, or BLA, with the FDA.

**Scientific Rationale and Supporting Studies**

One of our scientific founders, Dr. Tilly, has conducted animal studies in which mouse egg precursor cells were matured first into primary eggs, then into fully mature eggs and then fertilized. The results of these studies were published in *Nature Medicine* in 2012.

Third party researchers have conducted similar experiments in which mouse egg precursor cells were marked by the insertion of a gene. These egg precursor cells were injected into ovaries, matured to become primary eggs and then became mature eggs. These mature eggs were fertilized by natural mating and developed into a stage of the embryo called a blastocyst, which is the stage at which the embryo normally implants into the uterus. These mouse embryos developed and became normal, healthy mice that contained the marker gene. These healthy offspring were then mated and produced healthy next-generation offspring.

In other experiments conducted by Dr. Tilly, human egg precursor cells were injected into biopsied human ovarian tissue that was then grafted beneath the skin of immune-deficient mice. These human egg precursor cells matured into eggs that exhibited a genetic signature indicating that they could be fertilized. The results of these experiments were also published in the 2012 *Nature Medicine* article.

***Other Product Opportunities***

One element of our strategy is to expand our product offerings for the treatment of infertility. The first two additional opportunities we are considering are improved IVF culture media and egg precursor cell banking.

Table of Contents

**IVF Culture Media**

Culture media is the solution that is used to provide nutrients for eggs and embryos during the IVF process. We are planning to develop proprietary mitochondrial activators that can be added to culture media to improve egg and embryo quality. We are currently analyzing various compounds that have the potential to improve mitochondrial activity. We plan to test these compounds alone and in combination as we seek to develop an innovative culture media to improve viability and development of eggs and early stage embryos. We believe such culture media likely will be regulated by the FDA as a medical device. However, because we are still in the planning stages, we do not yet know precisely what regulatory regimen the FDA will apply.

**Egg Precursor Cell Banking**

Another opportunity that we plan to explore is the creation of an egg precursor cell banking service, or cryopreservation bank, to allow patients to plan for their future fertility. These banks would be similar to existing egg banks, but would preserve egg precursor cells instead of eggs. For example, women of childbearing age who are diagnosed with cancer face a number of challenges preserving fertility following treatment. Chemotherapy or radiation to the pelvic area may result in early menopause or damage to eggs in the ovaries, which can lead to infertility or difficulty getting pregnant. By capturing a woman's healthy egg precursor cells and cryopreserving them for future use, we may be able to give a woman the opportunity for biological motherhood later in life using AUGMENT or OvaTure, even if her fertility is impaired as a result of cancer treatments.

***Manufacturing***

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, as we anticipate AUGMENT will be, are subject to the FDA's cGTP requirements. By contrast, HCT/Ps that are regulated as drugs or biologics, as we anticipate OvaTure will be, are subject not only to the FDA's cGTP requirements, but also to its current good manufacturing practices, or cGMPs.

We currently have no processing or manufacturing personnel or facilities. We are initially contracting with a third party cGTP-compliant facility to perform the purification, isolation and dilution steps in the AUGMENT process for purposes of our AUGMENT Study and plan to do so for at least our initial commercial activities. We also intend to initially contract with a third party cGTP and cGMP-compliant facility to manufacture OvaTure for use in our preclinical studies, clinical trials and ultimately commercial activities. However, in the future, we may build our own cGTP-compliant facility to carry out these steps in the AUGMENT process and to manufacture OvaTure and our other product candidates and products. We expect to follow a similar strategy in the EU, first relying on third party facilities and perhaps later building our own facility or facilities, to process and manufacture our product candidates and products. In other geographies, we expect to contract with third parties, through partnerships, out-licenses or other arrangements, to process and manufacture our product candidates and products.

In February 2012, we entered into a master services agreement with Agenus, Inc. or Agenus, a cGTP-compliant facility, to perform the purification, isolation and dilution steps in the AUGMENT process. Under the agreement, we have engaged Agenus to perform process services for our AUGMENT Study pursuant to individual work orders mutually agreed to by the parties. We will be billed for the services in accordance with the terms of the applicable work order. We will own all materials, inventions, developments, data and discoveries generated on our behalf in the course of Agenus' provision of services under the agreement and which directly relate to our AUGMENT technology.

Table of Contents

The term of the Agenus agreement continues until the last to expire work order, unless terminated earlier. We may terminate the agreement or services under a work order for reasons other than a material breach by Agenus upon 60 days' prior written notice to Agenus, or 90 days' if at the time of such notice Agenus is processing clinical materials for us. In addition, either party may terminate the agreement or services under a work order if the other party materially breaches the agreement and fails to cure such breach within a specified cure period, the other party enters into bankruptcy proceedings, the other party makes an assignment for the benefit of its creditors or the assets of the other party are placed in the hands of a trustee or receiver and the trust or receivership is not dissolved within 30 days. In 2012, we transferred our AUGMENT process technology to Agenus.

***Marketing and Sales***

We have not yet established a sales and marketing team. However, our chief commercial officer has significant past experience in the female fertility market. We intend to recruit an in house commercial organization in the United States focused on promoting AUGMENT and, if approved by the FDA, OvaTure. We plan to target our marketing and sales efforts on physicians, nurses and clinic administrators at the 100 IVF centers performing the highest number of IVF cycles. These clinics are responsible for the majority of the IVF cycles performed in the United States annually.

We believe certain countries outside the United States have IVF centers serving large numbers of patients and that it will be possible to use a direct sales force to access those centers for AUGMENT and OvaTure. In 2012 we began, and in 2013 we plan to continue, conducting a market analysis to assess commercializing AUGMENT in certain countries outside the United States. As initial data from the AUGMENT Study in humans in the United States becomes available, we will seek to commercialize AUGMENT in certain other markets outside the United States in the second half of 2014. We currently expect we would commercialize AUGMENT on our own in select countries and consider potential partnerships for other countries.

We also believe there is a market opportunity for AUGMENT and OvaTure in the major Asian countries, including Japan, Korea, Taiwan and China, and elsewhere in the world. If we decide to access these market opportunities, we plan to do so through collaborations with third parties.

If we pursue the culture media and egg precursor banking opportunities, we expect to commercialize these offerings through collaborators.

***Intellectual Property***

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.

Table of Contents

**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 December 31, 2012, we held an exclusive license under this agreement to one issued U.S. patent owned by MGH, six pending U.S. non-provisional patent applications owned by MGH, one pending European patent application owned by MGH, two pending Canadian patent applications owned by MGH, one pending PCT international patent application 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 one pending PCT international patent application co-owned by MGH and Harvard.

One family of patents and applications that we have licensed from MGH is directed to methods of isolating female germline stem cells, and various uses for the 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, which will expire in May 2025, and includes claims directed to isolated non-embryonic stem cells that express the protein markers characteristic of female germline stem cells. We believe that this patent provides protection for therapeutic compositions comprising egg precursor cells, which are referred to in the patent as female germline stem cells. 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 bone marrow. This family includes one pending U.S. application which, if issued as a patent, also would expire in May 2025. We believe that patents issuing from this family may provide protection for an alternative method of obtaining egg precursor cells.

A third 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 peripheral blood. This family includes one pending U.S. application, and a Canadian counterpart application, which, if issued as patents, also would expire in May 2025. We believe that patents issuing from this family may provide protection for an alternative method of obtaining egg precursor cells.

A fourth 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 three pending U.S. non-provisional patent applications, and one pending PCT international patent application. Any patents claiming priority to the underlying provisional application would expire in April 2032. We believe that patents issuing from this family will provide protection for several aspects of the AUGMENT procedure.

A fifth 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 one pending PCT international patent application. 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.

**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.

Table of Contents

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 an additional patent right owned by Harvard for which MGH has the right to grant us a license. Under the agreement, 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 and the license under the Harvard-owned patent right is for *ex-vivo* human female fertility treatments.

Under the agreement, we agreed to pay MGH upfront license fees and reimbursed patent related fees and costs incurred by MGH and Harvard totaling approximately $335,000 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 $10,520,000 are triggered upon the achievement of specified developmental and commercialization milestones and are not creditable against royalties. Additionally, we are required to pay MGH $1,000,000 in connection with either the first underwritten public offering of our securities or a change of control. The royalty rate is in the low single digits as a percentage of net sales. Net sales do not include amounts billed to fertility patients by fertility 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 fertility 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.

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

Table of Contents

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.

***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 products for the treatment of infertility. Some of these products, similar to AUGMENT and OvaTure, are designed to address the shortcomings of IVF.

We are not aware of any company or organization developing a specific product that would compete directly with AUGMENT.

We are aware of two companies that are currently developing products intended to identify high quality embryos for use in IVF. Novocellus Ltd. is developing an embryo viability test, using culture media, to aid in the selection of embryos used in IVF. Auxogyn, Inc. is developing 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 product candidates.

We are also aware of one company, Ovacyte LLC, which is seeking to develop a method for culturing epithelial cells from a woman's ovaries. Based on public disclosures by Ovacyte LLC, we do not believe that Ovacyte LLC has begun development of its technology. If successfully developed, however, this method has the potential to compete with OvaTure.

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 products 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 product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. 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, 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 product candidates. At this time, we cannot evaluate how our product candidates, if successfully developed and commercialized, would compare technologically, clinically or commercially to any other potential products being developed or to be marketed by competitors.

Table of Contents

***Government Regulation***

Government authorities in the United States at the federal, state and local level, and in other countries, extensively 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 product depends on, among other things, how regulators classify that product. We believe that some of our product candidates, such as OvaTure, likely will be regulated as drugs or biologics, while others, such as AUGMENT, likely will be regulated pursuant to special regulations applicable to certain lower risk HCT/Ps. Regulators may classify other of our product candidates, such as our innovative culture media, as medical devices.

**Requirements Applicable to Drugs and Biologics**

We believe that the FDA will regulate our OvaTure product candidate as a biological product. Other product candidates may be regulated as either new drugs or biological products. In the United States, the FDA regulates drugs and biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act, or PHSA, and implementing regulations. Section 505 of the FDCA prohibits the introduction of a new drug into interstate commerce without an FDA-approved application for marketing authorization under section 505. Applications under FDCA section 505 include the new drug application, or NDA, the abbreviated new drug application, or ANDA, and the "505(b)(2)" application. Section 351 of the PHSA imposes a similar requirement for premarket approval for biological products. Applications under PHSA section 351 include the BLA and the biosimilar application. As further described below, we also will be required to obtain premarket approval for drugs and biological products in Europe and other countries.

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require 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 drug or 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 an NDA or a BLA, as applicable;

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 NDA or BLA.

Table of Contents

Before testing new drugs or biologics in humans, the product must go through the preclinical testing phase. Preclinical tests include laboratory evaluations of the product's 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 product candidate 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 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.

Clinical testing of a new drug or biologic generally proceeds in three phases, though in some cases these phases may overlap or be combined:

*Phase 1.* Phase 1 includes the initial introduction of an investigational new drug or biologic in humans with the targeted disease or condition or healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance and other characteristics of the investigational product, and if possible, to gain initial evidence of efficacy. Phase 1 trials typically include 20 to 80 participants.

*Phase 2.* Phase 2 testing includes clinical trials designed to evaluate the effectiveness of the investigational product for a particular indication(s) in patients with the targeted disease or condition, to determine optimal dosage and to identify possible adverse side effects. Phase 2 clinical trials are typically conducted in a small patient population, usually involving no more than several hundred participants.

*Phase 3.* Phase 3 clinical trials are conducted in an expanded patient population and are typically conducted at geographically dispersed sites. They are intended to further evaluate dosage, clinical effectiveness and safety, as well as to establish the overall benefit to risk ratio of the product and to provide the primary basis for approval. Phase 3 clinical trials usually involve several hundred to several thousand participants.

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.

Table of Contents

***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 an NDA or BLA requesting approval to market the product. The submission of an NDA or BLA is typically subject to the payment of substantial user fees.

In addition, under the Pediatric Research Equity Act of 2003, which was reauthorized in 2012 under the Food and Drug Administration Safety and Innovation Act, an NDA or BLA must contain data to assess the safety and effectiveness of the drug or biologic for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. We will therefore need to seek an appropriate waiver from the FDA for any product candidate for which we submit an NDA or BLA.

The FDA reviews all NDAs and 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 a drug is safe and effective, or, for biologics, whether the 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 product. 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 FDA may refer an application to an Advisory Committee for a recommendation as to whether the application should be approved. An Advisory Committee is a panel of experts who provide advice and recommendations to the agency. The FDA is not required to follow an Advisory Committee's recommendations.

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 product candidates as drugs or biologics, certain provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, or the Biologics Price Competition and Innovation Act of 2009, respectively, likely would apply.

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.

Also under the Hatch-Waxman Act, drugs that are new chemicals entities, or NCEs, are eligible for a five year data exclusivity period. During this period, the FDA may not accept for review an ANDA or a 505(b)(2) application submitted by another company that relies on any of the data submitted by the

Table of Contents

innovator company. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The Hatch-Waxman Act also provides three years of data exclusivity for an NDA, 505(b)(2) application or NDA supplement that is not an NCE if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed essential to approval. During this period, the FDA will not approve an application filed by a third party for the protected conditions of use that relies on any of the data that was submitted by the pioneer. Neither exclusivity period blocks the approval of full applications submitted to the FDA that do not rely on the pioneer's data.

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 by the FDA 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. 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 a post-marketing, or Phase 4, study or trial 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 conjunction with our plan to expand our product 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.

Table of Contents

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 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.

**Requirements Applicable to HCT/Ps**

We believe that the FDA will regulate AUGMENT under a special regulatory regime for certain lower risk HCT/Ps. 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,

Table of Contents

(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 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 the FDA will regulate the HCT/Ps involved in the AUGMENT procedure as 361 HCT/Ps. This is because, in our view, both the mitochondria taken from egg precursor cells and the eggs into which those mitochondria are injected during IVF (1) are minimally manipulated, (2) are intended for homologous use only, (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 and inspection. Failure to comply with these regulations can result in substantial sanctions, including warning letters, product seizure, orders to stop manufacturing and other penalties.

The Tissue Reference Group, or TRG, is a body within the FDA that is 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. If, however, the FDA disagrees with the manufacturer's determination and concludes that the product 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. We have, however, been contacted by the FDA regarding the AUGMENT Study, and a number of other matters relating to AUGMENT, including whether it qualifies for regulation as a 361 HCT/P. We continue to believe that AUGMENT qualifies as a 361 HCT/P; however, the FDA could disagree with our conclusion.

***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

Table of Contents

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 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 product claims made in promoting a product 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

Table of Contents

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 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 or possibly other, future products or services 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 products or services. However, to the extent that our products or services 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.

If AUGMENT or possibly other, future products or services 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 products 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 or other, future products or services of ours. Nonetheless, to the extent that any of our future products are approved as drugs or biological products and we wish to retain the possibility of Medicaid coverage for those products, 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.

Table of Contents

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, effective March 2013. 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.

In order to distribute products 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 products 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.

**Foreign Regulatory Requirements**

Regulatory authorities around the world impose similar 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 burdensome than those imposed in the United States. For example, some products that might be regulated as 361 HCT/Ps in the United States, thereby

Table of Contents

exempting them from premarket approval, may require premarket review and approval as advanced therapy medicinal products if they are placed on the market in the EU.

The primary authorization procedure in the EU for medicinal products containing a new active substance is the centralized authorization procedure. The centralized procedure gives rise to marketing authorizations that are valid throughout the EU and, by extension, in Norway, Iceland and Liechtenstein, which, together with the EU member states, comprise the European Economic Area, or EEA. Applicants file marketing authorizations with the European Medicines Agency, or EMA, where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use, or CHMP. The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for a decision to grant a marketing authorization. The centralized procedure is compulsory for human medicines that (1) are derived from biotechnology processes, (2) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions, (3) are officially designated orphan medicines and (4) are advanced therapy medicinal products, including gene therapy products, somatic cell therapy products and tissue engineered products, which are cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to regenerate, repair or replace a human tissue. For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, as long as the CHMP agrees that the medicine concerned is a significant therapeutic, scientific, or technical innovation, or if its authorization would be in the interest of public health.

For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization to the national medicines regulators through one of three procedures:

*National procedure.* The purely national procedure is rarely used. It allows an applicant to apply for marketing authorization in a single EU member state, but only if the product has not already been authorized in another EU member state.

*Decentralized procedure.* Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU member state for medicinal products that have not yet been authorized in any EU member state and that do not fall within the mandatory scope of the centralized procedure. The applicant selects a reference member state, or RMS, to lead the review of the application. Other member states are expected to recognize the RMS decision, unless they identify a serious risk to public health. If the member states cannot resolve any such concerns themselves, the matter is referred to the CHMP for an opinion and, ultimately, a binding European Commission decision.

*Mutual recognition procedure.* The mutual recognition procedure must be used if the product has already been authorized in at least one other EU member state, whether through a purely national procedure or the decentralized procedure. In this procedure, a member state in which the product has already been authorized acts as the RMS, and further marketing authorizations may be sought from other EU member states in a procedure whereby the countries concerned agree to recognize the validity of the original RMS marketing authorization. As in the decentralized procedure, these concerned member states must recognize the RMS approval unless they identify a serious risk to the public health. There is also a possibility for a CHMP referral if the member states cannot reach a consensus.

As in the United States, securing a marketing authorization for a medicinal product such as a drug or biologic in the EU requires the submission of extensive preclinical and clinical data and supporting information, including information about the manufacturing process, to the relevant regulatory authority to establish the product candidate's safety, efficacy and quality.

Table of Contents

Products regulated as medical devices in the EU are not currently subject to premarket review and approval by regulatory authorities. Rather, a medical device may be placed on the market within the EEA if it conforms to certain essential requirements. The most fundamental essential requirement is that the medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. To assist manufacturers in satisfying the essential requirements, the European Commission has adopted harmonized standards applicable to medical devices. While not mandatory, compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

Manufacturers must demonstrate that their devices conform to the relevant essential requirements through a conformity assessment procedure. The nature of the assessment depends upon the classification of the device. The classification rules are mainly based on three criteria, which are: (1) the length of time the device is in contact with the body, (2) the degree of invasiveness and (3) the extent to which the device affects human anatomy. Medical devices in all but the lowest risk classification are also subject to a notified body conformity assessment. Notified bodies are often private entities that are authorized or licensed by government authorities to perform such assessments. Manufacturers usually have some flexibility to select conformity assessment procedures for a particular class of device and to reflect their circumstances, for example, the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature for the product and post-market experience in respect of similar products already marketed. Notified bodies also may review the manufacturer's quality systems. If satisfied that a product conforms to the relevant essential requirements, the notified body issues a certificate of conformity. Following successful completion of the conformity assessment procedure, the manufacturer may draw up a declaration of conformity and apply to the device the CE mark, which indicates that the product may be legally placed on the market. Once a medical device has been CE marked it may be marketed throughout the EEA.

In the EU, 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 advanced therapy 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 an advanced therapy 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 as in the United States, we believe that we will be able to commercialize AUGMENT without first applying for or receiving marketing authorization. By contrast, it is more likely that we will be required to submit an application under the centralized procedure for OvaTure and possibly our other, future product candidates.

While we believe EU marketing authorization is not required, national member state rules may require us to obtain certain permissions prior to the use of AUGMENT. Examples of such permissions include national rules relating to the provision of IVF services or medical care. For example, in the United Kingdom the Human Fertilisation and Embryology Act of 1990, as amended, prohibits IVF treatment involving the use of eggs in which the nuclear or mitochondrial DNA have been altered. Although we do not interpret this legislation to prohibit use of AUGMENT in the United Kingdom, we have not consulted with the Human Fertilisation and Embryology Authority, which could adopt a

Table of Contents

different interpretation and prevent IVF clinics from using AUGMENT. In addition, certain other countries outside the EU and United States may have regulations that require us to obtain permission prior to commercializing AUGMENT.

***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 or likely other, future products and services we may attempt to commercialize. Thus, it is likely that IVF clinics and physicians will be able to use AUGMENT and other, future products and services of ours in the treatment of a patient only if the patient can afford and is willing to pay for our product out of pocket. The cost of AUGMENT and other, future products and services of ours 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 product or procedure may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product or procedure. Even if third party payors were to provide some minimal level of coverage and reimbursement for AUGMENT and possibly other, future products and services, 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 and possibly other, future products and services, 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 products 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 or likely other, future products or services we may attempt to commercialize.

A third party payor's decision to provide coverage for a product 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 or other, future products or services. 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 or other, future products or services. 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 or other, future products or services that we may develop.

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 products 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 products 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 products 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 or likely other, future products or services we may attempt to commercialize.

Table of Contents

***Employees***

As of December 31, 2012, we had 15 full-time employees, including a total of seven 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.

**Executive Officers**

The following table sets forth certain information about our executive officers as of February 15, 2013.

| Name | Age | Position |
|---|---|---|
| Michelle Dipp, M.D., Ph.D. | 36 | President, Chief Executive Officer, Director |
| Christopher A. Bleck | 55 | Vice President and Chief Commercial Officer |
| Scott Chappel, Ph.D. | 62 | Vice President and Chief Scientific Officer |
| Alison K. Lawton | 51 | Chief Operating Officer |

***Michelle Dipp, M.D., Ph.D.*** co-founded the company in April 2011 and has served as a member of our board of directors since July 2011, as our chief executive officer since June 2011 and as our president since September 2011. Dr. Dipp has served as a partner of Longwood Fund, LP, a venture capital investment fund, since 2010. Through Longwood, she invested in Alnara Pharmaceuticals, Inc., a pharmaceutical company, and co-founded Verastem, Inc., a biopharmaceutical company. From 2008 to 2009, Dr. Dipp was vice president and then, from 2009 to 2011, the senior vice president and head of the Centre of Excellence For External Drug Discovery (CEEDD), a business development unit at GlaxoSmithKline, a pharmaceutical and healthcare company. Prior to that, she was a founding employee of Sirtris Pharmaceuticals, Inc., a pharmaceutical company, where she served as vice president of corporate development from 2005 to 2008. Dr. Dipp serves on the Beth Israel Deaconess Medical Center Board of Trustees. Dr. Dipp earned her M.D. from Oxford University Medical School and a Ph.D. in physiology from the University of Oxford. We believe that Dr. Dipp is qualified to serve on our board of directors due to her scientific expertise and her experience in the life sciences industry as an entrepreneur and venture capitalist.

***Christopher A. Bleck*** has served as our chief commercial officer since January 2013 and served as our chief operating officer from November 2011 to January 2013. Mr. Bleck served as president and chief executive officer of Incept BioSystems, a privately-held biomedical device company, from January 2009 until June 2011, as president and chief executive officer at Intact Medical Corporation, a medical device company, from January 2005 to December 2008, and as vice president of commercial operations for Cytyc Corporation, a healthcare company, from December 2001 to December 2004. Previously, Mr. Bleck served in various senior management roles for 18 years at Abbott Laboratories. Mr. Bleck earned his M.B.A. and his B.S. in pharmacy from The University of Connecticut.

***Scott Chappel, Ph.D.*** has served as our chief scientific officer since July 2011. Dr. Chappel served as chief scientific officer and chief operating officer of Tokai Pharmaceuticals, a biotechnology company, from 2005 until 2011. Prior to joining Tokai, Dr. Chappel was the chief scientific officer at Serono, Inc. and an executive at companies including Dyax Corp., Diacrin, Inc., and Integrated Genetics. Dr. Chappel received his Ph.D. in neurophysiology from the University of Maryland School of Medicine.

***Alison K. Lawton*** has served as our chief operating officer since January 2013. Prior to joining us, Ms. Lawton had been with Genzyme Corporation, a biopharmaceutical company that is now a subsidiary of Sanofi, also a biopharmaceutical company, for 21 years. Most recently she served as senior vice president and general manager of Sanofi Biosurgery (previously Genzyme Biosurgery Business Unit), a position she obtained in April 2010. From May 2008 to April 2010, Ms. Lawton served as senior vice president, Global Market Access at Genzyme, and from November 2005 to April 2008,

Table of Contents

Ms. Lawton served as senior vice president, Global Regulatory Affairs, Corporate Quality Systems and Global Policy Programs at Genzyme. Ms. Lawton spent seven years from 1984 to June 1991 at Warner-Lambert/Parke-Davis, a pharmaceutical company and subsidiary of Pfizer Inc. She serves on the board of Cubist Pharmaceuticals, Inc. and Verastem, Inc.

***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.

***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

*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 are an early stage company. We only 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 product candidates, planning for and initiating our AUGMENT Study in humans and determining the preclinical and clinical path for our other product candidates. We have not yet commenced commercial sale of any product 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 product commercialization. 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.

Table of Contents

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 product candidates 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 $13,510,000 and $2,624,000 for the year ended December 31, 2012 and for the period from April 5, 2011 (inception) to December 31, 2011, respectively. To date, we have not generated any revenues and have financed our operations through private placements of our Series A preferred stock, Series B preferred stock and common stock. We have devoted substantially all of our efforts to acquiring our technology and developing AUGMENT. We recently initiated our AUGMENT Study in humans but have not initiated preclinical or clinical development of any of our other product candidates. Although we have initiated commercial preparations for AUGMENT and, assuming the final results of our AUGMENT Study are positive, plan to begin generating revenues from AUGMENT in the second half of 2014, we may not be able to do so on our current timeline, or at all. In addition, we expect that it will be many years, if ever, before we have any other product candidate ready for commercialization.

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 substantially if and as we:

- enroll additional patients in our AUGMENT Study in humans;
- continue our research and preclinical development of OvaTure and other product candidates;
- initiate clinical trials of OvaTure and other product candidates;
- seek approval from the FDA and similar regulatory agencies outside of the United States for our product candidates that require such approval;
- establish a sales, marketing and distribution infrastructure to commercialize AUGMENT and any other product candidates we successfully develop;
- maintain, expand and protect our intellectual property portfolio;
- hire additional scientific, clinical, quality control and management personnel to support our product development and commercialization efforts;
- add operational and financial personnel to handle the public company reporting and other requirements to which we are subject;
- seek to identify additional product candidates that treat infertility; and
- develop, acquire or in-license other products and technologies.

To become and remain profitable, we must continue to develop and commercialize AUGMENT and develop and eventually commercialize other products with significant market potential. This will require us to be successful in a range of challenging activities, including successfully initiating and completing our AUGMENT Study in humans, marketing and selling AUGMENT, completing research, preclinical testing and clinical trials of other product candidates, obtaining marketing approval, if required, and manufacturing, marketing and selling those products

that we successfully develop. 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 have not yet completed the development or commenced commercialization of AUGMENT and are currently designing the development program for our other product candidate, OvaTure. If we do achieve profitability, we may not be able to sustain

Table of Contents

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

***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 product development programs or commercialization efforts.***

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue to enroll additional patients in our AUGMENT Study and increase commercial activities for this product candidate. We expect to incur significant expenses in connection with these activities for AUGMENT. Assuming we complete our AUGMENT Study on time and with favorable results, and we increase commercial activities on schedule at the scale we expect, we anticipate we will incur between $3.6 million and $4.6 million in expenses to complete the AUGMENT Study and commence commercial activity in the United States. These estimated expenses consist of costs associated with the AUGMENT Study, including study site and manufacturing costs, as well as costs associated with commencing commercialization, including marketing activity and marketing and sales personnel costs. These costs assume that the FDA will regulate AUGMENT as a 361 HCT/P, rather than as a new drug or biologic, and that testing AUGMENT in humans will therefore not require an IND. 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, these costs would increase substantially.

In addition, we expect to incur significant expenses with respect to our research and development of OvaTure and other product candidates. The clinical trials we will be required to conduct for these product candidates 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 product sales, we expect that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements at least through the end of 2013. Our future capital requirements will depend on many factors, including:

- the timing and results of our AUGMENT Study in humans;
- our ability to successfully commercialize AUGMENT;
- the costs and timing of commercialization activities for AUGMENT, including manufacturing, product sales, marketing and distribution;
- revenue, if any, received from commercial activities of AUGMENT or any other product candidate;
- the scope, progress, results and costs of research, preclinical development, and clinical trials for our product candidates;
- the regulatory process, including the premarketing and marketing approval requirements, to which some of our product candidates may be subject;
- the costs, timing and outcome of regulatory review of our product candidates that are subject to such review;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish collaborations and partnerships on favorable terms, if at all; and

the extent to which we develop, acquire or in-license other products and technologies.

Table of Contents

Identifying potential product candidates and conducting preclinical testing and clinical trials 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 product sales for our product candidates. We do not expect to derive commercial revenues, if any, from AUGMENT until the second half of 2014 at the earliest. We do not expect to derive commercial revenues, if any, from other products for many more years, if at all. Accordingly, 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 product candidates.***

Until the time, if ever, that we can generate substantial product revenues, 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 product candidates or grant licenses on terms that may not be favorable to us.

**Risks Related to Research, Development and Commercialization of Our Product Candidates**

***The science underlying our two principal product candidates, AUGMENT and OvaTure, is based on recent discoveries and has not been tested in humans. We may not be successful in our studies designed to test the safety and efficacy of AUGMENT. In addition, we may not be able to successfully develop OvaTure or other product candidates.***

AUGMENT and OvaTure are based on recent scientific discoveries relating to egg precursor cells and have not been tested in humans. As a result, our AUGMENT 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. We recently commenced our AUGMENT Study in humans to test the safety and efficacy of AUGMENT. Our ability to commercialize and generate revenues from sales of AUGMENT will depend in significant part on the findings of this study, including whether, and by how much, the use of AUGMENT increases the pregnancy and live birth rates of IVF and the safety of this product candidate. If the results of our AUGMENT Study are unfavorable, AUGMENT may not be viable or significant additional time and expense could be required before we are able to market this product candidate.

While one of our scientific founders has successfully conducted laboratory experiments in animals and experiments with human egg precursor cells that form the basis for some aspects of OvaTure, there are 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 egg precursor cells into fertilizable eggs. Although our scientific founder's research has demonstrated the existence of egg precursor cells in human ovaries, research with respect to egg precursor cells is a new and emerging field. As a result, there is ongoing debate regarding the role of egg precursor cells in human reproduction as well as the ability of egg precursor cells to mature

Table of Contents

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 egg precursor cells into fertilizable eggs, the need for additional innovation and the absence of information from human clinical trials all increase the risks associated with this product candidate. In any event, we believe that it will be costly and time consuming to develop OvaTure.

***If we are unable to complete our AUGMENT Study on our current timeline or if the findings are not favorable, we may postpone or halt our commercial activities. In addition, if we experience delays or difficulties in the enrollment of patients in our AUGMENT Study or future clinical trials for our other product candidates, our ability to commercialize products could be delayed or prevented.***

Human studies, like our AUGMENT Study, are expensive, difficult to design and implement and uncertain as to outcome. 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 study will depend, in part, on our ability to enroll the study on the timeline expected. Enrollment in the study 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. If enrollment of our AUGMENT Study is delayed, or findings are not favorable, we may postpone or halt our commercial activities, and we may need to expend more cash and other resources than we anticipate to develop AUGMENT. As a result, we might need to delay or abandon development of AUGMENT or our other product candidates. In addition, delays in the time to complete the AUGMENT Study in the United States may impact our ability to commercialize AUGMENT in countries outside the United States.

We may not be able to initiate or continue any future clinical trials for OvaTure or other product candidates 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 approved fertility treatments or to enroll in other clinical trials.

Patient enrollment is affected by other factors including:

- the novelty of the product candidate 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 product candidate under study;
- known side effects of the product candidate under study, if any;
- efforts of IVF clinics to facilitate enrollment in clinical trials;
- patient referral practices of physicians;
- the 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 our clinical trials 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 product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

37

Table of Contents

***Preclinical testing and clinical trials of OvaTure and any of our other product candidates that require such testing and trials may not be successful. If we are unable to commercialize our product candidates 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 product candidates that treat infertility. Our ability to generate product revenues will depend heavily on the successful development and eventual commercialization of our product candidates. Unlike AUGMENT, which we expect the FDA will regulate in the United States as a 361 HCT/P, we expect that the FDA will regulate OvaTure and many of our other product candidates 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 products 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 products 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 clinical trials of OvaTure and other such product candidates, we will need to submit an IND to the FDA based on preclinical, animal and other tests. Upon submitting such an IND, the FDA might determine that the risks involved in OvaTure or our other products 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 products rely on new and complex technology that impacts human reproductive systems. Therefore, both the FDA and IRBs may be especially cautious in reviewing and approving our clinical protocols for such products.

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

Table of Contents

- 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 product candidates 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 product development programs;

- the number of patients required for clinical trials of our product candidates 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 product candidates for various reasons, including discovery that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our product candidates may be greater than we anticipate; and

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

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

- be delayed in obtaining marketing approval for our product candidates;

- not obtain marketing approval at all;

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

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

- be subject to additional post-marketing testing requirements; or

- have the product 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 product 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 product candidates or allow our competitors to bring products to market before we do. Such events could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Even if clinical trials for our product candidates are completed as planned, the FDA may still conclude that the risks inherent in our product candidates 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 product not commercially viable.

Table of Contents

If we experience delays in obtaining, or if we fail to obtain, approval of OvaTure or other product candidates, 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 product candidates or with any procedures with which our product candidates are used, we may need to abandon or limit our development of those product candidates.***

None of our product candidates has been proven effective and safe in humans. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or, to the extent required, will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected with respect to the patient or the child conceived using our product or product candidates, 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 product candidates are used is determined to be unsafe, we may be required to delay or abandon our product development or commercialization. For example, we expect AUGMENT will be administered as part of the ICSI process. A recent study published in the *New England Journal of Medicine* found that treatment with ICSI was associated with increased rates of birth defects as compared to natural conception. To the extent physicians limit or abandon the use of ICSI or other procedures with which AUGMENT is used, whether as a result of this recent study or otherwise, we may need to delay or abandon our development or commercialization of AUGMENT.

***Even if we are able to commercialize any of our product candidates, 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 if any of our other product candidates 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 on current treatments, including fertility drugs and traditional IVF, which are well established in the medical community. In addition, the novel nature of AUGMENT and OvaTure may affect market acceptance by physicians and patients. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of AUGMENT and our other product candidates, if approved 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 and ease of administration as compared to alternative treatments;

adverse effects on patients or children conceived using our product candidates;

ability to improve the side effect profile of infertility treatment;

Table of Contents

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 or other product candidates, 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 products, which, in the case of AUGMENT, will be in addition to the price of a standard IVF procedure;

any negative publicity or political action related to our or similar products or IVF; and

the strength of marketing and distribution support.

In addition, our ability to successfully commercialize our products will depend on the continued use and acceptance of IVF, ICSI and fertility treatments generally. In a recent study published in the *New England Journal of Medicine*, treatment with ICSI was associated with an increased risk of birth defects, as compared with natural conception. To the extent these or other studies or findings lead the medical community or patient population to determine that these procedures are unsafe or are otherwise not generally accepted, the market for our products 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 product candidates we may not be successful in commercializing them.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of products for the treatment of infertility. To achieve commercial success for any product, we must either develop a sales and marketing team or outsource these functions to third parties. In anticipation of the commercial launch of AUGMENT in the United States, we plan to recruit a sales and marketing team. We also plan to recruit a sales and marketing team in each country outside the United States in which we determine to commercialize AUGMENT on our own, if any. In the future, we may choose to expand the sales force for AUGMENT or other product candidates.

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 product launch. If the commercial launch of AUGMENT or another product candidate 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 product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products 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 products effectively and in compliance with applicable laws.

Table of Contents

***We may not be successful in our efforts to identify or discover additional product candidates. If we do identify additional product candidates, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates 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 product candidates based on our egg precursor cell technology. We may be unable to identify any such product candidates. If we do identify additional candidates, we may not advance such candidates into clinical development for a number of reasons, including:

- 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 product candidates 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 product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates may not yield any commercially viable products. For example, the programs we are considering relating to culture media and egg precursor cell 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 product candidate, we may relinquish valuable rights to that product candidate 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 product candidate.

***We may not be successful in obtaining necessary rights to additional technologies or product candidates, 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 product candidates 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 product candidates 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 product candidates 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 product candidates 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 product candidate 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 product candidates on terms that would allow us to make an appropriate return on our investment.

Table of Contents

We expect competition for acquisition and in-licensing product candidates 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 product candidates 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 products 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 products that improve pregnancy and live birth rates and reduce risks and side effects, as compared to existing treatments. The ability of any products 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 product candidates. We are not aware of any company or organization developing a specific product that would compete directly with AUGMENT. There are a number of pharmaceutical companies, biotechnology companies, universities and research organizations actively engaged in research and development of products for the treatment of infertility. Some of these products, similar to AUGMENT and OvaTure, are designed to address the shortcomings of IVF. In particular, we are aware of two companies that are currently developing products intended to identify high quality embryos for use in IVF. Novocellus Ltd. is developing an embryo viability test, using culture media, to aid in the selection of embryos used in IVF. Auxogyn, Inc. is developing 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 product candidates. We are also aware of one company, Ovacyte LLC, which is seeking to develop a method for culturing epithelial cells from a woman's ovaries. Based on public disclosures by Ovacyte LLC, we do not believe that Ovacyte LLC has begun development of its technology. If successfully developed, however, this method has the potential to compete with OvaTure. At this time, we cannot evaluate how our products, 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 which establish market positions before the time, if any, at which we are able to bring products 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 safer, more effective or more effectively marketed and sold, than any treatment we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

Table of Contents

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

Our products are based on innovative science regarding eggs, embryos and fertilization. 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 product candidates. This may result in our incurring costs beyond what we anticipate in order to develop and commercialize our product candidates or may make it impossible to develop our product candidates 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 product candidates and, as a result, on our business.

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

We face an inherent risk of product liability exposure related to the testing of our product candidates in human studies and clinical trials and will face an even greater risk if we commercialize AUGMENT or any other products that we may develop. Product liability claims involving our activities may be made for significant amounts because our product candidates involve mothers and children. For example, it is possible that we will be subject to product liability claims that assert that our product candidates or products have caused birth defects in children or that assert 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 product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products 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 to trial participants or patients;
- loss of revenue;
- the diversion of management's resources; and
- the inability to commercialize any products that we may develop.

We obtained product liability insurance coverage when we initiated our AUGMENT Study. We will need to maintain product liability insurance coverage during our AUGMENT Study in humans and clinical trials for our other product candidates. 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 or other product candidates. 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.

Table of Contents

***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, including IVF clinics, fail to comply with these standards, our commercial prospects could be harmed because patients may prefer to use the services and products of companies that meet these voluntary standards. Similarly, physicians or IVF clinics may be less likely to endorse or use procedures or products that would violate 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 Product Candidates and Other Regulatory Matters**

***Our current business plan assumes that the FDA will regulate AUGMENT as a 361 HCT/P rather than as a new drug or biologic and, therefore, AUGMENT will not be subject to premarket review and approval. If the FDA disagrees with our interpretation of the applicable regulations, disagrees with our characterization of the AUGMENT procedure or changes its position with respect to such rules and regulations, we may not be able to commercialize AUGMENT on the timeline or with the resources we expect, if at all. We could also be forced to halt human studies, remove the product from the market or be subject to substantial fines or other civil or criminal sanctions.***

The FDA regulates 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 the FDA will regulate AUGMENT 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 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.

Table of Contents

We have not consulted the TRG. We have, however, been contacted by the FDA regarding the AUGMENT Study, and a number of other matters relating to AUGMENT, including whether it qualifies for regulation as a 361 HCT/P. We continue to believe that AUGMENT qualifies as a 361 HCT/P; however, the FDA could disagree with our conclusion.

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 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. 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 determines that AUGMENT is not a 361 HCT/P, regulates it as a new drug or biologic and, therefore, requires premarket review, we may be required to halt our AUGMENT Study or other uses of AUGMENT in humans and conduct a more time-consuming and expensive clinical trial program for this product candidate. We may also be required to submit an IND and an NDA or BLA to secure marketing authorization. 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. If, at the time the FDA determines that AUGMENT is not a 361 HCT/P, we are already marketing the product, we may be required to withdraw it from the market pending submission, review and FDA approval of a BLA or NDA. We cannot guarantee that we would ever be able to secure such approval. We could also be subject to a warning letter, substantial fines and other civil or criminal penalties. As a result, our business could be materially harmed.

***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 could substantially impair our ability to generate revenue.***

Although as a 361 HCT/P we may 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. Through our AUGMENT Study in humans and other endeavors, we intend to generate such adequate substantiation for any claims we make about

Table of Contents

the AUGMENT procedure. If, however, after we commence marketing of AUGMENT, the FTC or one or more states conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties or may be forced to alter 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 the HCT/P is not intended for homologous use, the FDA might consider the product to be a new drug or biologic. We will therefore be limited in the promotional claims that we could make about AUGMENT.

***We may not be able to continue our AUGMENT Study as planned.***

We believe that the FDA will regulate AUGMENT as a 361 HCT/P and, therefore, will not require an IND for our AUGMENT Study in humans. However, the FDA could disagree with our conclusion and require us to submit an IND. Moreover, even if our study does not require an IND, it will still be subject to various requirements designed to protect the safety of study participants. For example, we have received IRB approval and monitoring of our AUGMENT Study. The IRB could, however, require us to alter our program. Such changes could materially impact the time and costs required to complete the program.

***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.

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

To market any products 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 product candidates. 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 product candidates. 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 products, which will have a negative effect on our ability to generate and grow revenues.

Table of Contents

***Failure to obtain required marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.***

In order to market and sell our products in the EU and many other jurisdictions, 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 may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally is subject to all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We or these third parties 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, for example, our products 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 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 product candidate'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. Products regulated as medical devices in the EU are not subject to premarket review and approval by regulatory authorities. However, before placing the product on the market in the EU the manufacturer must demonstrate that the product 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 the AUGMENT procedure 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 product 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 the European Commission or other regulatory authority 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 product candidate 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. For example, in the United

Table of Contents

Kingdom the Human Fertilisation and Embryology Act of 1990, as amended, prohibits IVF treatment involving the use of eggs in which the nuclear or mitochondrial DNA have been altered. While we do not interpret this legislation to prohibit use of AUGMENT in the United Kingdom, there is a risk that the Human Fertilisation and Embryology Authority could adopt a different interpretation and prevent IVF clinics from using AUGMENT. In addition, certain other countries outside the EU and United States may have regulations that require us to obtain permission prior to commercializing AUGMENT.

***Even if we obtain marketing approval 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 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.

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

Even if the FDA allows AUGMENT or any other product candidate 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 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 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 products that we develop, as well as enforcement actions.

Moreover, even if the FDA allows AUGMENT or any other product candidate to be marketed without premarket approval, the FDA could still seek to withdraw the product from the market for a variety of reasons, including if the agency develops concerns regarding the safety or efficacy of the product or the product's manufacturing process.

Table of Contents

***OvaTure and any other product candidates 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 product candidate for which we obtain marketing approval or clearance will be subject to continuing regulation by the FDA and other regulatory authorities. For example, such products 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 product candidate is granted, the approval or clearance may be subject to limitations on the uses for which the product 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 product. The FDA closely regulates 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 imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market our products 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 products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

restrictions on the labeling or marketing of a product;

restrictions on product distribution or use;

requirements to conduct post-marketing clinical trials;

warning or untitled letters from the FDA;

withdrawal of the products from the market;

refusal to approve pending applications or supplements to approved applications;

recall of products;

fines, restitution or disgorgement of profits or revenue;

suspension or withdrawal of marketing approvals;

refusal to permit the import or export of our products;

product seizure;

injunctions; or

the imposition of civil or criminal penalties.

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

Many third party payors, both in the United States and the EU, 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 the EU, will reimburse for AUGMENT or

Table of Contents

likely our other future products and services. Thus, it is likely that IVF clinics and physicians will be able to use AUGMENT and our other products and services in the treatment of a patient only if the patient can afford and is willing to pay out-of-pocket. The cost of AUGMENT and our other future products and services may be beyond the means of many patients. This may limit the size of the market for AUGMENT or our future products and services and, thereby, limit our future revenues.

Even in those limited situations in which government or private payors may cover AUGMENT or other, future products 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 products or services;

further limiting products and services covered;

challenging whether products or services are medically necessary;

taking measures to limit utilization of products and services;

negotiating prospective or discounted contract pricing;

adopting capitation strategies; and

seeking competitive bids.

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 products 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 products and services covered by such programs or the reimbursement rates paid directly or indirectly for such products and services. Such changes could further limit our ability to sell our products, 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 products 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 new 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 all of the risks associated with reimbursement in the United States, including the risk that it is unlikely that third party payors will cover or reimburse AUGMENT or other, future products 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

Table of Contents

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 and our future products 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 and other future products 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 products.

***Several states have enacted legislation that may hamper the ability of IVF clinics and physicians to pass through the cost of our products to patients or third party payors.***

Several states, including California and New York, 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 available to physicians who contract out the technical component of certain laboratory and pathology procedures.

To the extent that AUGMENT or possibly other, future products or services are treated as laboratory or pathology services for purposes of reimbursement, these laws may make it difficult for us to market those products 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 products. Any additional legislation or regulation in this area could also adversely affect our ability to market our products.

***Even though we anticipate very limited third party coverage and reimbursement for AUGMENT and our future products and services, our future arrangements with third party payors and IVF clinics and physicians may be subject to 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 and possibly other, future products 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 and possibly other, future products 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

Table of Contents

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 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 products or medical devices, 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.

Table of Contents

***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 and possibly other, future products 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 94/46/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.

***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

Table of Contents

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 Product Candidates**

***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 product candidates for preclinical testing, clinical trials and commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products 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 have any processing or manufacturing facilities or personnel. In February 2012, we entered into a master services agreement with a third party, Agenus, to provide services for the manufacture of AUGMENT. This agreement requires only that Agenus provide AUGMENT manufacturing services pursuant to mutually agreed purchase orders. As a result, the agreement can effectively be terminated by Agenus following completion of any agreed upon purchase order and, therefore, may not provide us with a continuous or long-term source for AUGMENT. While we believe that Agenus 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. We do not have internal or external capabilities to manufacture AUGMENT or OvaTure or any other product candidate.

Reliance on third party manufacturers and laboratories, such as Agenus, 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
- 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 product candidates 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, including Agenus, 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 product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business and results of operations.

Table of Contents

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. If Agenus, our current contract manufacturer, cannot perform as agreed, we may be required to replace Agenus. Although we believe that there are other potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

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

We do not currently have a manufacturer for AUGMENT outside of the United States. If Agenus is unable to supply AUGMENT for countries outside the United States, we will need to contract with third party manufacturers that comply with cGTP regulations to supply AUGMENT in EU countries and other jurisdictions in which we decide to commercialize AUGMENT, if any. Although we believe there are other manufacturers who could manufacture our product candidates 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 jurisdictions outside the United States requires coordination internally among our employees and externally with physicians, IVF clinics, regulatory authorities 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 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 product. If we are unable to coordinate appropriately, we may encounter delays, incur additional costs or adversely affect our ability to commercialize AUGMENT.

***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 are at an early stage in developing 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 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, 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 in the United States. 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 in the United States. 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

Table of Contents

be costly and time consuming to recruit necessary additional personnel for the operation of the facility. We do not 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 product to meet our expected AUGMENT Study 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 product, including:

- difficulties in the timely shipping of patient-specific materials to us or in the shipping of our product candidates 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 product candidates 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 product candidates during storage at our facilities;
- failure to maintain precise patient records to ensure the chain of custody, meaning the patient ovarian tissue biopsy creates the mitochondria sample that is delivered back to the IVF clinic and used in the same patient;
- destruction of, or damage to, patient-specific materials or our product candidates stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians; and
- failure to ensure adequate quality control and assurances in the AUGMENT process as we increase production quantities.

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, such as those imposed under the CLIA. Some or all of these risks may also be applicable to OvaTure and any other future product candidates.

Table of Contents

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

***We rely on a third party to conduct our AUGMENT Study and intend to rely on third parties to conduct our clinical trials for other product candidates. Such third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.***

We are relying on a third party clinical research organization to conduct our AUGMENT Study and intend to rely on third parties, such as clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct clinical trials for our other product candidates. Our reliance on these third parties for clinical development activities will reduce our control over these activities.

We will remain responsible for ensuring that our AUGMENT Study and each of our future clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA will require us to comply with cGTPs with respect to any clinical trials conducted in connection with a submission to the FDA, including an IND, 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.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. 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.

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

We currently intend to commercialize AUGMENT ourselves in the United States and certain EU member states and to collaborate with third parties to commercialize AUGMENT and any future product candidates in other international markets. In addition, we may seek partners for further development and commercialization of our other product candidates. These collaborations could take the form of license, distribution, sales representative, joint venture, sponsored research or other arrangements with pharmaceutical and biotechnology companies, other commercial entities and academic and other institutions.

If we do enter into 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 product candidates. Collaboration agreements may not lead to development or commercialization of product candidates 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 product candidates 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 product candidates than we expect them to;

Table of Contents

a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of our product or products;

collaborators may not pursue development and commercialization of our product candidates 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 or abandon a product candidate or repeat or conduct new clinical trials;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our 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 product candidates 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 product candidates.

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

Our product development programs and the potential commercialization of our product candidates 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 product candidates. For example, we currently intend to seek to collaborate with third parties to commercialize AUGMENT and other product candidates 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 product candidate, the potential market for such product candidate, the costs and complexities of manufacturing and delivering the product candidate to patients, the potential and relative cost of competing products, uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications 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 product candidate. 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 and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

Table of Contents

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 or 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 product candidates or bring these product candidates to market and generate product 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. Our existing MGH license agreement imposes, and we expect that future license agreements will impose, various obligations on us, including diligence, milestone payments, 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 products 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 products that are covered by these agreements, or to convert our licenses to non-exclusive licenses, which could materially adversely affect the value of the products 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 products. 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 products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products 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 products. We and our licensors have sought to protect our proprietary position by filing patent applications related to our novel technologies and products 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 products that we seek. If we and our licensors are unable to obtain and maintain patent protection of sufficient scope for our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and in that case our ability to successfully commercialize our technology and products 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 or patent applications.

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 products. 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

Table of Contents

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 products.

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 products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. 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.

Assuming the other requirements for patentability are met, currently in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is generally entitled to the patent. Under the America Invents Act enacted in September 2011, the United States is moving to a first inventor to file system in March 2013. 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 products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

***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 commercialize technology and products 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 products 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 products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, certain of the U.S. patents 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 products similar or identical to ours.

Table of Contents

***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.

***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 product candidates 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 products 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 products 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 product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated 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

Table of Contents

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.

***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 product candidates, 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 and our other potential product candidates, which will involve significant unpatented know-how. 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, Ms. Lawton, our chief operating officer, Mr. Bleck, our chief commercial officer, and Dr. Chappel, our chief scientific 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, Ms. Lawton, Mr. Bleck and Dr. Chappel 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.

Table of Contents

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 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 development, regulatory 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 significant growth in the number of our employees and the scope of our operations, particularly in the areas of research and development, regulatory affairs 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.

**Risks Associated with Our Capital Stock**

***Because we are quoted on the OTC Bulletin Board and the OTC Market Group's OTC Link quotation system, our investors may experience significant volatility in the market price of our stock and have difficulty selling their shares.***

The OTC Bulletin Board and the OTC Market Group's OTC Link quotation system are regulated quotation services that display real-time quotes, last sale prices and volume limitations in over-the-counter securities. Trading in shares quoted on the OTC Bulletin Board and the OTC Market Group's OTC Link quotation system is often thin and characterized by wide fluctuations in trading prices, due to many factors that may have little to do with our operations or business prospects. As a result, there may be volatility in the market price of our common stock for reasons unrelated to operating performance. Moreover, the OTC Bulletin Board and the OTC Market Group's OTC Link quotation system are not stock exchanges, and trading of securities on them is often more sporadic than the trading of securities listed on the NASDAQ Stock Market or another securities exchange. Accordingly, stockholders may have difficulty reselling any of their shares.

***We may not be successful in our plans to have our common stock listed on a national securities exchange.***

We plan to seek to list our common stock on the NASDAQ Stock Market or another national securities exchange. However, we may not be successful in doing so and cannot assure you that our common stock will be listed on a national securities exchange. Even though our common stock is quoted for sale on an over-the-counter quotation system, an investor may find it more difficult to dispose of shares or obtain accurate quotations as to the market value of our common stock than would be the case if and when our common stock is listed on the NASDAQ Stock Market or another national securities exchange. We do not currently meet the initial listing standards of any national securities exchange. We cannot assure you that we will be able to meet the initial listing standards of

Table of Contents

any national securities exchange, or, if we do meet such initial listing standards, that we will be able to maintain any such listing.

***Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.***

Because we did not become a reporting company by conducting an underwritten initial public offering, or IPO, of our common stock, and because we are not listed on a national securities exchange, security analysts of brokerage firms may not provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we were to become a public reporting company by means of an IPO because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

***Our common stock may become subject to the penny stock rules of the SEC, which may make it difficult for broker-dealers to complete customer transactions and could adversely affect trading activity in our securities.***

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our common stock may be less than $5.00 per share for some period of time and therefore would be a "penny stock" according to SEC rules, unless we are listed on a national securities exchange. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser's prior written agreement to the transaction;
- provide the purchaser with risk disclosure documents which identify certain risks associated with investing in "penny stocks" and which describe the market for these "penny stocks" as well as a purchaser's legal remedies; and
- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a "penny stock" can be completed.

If required to comply with these rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected.

***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 initiate or complete the AUGMENT Study in humans or adverse results from such study;
- results of preclinical testing or clinical trials of our product candidates or those of our competitors;

Table of Contents

- the cost of our development programs;
- the success of competitive products or technologies;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals, new product introductions and commercial results;
- the recruitment or departure of key personnel;
- developments concerning our licensors or manufacturers;
- the results of our efforts to discover, acquire or in-license additional product candidates or products;
- litigation and other developments relating to our issued patents or patent applications or other proprietary rights or those of our competitors;
- disagreement by the FDA or other regulatory agencies regarding the regulatory pathway applicable to AUGMENT;
- 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 January 31, 2013, we had outstanding 14,268,068 shares of common stock. Of these, 7,606,483 shares may be immediately sold pursuant to the registration statement on Form S-1 we filed on August 29, 2012, or Resale S-1, and 36,334 shares may be sold pursuant to Rule 144.

6,599,687 outstanding shares are restricted as a result of lock-up agreements. These 6,599,687 shares will become free from restriction and eligible for sale under Rule 144 as follows:

25,300 shares, subject to applicable volume limitations, on the earlier of:

(1) the date on which our common stock commences trading on a national securities exchange; and

(2) August 13, 2013;

Table of Contents

3,064,753 shares, subject to applicable volume limitations, on the earlier of:

(1) 180 days following the date on which our common stock commences trading on a national securities exchange; and

(2) March 29, 2014;

3,509,634 shares, subject to applicable volume limitations and rights of repurchase (which expire over time), on the earlier of:

(1) 270 days following the date on which our common stock commences trading on a national securities exchange; and

(2) March 29, 2015.

We have also filed a Form S-8 registration statement 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.

***Certain of our stockholders have rights that could limit our ability to undertake corporate transactions and inhibit changes of control.***

We are party to an amended and restated voting agreement with certain of our stockholders, holding in the aggregate approximately 67% of our outstanding common stock as of January 31, 2013, which we refer to as our voting agreement. The parties to our voting agreement include certain of our founders, directors, executive officers and 5% stockholders and their affiliates. Pursuant to the voting agreement, the parties have agreed, until such time as our common stock is traded on a national securities exchange, to vote their shares in such a way as to ensure that a designee of each of our three lead investors will serve on the board for so long as the entity remains a significant investor. Our three lead investors are the entities affiliated with Bessemer Venture Partners, General Catalyst and Longwood Fund, LP. The board member designated by General Catalyst resigned on February 21, 2013, and as of February 25, 2013, General Catalyst has not designated a replacement.

Until our common stock is listed on a national securities exchange, without the approval of our board, including at least two directors designated by our lead investors, we cannot:

make loans or guarantees;

make certain investments;

enter into related party transactions;

hire, fire or change the compensation of executive officers; or

sell or encumber our material intellectual property.

As a result of the rights our lead investors have, we may not be able to undertake certain corporate transactions, including equity or debt offerings necessary to raise sufficient capital to run our business, change of control transactions or other transactions that may otherwise be beneficial to our businesses. If a trading market for our common stock were to be established, the market price of our common stock could be adversely affected by the rights of our lead investors. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions

Table of Contents

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.

***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.

***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 83% of our outstanding capital stock as of January 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;

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 charter or by-laws.

Table of Contents

In addition, our certificate of incorporation and by-laws that will become effective at the time our common stock commences trading on a national securities exchange require that stockholder actions must be effected at a duly called stockholders meeting and prohibit actions by our stockholders by written consent.

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.

***We are an "emerging growth company," and may elect to comply with 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. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various public company reporting requirements. 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 will incur 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, on which we plan to seek to list our common stock for trading, 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 will need to devote a substantial amount of time to these compliance

Table of Contents

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 will be required to furnish a report by our management on our internal control over financial reporting, including, once we cease to be an emerging growth company, 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 will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. 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. Despite our efforts, there is a risk that neither we nor, when required, our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

None.

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

We currently occupy approximately 6,000 square feet of office and laboratory space in Cambridge, Massachusetts under a lease that expires in August 2017. 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***

None.

**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 was approved for quotation on the OTC Bulletin Board and the OTC Market Group's OTC Link quotation system 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 closing prices and the high and low bid information of our common stock as reported by the OTC Bulletin Board:

| | High Closing Price | Low Closing Price | High Bid Price | Low Bid Price |
|---|---|---|---|---|
| Fourth Quarter 2012 (beginning November 14, 2012) | $ 10.00 | $ 7.50 | $ 9.75 | $ 7.00 |

These over-the-counter market quotations 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 22, 2013, the closing price of a share of our common stock, as reported by the OTC Bulletin Board, was $8.99.

**Holders**

As of January 31, 2013, there were 14,268,068 shares of common stock outstanding, which were held by approximately 283 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.

**Securities Authorized for Issuance under Equity Compensation Plans**

The following table sets forth information regarding our equity compensation plans as of December 31, 2012. There are no equity compensation plans that have not been approved by our security holders.

| Plan Category | Number of securities to be issued upon exercise of outstanding options, warrants and rights | Weighted average exercise price of outstanding options, units, warrants and rights ($) | Number of securities remaining available for future issuance under equity compensation plans |
|---|---|---|---|
| Equity compensation plans approved by security holders | 1,410,461 | 3.30 | 712,374 |

**Recent Sales of Unregistered Securities**

Set forth below is information regarding shares of common stock and Series B preferred stock issued, and options granted, by us between January 1, 2012 and December 31, 2012 that were not registered under the Securities Act. Also included is the consideration, if any, received by us, for such shares and options and information relating to the section of the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

Table of Contents

(1) In February 2012, we granted stock options under our 2011 Stock Incentive Plan, or 2011 Plan, to purchase an aggregate of 73,155 shares of our common stock (net of cancellations) to our employees, at an exercise price of $4.01 per share. In May 2012, we granted additional stock options under our 2011 Plan to purchase an aggregate of 81,022 shares of our common stock (net of cancellations) to our employees, at an exercise price of $4.39 per share. As of December 31, 2012, 5,792 options have been exercised and 108,376 options have been forfeited.

(2) In March 2012, we issued and sold an aggregate of 6,770,563 shares of Series B preferred stock to investors for an aggregate purchase price of $37,238,096. Leerink Swann LLC acted as placement agent for purposes of the sale of our Series B preferred stock. Entities and individuals affiliated with Leerink Swann LLC purchased an aggregate of 25,456 shares of our Series B preferred stock in the financing on the same terms as the other investors. Our Series B preferred stock converted into common stock on a one-for-one basis on August 13, 2012.

(3) In August 2012, we issued and sold an aggregate of 897,554 shares of our common stock to investors for an aggregate purchase price of $4,936,547. Leerink Swann LLC and ROTH Capital Partners, LLC acted as placement agents for purposes of such private placement of common stock. Entities and individuals affiliated with Leerink Swann LLC and ROTH Capital Partners, LLC purchased an aggregate of 6,454 and 846 shares, respectively, of our common stock in the private placement on the same terms as the other investors.

No underwriters were involved in the foregoing issuances of securities.

The offers, sales and issuances of the securities described in paragraph (1) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, officers, bona fide consultants and advisors and received the securities under our 2011 Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales and issuances of the securities described in paragraph (2) and (3) 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.

**Purchase of Equity Securities**

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

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

As a smaller reporting company, we are not required to provide the information required by this item.

Table of Contents

**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**

We are a life science company developing proprietary products to improve the treatment of female infertility based on recent scientific discoveries about the existence of egg precursor cells. In 2004, one of our scientific founders, Jonathan Tilly, Ph.D., discovered the existence of egg precursor cells within the ovaries of adult mice. Subsequent research by Dr. Tilly demonstrated that these egg precursor cells also exist in human ovaries and have the potential to mature into eggs and, therefore, to replenish a woman's egg supply. These discoveries put into question the long held belief that a woman is born with a finite number of eggs. Dr. Tilly's research also demonstrated that these egg precursor cells might provide a source of fresh cellular components, such as mitochondria, that could potentially be used to enhance existing eggs.

Dr. Tilly performed his research at MGH. We hold an exclusive license from MGH to an issued patent and various patent applications directed to methods of identifying and purifying egg precursor cells, compositions comprising egg precursor cells and methods of using egg precursor cells to treat infertility and related disorders. We are working to develop product candidates based on these egg precursor cell discoveries, with the goal of improving the success of IVF. In an IVF procedure, a woman's own eggs, or the eggs of a donor, are fertilized outside of the woman's body and the resulting embryos are transferred back into the woman's uterus.

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

**Our Product Candidates**

***Augment***

Our first product candidate is AUGMENT, which stands for autologous germline mitochondria energy transfer. We are designing AUGMENT to increase the success of IVF by isolating fresh mitochondria from a woman's own egg precursor cells and then adding the mitochondria into the woman's egg during IVF. Mitochondria are the structures within cells responsible for energy production. As a result of the passage of time and other factors, the eggs of women of advanced reproductive age often contain mitochondria that produce inadequate amounts of energy. We believe that by supplementing preexisting egg mitochondria with fresh mitochondria from egg precursor cells we will improve the likelihood that, after fertilization, the egg will develop into a viable embryo and thereby reduce the number of IVF cycles as well as the number of embryos transferred per cycle required to achieve a live birth. In late 2012, we initiated our AUGMENT Study in up to 40 women aged 38 to 42 who have failed two to five IVF cycles to assess both safety and effectiveness. We have initiated commercial preparations for AUGMENT and, assuming the final results of the AUGMENT Study are positive, plan to begin generating revenues from AUGMENT in the second half of 2014. As

Table of Contents

initial data from the AUGMENT Study in humans in the United States becomes available, we will seek to commercialize AUGMENT in certain other markets in the second half of 2014. We currently expect we would commercialize AUGMENT on our own in select countries and consider potential partnerships for other countries. In support of our commercial strategy, we also plan to conduct a study of AUGMENT in humans outside of the United States beginning in the first half of 2014. We do not believe we will be required to seek premarket approval or clearance of AUGMENT from regulatory authorities in the United States or certain other countries. Thus, our current financial and business plans assume that we will not need to seek or obtain pre-marketing approvals for AUGMENT.

***OvaTure***

Our second product candidate is OvaTure. We have preliminarily designed and plan to continue to optimize the design for our OvaTure program as a potential next generation of IVF. OvaTure involves the creation of mature fertilizable eggs from a woman's own egg precursor cells. If successful, this would allow women with compromised eggs due to age or other factors to undergo IVF using their own higher quality eggs. In addition, we believe OvaTure would reduce or eliminate the need for hormonal hyperstimulation for egg retrieval in the IVF process. Hormonal hyperstimulation is used in IVF to cause the maturation of multiple eggs. It is associated with significant side effects and is not appropriate for use by all women, for example, women with hormone-dependent cancers. We initiated preclinical development of OvaTure in 2012. We expect we will need to obtain regulatory approval of OvaTure in both the United States and the EU prior to commercialization.

***Other Product Opportunities***

We also plan to develop and may acquire additional product offerings related to the treatment of female infertility. We are currently considering two opportunities:

development of IVF culture media, which is the solution used to provide nutrients for eggs and embryos in the IVF process, that can increase the activity of mitochondria; and

cryopreservation, or banking, of egg precursor cells for future fertility treatments.

**Financial Operations Overview**

***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 and our other product candidates.

***Research and Development Expenses***

Research and development expenses consist of costs associated with our research activities, discovery efforts and the development of our product candidates. Our 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, manufacturing organizations and consultants, including our scientific advisory board;

license fees; and

facilities, laboratory supplies and other allocated expenses.

Table of Contents

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 allocate employee-related expenses or facilities to any particular project. Because all of our development projects are in early stage development, we do not track research and development costs by project. The components of our research and development costs are described in more detail in " Results of Operations."

We anticipate that our research and development expenses will increase significantly in future periods as we increase the scope and rate of our research efforts and begin costlier development activities, including our AUGMENT Study in humans and clinical trials for our other product candidates in the future.

Our first product candidate is AUGMENT. We are designing AUGMENT as a procedure to increase the success of IVF by isolating fresh mitochondria from a woman's own egg precursor cells and then injecting the fresh mitochondria back into the woman's own egg during IVF. We believe that by adding fresh mitochondria from the egg precursor cells we will improve the likelihood that after fertilization the egg will develop into a viable embryo. We recently initiated our AUGMENT Study in humans to determine AUGMENT's safety and effectiveness in up to 40 women aged 38 to 42 who have failed two to five IVF cycles. We have also initiated commercial preparations for AUGMENT.

Our second product candidate is OvaTure. We are currently designing our OvaTure program, the goal of which will be to use egg precursor cells to generate mature, fertilizable eggs *in vitro* that can be used in IVF. If successful, this would allow women who have poor quality existing eggs to undergo IVF using higher quality nondonor eggs. In addition, because we would generate the egg from the woman's own egg precursor cells, as opposed to retrieving it from the woman's body during a controlled ovarian stimulation procedure, we believe OvaTure would reduce or eliminate the need for much of the hormonal manipulation typically required in IVF. We initiated preclinical development of OvaTure in 2012. OvaTure will require regulatory approval in both the United States and the EU prior to commercialization.

We also plan to develop and may acquire additional product offerings to treat infertility. We are currently considering two opportunities:

- the development of IVF culture media, which is the solution used to provide nutrients to eggs and embryos in the IVF process, that can increase the activity of mitochondria; and
- the cryopreservation, or banking, of egg precursor cells for future fertility use.

The successful development of our product candidates 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 product candidates or the period, if any, in which material net cash inflows from our product candidates may commence. This is due to the numerous risks and uncertainties associated with developing products, 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 product candidates as compared to traditional IVF or other therapies;
- our ability to market, commercialize and achieve market acceptance for AUGMENT or any of our other product candidates that we are developing or may develop in the future;

Table of Contents

results of our AUGMENT Study and any future clinical trials;

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 product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA were to regulate AUGMENT as a new drug or biologic or require us to conduct clinical trials beyond those which we currently anticipate will be required for the completion of the development of a product candidate or if we experience significant delays in enrollment in our AUGMENT Study or any future clinical trial, we could be required to expend significant additional financial resources and time on the completion of the product development.

***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 and business development functions. Other general and administrative expenses include allocated facility costs, patent costs, including amounts paid to MGH as reimbursement for patent costs incurred by MGH, and professional fees for legal, investor and public relations, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in future periods to support increases in our research and development activities and as a result of increased headcount, expanded infrastructure, increased legal, compliance, accounting and investor and public relations expenses associated with being a public company and increased insurance premiums, among other factors.

***Interest Income***

From inception until March 2012, our cash was invested in non-interest-bearing accounts. Beginning in March 2012, the proceeds from our Series B preferred stock financing and our private placement of common stock were invested in cash in bank deposits, money market accounts and corporate debt securities where we earned $19,000 in interest through December 31, 2012.

**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 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.

Table of Contents

***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.

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 expand our headcount, 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. 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. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Since our common stock is quoted on the OTC Bulletin Board and the OTC Market Group's OTC Link quotation system and the market price of our shares may be subject to volatility for reasons unrelated to operating performance, we utilized data from a representative group of public companies to estimate expected stock price volatility. We selected companies from the life sciences industry with similar characteristics to us, including stage of product development and life science industry focus. As a result of being a development stage company in a very early stage of product development with no revenues, the representative group of companies have certain similar, but not all similar, characteristics to us. We believe the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of us. We used the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to

Table of Contents

calculate the expected term of stock option grants to employees as we do not have sufficient historical data about stock option exercises to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilized a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life.

Stock-based compensation expense associated with stock options granted to employees and consultants and restricted stock grants awarded to employees and non-employees totaled $346,000 for the period April 5, 2011 (inception) to December 31, 2011, and totaled $1,380,000 for the year ended December 31, 2012. As of December 31, 2012, we had $7,118,000 of total unrecognized stock-based compensation related to unvested stock options and restricted stock, net of related forfeiture estimates, which we expect to recognize over a remaining weighted average vesting period of approximately 2.9 years.

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. Due to the lack of historical forfeiture activity with respect to our equity awards and a review of data from the representative group of companies with similar characteristics to us, we estimated our forfeiture rate to be 5% for employee grants and zero for our non-employee awards. We will continue to evaluate our estimated forfeiture rate at the end of each reporting period.

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.

The following table sets forth information with respect to stock options we have granted to employees, advisors and consultants from April 5, 2011 (inception) through December 31, 2012.

| | Number of shares underlying options granted | Exercise price per share | Estimated fair value per common share at grant date | Retrospective common stock fair value per share on grant date(1) |
|---|---|---|---|---|
| September 29, 2011 | 472,801 | $ 0.04 | $ 0.04 | $ 0.85 |
| December 7, 2011 | 144,832 | $ 0.04 | $ 0.04 | $ 2.31 |
| December 31, 2011 | | | | $ 3.54 |
| February 8, 2012 | 68,707 | $ 4.01 | $ 4.01 | (2) |
| February 22, 2012 | 4,448 | $ 4.01 | $ 4.01 | (2) |
| March 31, 2012 | | | $ 4.39 | (2) |
| May 4, 2012 | 81,022 | $ 4.39 | $ 4.39 | (2) |
| June 27, 2012 | 13,098 | $ 5.40 | $ 5.40 | (2) |
| September 7, 2012 | 141,000 | $ 5.48 | $ 5.48 | (2) |
| October 24, 2012 | 13,098 | $ 5.50 | $ 5.50 | (2) |
| December 5, 2012 | 397,563 | $ 7.80 | $ 7.80 | (3) |

(1) The fair value of common stock at the grant date was adjusted in connection with our retrospective fair value assessment for financial reporting purposes, as described below.

Table of Contents

(2) The fair value of common stock at the grant date was determined using a contemporaneous assessment.

(3) The fair value of common stock 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.

The following table sets forth information with respect to restricted stock units we have granted to employees, advisors and consultants from April 5, 2011 (inception) through December 31, 2012.

| | Number of shares underlying options granted | Exercise price per share | Estimated fair value per common share at grant date | Retrospective common stock fair value per share on grant date |
|---|---|---|---|---|
| December 5, 2012 | 192,308 | $ 0.0010 | $ 7.80 | (1) |

(1) The fair value of common stock 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.

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 product candidates;
- 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.

We were incorporated in April 2011. In July 2011, we sold 6,200,000 shares of Series A preferred stock to accredited and institutional investors at $1.00 per share for aggregate net proceeds of $6,099,000. Management performed a contemporaneous valuation as of July 31, 2011 in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of*

*Privately-Held-Company Equity Securities Issued as Compensation*, or the Practice Aid. Based on the valuation methodology selection criteria set forth in the Practice Aid, with a focus on the early stage of our development as a company, including the early stage status of our development efforts, very limited operations and the fact that we had an incomplete management team, we determined that an asset-based approach was the most appropriate method to use to determine the enterprise value of our company. We then allocated the enterprise value using the current value method. We concluded that this was the most appropriate method since we did not have any

Table of Contents

projections as of the valuation date due to the early stage of our research and development and, as such, an income approach would not have provided a reliable fair value determination. In addition, as a result of the lack of comparative information available for publicly traded or privately held start-up enterprises, and because any investments in shares of stock are unlikely to be a reliable indicator of fair value at such an early stage, we concluded that the market approach would also not provide a reliable fair value determination as of this date. The results of this valuation methodology were consistent with our expectations, as we would not have expected any significant value to have been created for the common stockholders. Based upon this valuation, our board determined the fair value of our common stock was $0.04 per share as of July 31, 2011.

On September 29, 2011, we issued stock options for the purchase of an aggregate of 472,801 shares of common stock with an exercise price of $0.04 per share and our board of directors approved and we later issued 19,772 shares of restricted common stock with a purchase price of $0.002 per share.

On December 7, 2011, we issued stock options for the purchase of an aggregate of 144,832 shares of common stock with an exercise price of $0.04 per share.

On December 14, 2011, we received IRB approval to enroll patients in our AUGMENT Study at IVF clinics without additional animal or human data.

Subsequent to December 14, 2011, we discussed with financial advisors the possibility of a Series B preferred stock financing. During the discussions concerning a possible Series B preferred stock financing, the financial advisors introduced the possibility of undertaking the filing of a Form 10 registration statement to become a public company and subsequently seeking to have our shares of common stock listed on a national securities exchange. We believed that the principal advantage of filing the Form 10 registration statement was that it would enable some public company investors to participate in our Series B preferred stock financing. In late December 2011, we engaged a lead placement agent to assist us with the Series B preferred stock financing, with the plan of then filing our registration statement on Form 10, which we refer to as the Form 10, and becoming a public reporting company and later seeking to have our common stock quoted on the OTC Bulletin Board and applying to have our shares listed on the NASDAQ Stock Market or another stock exchange.

As a result, and in connection with the filing of the Form 10 and the preparation of our audited financial statements for the period from April 5, 2011 (inception) to December 31, 2011, management performed retrospective valuations for each of the common stock option grant dates of September 29, 2011 and December 7, 2011 and the restricted stock vesting date of December 31, 2011. Management also performed contemporaneous valuations for the option grant date of February 8, 2012 and the restricted stock vesting date of March 31, 2012.

For the stock option grant date of September 29, 2011, we retrospectively updated our common stock valuation, which resulted in a fair value of $0.85 per share. This was an increase from the previous fair value of our common stock of $0.04, as determined by our board of directors, with input from management, in July 2011. The increase in value from July 2011 was primarily due to the following factors:

- we formed our scientific advisory board with leaders from the female infertility field;
- we amended our MGH license to include media patents for potential additional products; and
- we developed and our board approved an initial business plan.

Table of Contents

We performed the retrospective valuation of our common stock as of September 29, 2011 in accordance with the framework of the Practice Aid. Based on the valuation methodology selection criteria set forth in the Practice Aid and the stage of our development as a company as of September 29, 2011, we determined that the reverse backsolve method was the most appropriate valuation methodology to estimate the fair value of our common stock. Key variables in the option pricing method were as follows:

Underlying equity value To estimate the value of our total equity, including both common and preferred equity, we relied upon our Series A preferred stock financing price of $1.00 per share, or $2.023 per share on a common stock equivalent basis as a result of the reverse stock split of our common stock that was effected on March 28, 2012, which we believed to be the most indicative of our value. This valuation technique used to estimate the enterprise value of our company is referred to as the reverse backsolve method. According to the 2004 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, in an option pricing method framework, the reverse backsolve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the time to liquidity, volatility and risk free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid. We applied the reverse backsolve method utilizing the Black-Scholes option pricing model to solve for the value of the company's total equity. This results in a price for the Series A preferred stock of $1.00 per share, which is consistent with the price paid by the Series A preferred stock investors. This approach takes into account the economic rights of the various classes of stock such as liquidation preferences, conversion rights and dividend rights and then allocates the value accordingly to the rights and privileges of each class of stock. Because the Series A Preferred stock financing was led by unrelated investors and was an arms length transaction, we determined it was the most appropriate method to determine the fair value of our common stock given the early stage nature of the company.

Volatility We estimated volatility based on the representative group of publicly traded companies over a three year period. We performed a sensitivity analysis and determined a 30% change in the volatility rate would be immaterial to the calculation of stock-based compensation.

Time to liquidity We estimated time to a liquidity event based on the projected time to significant development events for our product candidates, including results from our AUGMENT Study in humans, that we believed could lead to a sale of our company. The estimated time to a liquidity event of three years assumed a sale transaction.

Risk-free interest rate We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a liquidity event for our stockholders.

Discounts for lack of marketability Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black- Scholes option pricing model. We also considered that our preferred stock had rights that our common stock did not have, including anti-dilution protection, liquidation preferences, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing. Our preferred stockholders had control and influence over the enterprise, which provided them with the optionality over future liquidity, financing and other decisions that the common stock option holders did not control.

Table of Contents

For the stock option grant date of December 7, 2011, we retrospectively updated our common stock valuation, which resulted in a fair value of $2.31 per share. This was an increase of $1.46 per share, or 172%, from our previous retrospective fair market valuation of our common stock of $0.85 per share, as of September 29, 2011. The increase in value from September 29, 2011 was primarily due to the following factors:

- we refined our development and commercial strategy; and
- we hired a chief operating officer with a commercial background in female infertility.

As of December 7, 2011, we concluded that a liquidity event was possible within three years. It was not until after December 14, 2011, the date on which we received notification from the IRB about our ability to commence our AUGMENT Study without additional animal or human data, that our financial advisors introduced the possibility of undertaking the filing of a Form 10 registration statement to become a public company, and on December 7, 2011 we believed that a sale was more likely to occur than an IPO or public trading. We calculated valuations using both liquidity event assumptions and weighted the results to estimate the fair value of our common stock. We applied an 85% weighting to a sale scenario and a 15% weighting to the public trading scenario.

In the public trading scenario, we assumed all of our outstanding shares of preferred stock would convert into common stock and the present value of the future projected enterprise value was based on the value of the anticipated Series B preferred stock financing. There was no discount for lack of marketability applied to the public trading scenario. The estimated time to complete the public trading scenario was approximately nine months.

For the sale scenario, we utilized the option pricing method and key assumptions were as follows:

Underlying equity value  To estimate the value of our total equity, including both common and preferred equity, we relied upon our anticipated Series B preferred stock financing which we believed to be the most indicative of our value. The financing closed on March 29, 2012 and was led by a previously unrelated investor.

Volatility  We estimated volatility based on the representative group of publicly traded companies with a term consistent with the timeline to the liquidity event. We performed a sensitivity analysis and have determined a 30% change in the volatility rate would be immaterial to the calculation of stock-based compensation.

Time to liquidity  We estimated a weighted average time to a sale event of 2.73 years based on the projected time to significant development events, including the results from our AUGMENT Study in humans, for our product candidates.

Risk-free interest rate  We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a sale event for our stockholders.

Discounts for lack of marketability  Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black- Scholes option pricing model. We also considered that our preferred stock had rights that our common stock did not have, including anti-dilution protection, liquidation preferences, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing. Our preferred stockholders had control and

Table of Contents

influence over the enterprise, which provided them with the optionality over future liquidity, financing and other decisions that the common stock option holders did not control.

For the stock option grant date of December 31, 2011, we retrospectively updated our common stock valuation, which resulted in a fair value of our common stock of $3.54 per share. This was an increase from the previous fair value of $1.23 per share, or 53%, from the previous retrospective fair market valuation of $2.31 per share, as of December 7, 2011. The increase from December 7, 2011 was due primarily to the following factors:

- on December 14, 2011, we received IRB approval to enroll patients in our AUGMENT Study at IVF clinics without additional animal or human data;
- the IRB approval supported our timeline of increasing commercial activities for AUGMENT in late 2013;
- we believed there was strong investor interest in a Series B preferred stock financing, specifically from investors that typically invest in public companies; and
- we formally engaged an investment bank on December 29, 2011 to lead a Series B preferred stock financing and began to plan for the filing of the Form 10.

As of December 31, 2011, we concluded that a liquidity event was possible within three years. We also believed that public trading of our common stock was slightly more likely to occur than a sale. We calculated valuations using both liquidity event assumptions and weighted the results to estimate the fair value of our common stock. We applied a 60% weighting to the public trading scenario and a 40% weighting to the sale scenario. The change in probability in the public trading scenario from 15% to 60% was due to the significance of having received IRB approval on December 14, 2011 to enroll patients without additional animal or human data, the increased likelihood of increasing commercial activities in late 2013 and the increased likelihood of public trading of our common stock based on discussions with our financial advisors after December 14, 2011.

In the public trading scenario, we assumed all of our outstanding shares of preferred stock would convert into common stock and the present value of the future projected enterprise value was based on the value of the anticipated Series B preferred stock financing. There was no discount for lack of marketability applied to the public trading scenario. The estimated time to complete the public trading scenario was approximately eight months.

For the sale scenario, we utilized the option pricing method and key assumptions were as follows:

- Underlying equity value  To estimate the value of our total equity, including both common and preferred equity, we relied upon the anticipated transaction of the Series B preferred stock financing with the third party investors which we believed to be the most indicative of our value. The financing closed on March 29, 2012 and was led by a previously unrelated investor.
- Volatility  We estimated volatility based on the representative group of publicly traded companies over with a term consistent with the timeline to the liquidity event. We performed a sensitivity analysis and determined a 30% change in the volatility rate would be immaterial to the calculation of stock-based compensation.
- Time to liquidity  We estimated a weighted average time to a sale event of 2.67 years based on the projected time to significant development events, including the results from our AUGMENT Study in humans, for our product candidates.
- Risk-free interest rate  We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a sale event for our stockholders.

Table of Contents

Discounts for lack of marketability Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black- Scholes option pricing model. We also considered that our preferred stock had rights that our common stock did not have, including anti-dilution protection, liquidation preferences, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing. Our preferred stockholders had control and influence over the enterprise, which provided them with the optionality over future liquidity, financing and other decisions that the common stock option holders did not control.

On February 8, 2012 and February 22, 2012, we issued stock options for the purchase of an aggregate of 68,707 and 4,448 shares of common stock, respectively, with an exercise price of $4.01 per share.

For the period from February 8, 2012 to March 28, 2012, our board of directors contemporaneously determined the fair value of our common stock to be $4.01 per share. This was an increase of $0.47 per share, or 13%, from our previous retrospective fair market valuation of $3.54 per share, as of December 31, 2011. The increase from December 31, 2011 was primarily due to the following factors:

the announcement that the journal *Nature Medicine* would publish in March 2012 Dr. Tilly's research results demonstrating that ovaries of reproductive age women possess egg precursor cells that can mature into eggs;

scientific work confirmed for the first time the binding of an antibody to egg precursor cells; and

a lead investor was identified for a Series B preferred stock financing.

Management performed a contemporaneous valuation as of February 8, 2012, and concluded that a liquidity event was possible within three years. We also believed that public trading of our common stock was more likely to occur than a sale. We calculated valuations using both liquidity event assumptions and weighted the results to estimate the fair value of our common stock. We applied a 75% weighting to the public trading scenario and a 25% weighting to the sale scenario. The increase in the probability for the public trading scenario was a result of the progress made in the Series B preferred stock financing.

In the public trading scenario, we assumed all of our outstanding shares of preferred stock would convert into common stock and the present value of the future projected enterprise value was based on the value of the anticipated Series B preferred stock financing. There was no discount for lack of marketability applied to the public trading scenario. The estimated time to complete the public trading scenario was approximately seven months.

For the sale scenario, we utilized the option pricing method and key assumptions were as follows:

Underlying equity value To estimate the value of our total equity, including both common and preferred equity, we relied upon our anticipated Series B preferred stock financing which we believed to be the most indicative of our value. The financing closed on March 29, 2012 at a price that was within the range of our estimate and was led by a previously unrelated investor.

Volatility We estimated volatility based on the representative group of publicly traded companies with a term consistent with the timeline to the liquidity event. We performed a sensitivity analysis and have determined a 30% change in the volatility rate would be immaterial to the calculation of stock- based compensation.

Table of Contents

Time to liquidity We estimated a weighted average time to a sale event of 2.65 years based on the projected time to significant development events, including the results from our AUGMENT Study in humans, for our product candidates.

Risk-free interest rate We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a sale event for our stockholders.

Discounts for lack of marketability Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black- Scholes option pricing model. We also considered that our preferred stock had rights that our common stock did not have, including anti-dilution protection, liquidation preferences, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing. Our preferred stockholders had control and influence over the enterprise, which provided them with the optionality over future liquidity, financing and other decisions that the common stock option holders did not control.

On March 29, 2012, we sold 6,770,563 shares of Series B preferred stock to accredited and institutional investors at $5.50 per share for aggregate net proceeds of approximately $35,000,000. On May 4, 2012, we issued stock options for the purchase of an aggregate of 81,022 shares of common stock with an exercise price of $4.39 per share.

For the period from March 29, 2012 to May 4, 2012, our board of directors determined the fair value of our common stock to be $4.39 per share. This was an increase of $0.38 per share, or 9.5%, from the previous retrospective fair market valuation of $4.01 per share, as of February 8, 2012. The increase from February 8, 2012 was primarily due to the following factors:

on March 29, 2012 we closed our Series B preferred stock financing at a price per share of $5.50;

we signed a cGTP lab facility contract with a vendor that will perform the primary services in connection with our AUGMENT Study and made significant progress on the manufacturing process; and

scientific work confirmed that mitochondria could be frozen and that there is no reduction in ATP activity after thawing.

Management performed a contemporaneous valuation as of March 29, 2012, and concluded that a liquidity event was possible within three years. We also believed that public trading of our common stock was more likely to occur than a sale. We calculated valuations using both liquidity event assumptions and weighted the results to estimate the fair value of our common stock. We applied an 85% weighting to the public trading scenario and a 15% weighting to the sale scenario. The increase in the probability of the public trading scenario from February 8, 2012 was due primarily to the closing of the Series B preferred stock financing and our plan to undertake the filing of the Form 10.

In the public trading scenario, we assumed all of our outstanding shares of preferred stock would convert into common stock and the present value of the future projected enterprise value was based on the value of the Series B preferred stock financing. There was no discount for lack of marketability applied to the public trading scenario. The estimated time to complete the public trading scenario was approximately six months.

Table of Contents

For the sale scenario, we utilized the option pricing method and key assumptions were as follows:

Underlying equity value To estimate the value of our total equity, including both common and preferred equity, we relied upon our completed Series B preferred stock financing which we believed to be the most indicative of our value. The financing closed on March 29, 2012 and was led by a previously unrelated investor.

Volatility We estimated volatility based on the representative group of publicly traded companies with a term consistent with the timeline to the liquidity event. We performed a sensitivity analysis and have determined a 30% change in the volatility rate would be immaterial to the calculation of stock- based compensation.

Time to liquidity We estimated a weighted average time to a sale event of 2.50 years based on the projected time to significant development events, including the results from our AUGMENT Study in humans, for our product candidates.

Risk-free interest rate We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a sale event for our stockholders.

Discounts for lack of marketability Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black- Scholes option pricing model. We also considered that our preferred stock had rights that our common stock did not have, including anti-dilution protection, liquidation preferences, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing. Our preferred stockholders had control and influence over the enterprise, which provided them with the optionality over future liquidity, financing and other decisions that the common stock option holders did not control.

For the period from May 5, 2012 to June 27, 2012, our board of directors determined the fair value of our common stock to be $5.40 per share. This was an increase of $1.01 per share, or 23.0%, from the previous fair market valuation of $4.39 per share, as of March 29, 2012. The increase from March 29, 2012 was primarily due to the following factors:

we filed the Form 10 with the SEC which became effective on June 11, 2012; and

we initiated a private placement of our common stock at a price per share of $5.50.

Management performed a contemporaneous valuation as of June 27, 2012, and concluded that a liquidity event was possible within two and one-half years. We also believed that public trading of our common stock was more likely to occur than a sale. We calculated valuations using both liquidity event assumptions and weighted the results to estimate the fair value of our common stock. We applied a 90% weighting to the public trading scenario and a 10% weighting to the sale scenario. The increase in the probability of the public trading scenario from March 29, 2012 was due primarily to the Form 10 becoming effective and our plan to undertake a private placement of our common stock.

In the public trading scenario, we assumed all of our outstanding shares of Series A preferred stock and Series B preferred stock would convert into common stock. Because the private placement had not yet been completed for purposes of the June 27, 2012 valuation, we relied on an income approach, specifically the discounted future cash flows model, to arrive at the present value of the future projected enterprise value.

Table of Contents

The key assumptions utilized in the discounted future cash flows model were as follows:

We prepared a set of financial projections for the years ending December 31, 2012 through 2021.

We utilized a discount rate based upon the venture capital rate of return studies.

We calculated a terminal value based upon the constant growth method.

We added the value of our cash, as of the valuation date, and the present value of the net operating loss carryforward to the present value of the discrete cash flows and terminal value to determine our enterprise value as of the valuation date.

There was no discount for lack of marketability applied to the public trading scenario. The estimated time to complete the public trading scenario was approximately three months.

For the sale scenario, we utilized the option pricing method and key assumptions were as follows:

Underlying equity value To estimate the value of our total equity, including both common and preferred equity, we relied upon our completed Series B preferred stock financing, which we believed to be the most indicative of our value. The financing closed on March 29, 2012 and was led by a previously unrelated investor.

Volatility We estimated volatility based on the representative group of publicly traded companies with a term consistent with the timeline to the liquidity event.

Time to liquidity We estimated a weighted average time to a sale event of 2.50 years based on the projected time to significant development events, including the results from our AUGMENT Study in humans, for our product candidates.

Risk-free interest rate We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a sale event for our stockholders.

Discounts for lack of marketability Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black-Scholes option pricing model. We also considered that our Series A preferred stock and Series B preferred stock had rights that our common stock did not have, including anti-dilution protection, liquidation preferences, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing. Our Series A preferred stock and Series B preferred stockholders had control and influence over the enterprise, which provided them with the optionality over future liquidity, financing and other decisions that the common stock option holders did not control.

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 $4,039,000. 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.

For the period from June 28, 2012 to September 7, 2012, our board of directors determined the fair value of our common stock to be $5.48 per share. This was an increase of $0.08 per share, or 1.5%,

Table of Contents

from the previous fair market valuation of $5.40 per share, as of June 27, 2012. The increase from June 27, 2012 was primarily due to the following factors:

- we completed the private placement of 897,554 shares of common stock at a price per share of $5.50.
- we filed the Resale S-1 covering the resale of the 7,630,683 shares of common stock on August 29, 2012.

Management performed a contemporaneous valuation as of September 6, 2012, and concluded that a liquidity event was possible within two and one-half years. We also believed that public trading of our common stock was more likely to occur than a sale. We calculated valuations using both liquidity event assumptions and weighted the results to estimate the fair value of our common stock. We applied a 90% weighting to the public trading scenario and a 10% weighting to the sale scenario.

In the public trading scenario, we relied on an income approach, specifically the discounted future cash flows model, to arrive at the present value of the future projected enterprise value.

The key assumptions utilized in the discounted future cash flows model were as follows:

- We prepared a set of financial projections for the years ending December 31, 2012 through 2021.
- We utilized a discount rate based upon the venture capital rate of return studies.
- We calculated a terminal value based upon the constant growth method.
- We added the value of our cash, as of the valuation date, and the present value of the net operating loss carryforward to the present value of the discrete cash flows and terminal value to determine our enterprise value as of the valuation date.

There was no discount for lack of marketability applied to the public trading scenario. The estimated time to complete the public trading scenario was approximately one month.

For the sale scenario, we utilized the option pricing method and key assumptions were as follows:

- Underlying equity value To estimate the value of our total equity, including both common and preferred equity, we relied upon our completed private placement which we believed to be the most indicative of our value. The financing closed on August 13, 2012 and primarily included unrelated investors.
- Volatility We estimated volatility based on the representative group of publicly traded companies with a term consistent with the timeline to the liquidity event.
- Time to liquidity We estimated a weighted average time to a sale event of 2.50 years based on the projected time to significant development events, including the results from our AUGMENT Study in humans, for our product candidates.
- Risk-free interest rate We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a sale event for our stockholders.

Discounts for lack of marketability  Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black-Scholes option pricing model.

Table of Contents

For the period from September 8, 2012 to October 24, 2012, our board of directors determined the fair value of our common stock to be $5.50 per share. This was an increase of $0.02 per share, or 0.04%, from the previous fair market valuation of $5.48 per share, as of September 6, 2012. The increase from September 6, 2012 was primarily due to the following factors:

- Our Resale S-1 was declared effective on September 13, 2012.

Management performed a contemporaneous valuation as of October 22, 2012, and concluded that a liquidity event was possible within two and one-half years. We also believed that public trading of our common stock was more likely to occur than a sale. We calculated valuations using both liquidity event assumptions and weighted the results to estimate the fair value of our common stock. We applied a 95% weighting to the public trading scenario and a 5% weighting to the sale scenario. The increase in the probability of the public trading scenario from September 6, 2012 was due primarily to the effectiveness of the Resale S-1.

In the public trading scenario, we relied on an income approach, specifically the discounted future cash flows model, to arrive at the present value of the future projected enterprise value.

The key assumptions utilized in the discounted future cash flows model were as follows:

- We prepared a set of financial projections for the years ending December 31, 2012 through 2021.
- We utilized a discount rate based upon the venture capital rate of return studies.
- We calculated a terminal value based upon the constant growth method.
- We added the value of our cash, as of the valuation date, and the present value of the net operating loss carryforward to the present value of the discrete cash flows and terminal value to determine our enterprise value as of the valuation date.

There was no discount for lack of marketability applied to the public trading scenario. The estimated time to complete the public trading scenario was approximately one month.

For the sale scenario, we utilized the option pricing method and key assumptions were as follows:

- Underlying equity value  To estimate the value of our total equity, including both common and preferred equity, we relied upon our completed private placement which we believed to be the most indicative of our value. The financing closed on August 13, 2012 and primarily included unrelated investors.
- Volatility  We estimated volatility based on the representative group of publicly traded companies with a term consistent with the timeline to the liquidity event.
- Time to liquidity  We estimated a weighted average time to a sale event of 2.50 years based on the projected time to significant development events, including the results from our AUGMENT Study in humans, for our product candidates.
- Risk-free interest rate  We determined the risk-free interest rate based on the yield of a U.S. Treasury bill with a maturity date closest to the estimated time to a sale event for our stockholders.
- Discounts for lack of marketability  Because we were a privately held company, shares of our common stock were highly illiquid and, as such, warranted a discount in value from their estimated "marketable" price. We estimated the discount factor of 10% in the sale scenario for illiquidity using legal guidelines from U.S. Tax Court cases regarding privately held business

valuations, fundamental business factors, and empirical studies on the discount for lack of marketability. We corroborated the discount factor based on the value of a put option compared to the value of common stock using a Black-Scholes option pricing model.

Table of Contents

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding our future performance, including the successful completion of our AUGMENT Study and other development efforts and the time to completing public trading or a sale, as well as the determination of the appropriate valuation methods at each valuation date. If we had made different assumptions, our stock-based compensation expense could have been different. The foregoing valuation methodologies are not the only methodologies available and they were used to value our common stock for the periods prior to when our common stock began trading on the OTC Bulletin Board and the OTC Market Group's OTC Link quotation system. Accordingly, investors are cautioned not to place undue reliance on the foregoing valuation methodologies as an indicator of our future stock price.

**Results of Operations**

We were incorporated on April 5, 2011. As a result, our results of operations reflect the year ended December 31, 2012 and the period from April 5, 2011 (inception) to December 31, 2011. There is no comparable period for 2011.

***Discussion of the Year Ended December 31, 2012 and Period April 5, 2011 (Inception) through December 31, 2011***

**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 and our other product candidates.

**Research and Development Expenses**

Research and development expenses were $6,323,000 for the year ended December 31, 2012 as compared to $1,170,000 for the period April 5, 2011 (inception) through December 31, 2011. In both periods, substantially all research and development expenses related to the development of AUGMENT.

The $5,153,000, or 440%, increase in research and development expense for the year ended December 31, 2012 as compared to the period ended December 31, 2011 included the following components, substantially all of which related to the development of AUGMENT:

- an increase in contract research organization expenses of $2,254,000 comprised of expenses for outsourced biology, chemistry, clinical and development services;
- an increase in payroll expense of $1,112,000, including salaries, bonus, payroll taxes and benefits for our employees in research and development, due to increased research and development headcount;
- an increase in stock-based compensation expense of $872,000 primarily related to non-employee stock options granted in prior periods to members of our scientific advisory board;
- an increase in consulting fees of $380,000;
- an increase in travel expense, laboratory supply expense and other miscellaneous expense of $302,000;
- an increase in occupancy expense of $151,000, which in both periods represents an allocated portion of rent and other occupancy costs; and
- an increase in license fees of $82,000, related to our license from MGH.

Table of Contents

We expect research and development costs to continue to increase through 2013 as a result of expenses associated with our AUGMENT Study, which we commenced during the last quarter of 2012.

**General and Administrative Expenses**

General and administrative expenses were $7,206,000 for the year ended December 31, 2012 as compared to $1,454,000 for the period from April 5, 2011 (inception) through December 31, 2011. The $1,454,000 of general and administrative expenses for the period ended December 31, 2011 was principally attributable to consulting fees, market research fees and patent expenses.

The $5,752,000, or 396%, increase in general and administrative expense, for the year ended December 31, 2012 as compared to the period from April 5, 2011 (inception) through December 31, 2011 was primarily due to our continued growth as a company and included the following components:

- an increase in professional fee expense of $2,575,000, comprised of fees for audit, tax and legal services, corporate filing fees and investor relations fees primarily related to activities associated with becoming a publicly traded company. Included in the aggregate professional fees of $3,169,000 for the year ended December 31, 2012 are approximately $1,410,000 of legal and accounting fees related to the Form 10, which are not expected to be recurring in future periods;

- an increase in payroll expense of $1,028,000, including salaries, bonus, payroll taxes and benefits as a result of increased general and administrative headcount;

- an increase in market research analysis and public relations expense of $470,000;

- an increase in occupancy expense of $263,000, which in both periods represents an allocated portion of rent and other occupancy costs;

- an increase in travel expense, office supply expense and other miscellaneous expense of $433,000, including travel, meals, entertainment, conferences and insurance expense;

- an increase in consulting fees of $490,000, as a result of retaining business planning and strategy consultants;

- an increase in recruiting fees of $331,000 associated with the growth in general and administrative headcount; and

- an increase in stock-based compensation expense of $162,000 primarily related to the issuance of restricted stock in prior periods.

**Interest Income**

The proceeds from our Series B Preferred Stock financing and our private placement of common stock are invested in cash in bank deposits, money market funds and corporate debt securities where we earned $19,000 in interest through December 31, 2012.

**Liquidity and Capital Resources**

***Sources of Liquidity***

Since inception we have funded our operations primarily through the private placement and issuance of preferred stock and common stock. To date, we have not generated any revenues. From inception (April 5, 2011) through December 31, 2012, we have received approximately $41,091,000 in net proceeds from the issuance of preferred stock and approximately $4,039,000 in net proceeds from the sale of common stock.

As of December 31, 2012, we had cash, cash equivalents and marketable securities totaling $31,391,000. On August 13, 2012, our preferred stock automatically converted into shares of common stock. Historically we have primarily invested our cash in bank deposits, money

Table of Contents

market funds and corporate debt securities. Going forward, we currently plan to primarily invest our cash in U.S. Treasury obligations, commercial paper and corporate debt securities in accordance with our investment policy.

***Cash Flows***

The following table sets forth the primary sources and uses of cash for the periods set forth below.

| (in thousands) | Year Ended December 31, 2012 | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2012 |
|---|---|---|---|
| Net cash used in operating activities | $ (11,156) | $ (1,560) | $ (12,716) |
| Net cash used in investing activities | $ (17,640) | $ | $ (17,640) |
| Net cash provided by financing activities | $ 39,031 | $ 6,101 | $ 45,132 |
| Net increase in cash and cash equivalents | $ 10,235 | $ 4,541 | $ 14,776 |

*Operating activities.* The use of cash resulted primarily from our net loss adjusted for non-cash charges and favorable changes in the components of working capital. The cash used in operating activities is for research and development expenses as we (1) increased our research and development headcount, (2) incurred expenses related to external research and development costs and consulting costs and (3) increased our balance of accounts payable and accrued expenses. In addition, for the year ended December 31, 2012, we used cash in operating activities for general and administrative expenses such as legal and audit fees in connection with our Form 10. We commenced operations in April 2011 and, as such, the period ended December 31, 2011 reflects approximately nine months of activity. We expect cash used in operating activities to continue to increase for the foreseeable future as we fund our increased research and development activities.

*Investing activities.* The cash used in investing activities for the year ended December 31, 2012 reflects the purchase of short term investments of $16,698,000, the purchase of property, plant and equipment, including leasehold improvements of $849,000 and the restriction of $93,000 of cash related to our new facility lease. During the period from April 5, 2011 (inception) to December 31, 2011, there were no investing activities.

*Financing activities.* The 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 $34,992,000 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 $4,039,000.

The cash provided by the financing activities in the period from April 5, 2011 (inception) to December 31, 2011was primarily the result of the sale and issuance of 6,200,000 shares of our Series A preferred stock for net proceeds of $6,099,000.

***Funding Requirements***

All of our product candidates are still in the early stage of development. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- continue our AUGMENT Study in humans;
- continue our research and preclinical development of OvaTure and other product candidates;
- initiate clinical trials of OvaTure and other product candidates;

Table of Contents

seek approval from the FDA and similar regulatory agencies outside of the United States for our product candidates that require such approval;

establish a sales, marketing and distribution infrastructure to commercialize AUGMENT and any other products we successfully develop;

maintain, expand and protect our intellectual property portfolio;

hire additional scientific, clinical, quality control and management personnel to support our product development and commercialization efforts;

add operational and financial personnel to handle the public company reporting and other requirements to which we are subject;

seek to identify additional product candidates that treat infertility; and

develop, acquire or in-license other products and technologies.

Assuming we have no revenue from product sales, we expect our existing cash, cash equivalents and marketable securities of $31,391,000 at December 31, 2012 will enable us to fund our operating expenses and capital expenditure requirements at least through the end of 2013. 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 product candidates, and the extent to which we may enter into collaborations with third parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

the timing and results of our AUGMENT Study in humans;

our ability to successfully commercialize AUGMENT;

the costs and timing of commercialization activities for AUGMENT, including manufacturing, sales, marketing and distribution;

revenue, if any, received from commercial activities of AUGMENT or any other product candidates;

the scope, progress, results and costs of research, preclinical development and clinical trials for our product candidates;

the regulatory process, including the premarketing and marketing approval requirements, to which some of our product candidates will be subject;

the costs, timing and outcome of regulatory review of our product candidates that are subject to such review;

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

our ability to establish collaborations and partnerships on favorable terms, if at all; and

the extent to which we develop, acquire or in-license other products and technologies.

Until such time, if ever, as we can generate substantial product 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

Table of Contents

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 product candidates 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 product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

**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.

**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 $31,391,000 as of December 31, 2012 and $4,541,000 as of December 31, 2011. The cash and cash equivalents as of December 31, 2012 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. Due to the short term duration of our investment portfolio and the low risk profile of our investments, we would not expect an immediate 100 basis point change in interest rates to have a material effect on the fair market value of our portfolio.

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, 2012, 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-24 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 chief executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2012.

Table of Contents

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, 2012, our chief executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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

**Changes in Internal Controls.**

No change in our internal control over financial reporting occurred during the fiscal quarter ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, the our internal control over financial reporting.

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

On February 21, 2013, John Simon resigned from our board of directors. Mr. Simon's resignation is not the result of any disagreement with the company on any matter relating to the company's operations, policies or practices. Pursuant to our voting agreement, the parties thereto have agreed, until such time as our common stock is traded on a national securities exchange, to vote their shares in such a way to ensure that a designee of each of our three lead investors, of which General Catalyst is one, will serve on the board for so long as the entity remains a significant investor. John Simon was serving on our board as a designee of General Catalyst. As of February 25, 2013, General Catalyst has not designated a replacement.

Table of Contents

## PART III

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

Certain information with respect to our executive officers and directors may be found under the section captioned "Employees" in Part I of this Annual Report on Form 10-K. Other information required by Item 10 of Form 10-K may be found in the definitive proxy statement to be delivered to stockholders in connection with our 2013 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 2013 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 in the definitive proxy statement to be delivered to stockholders in connection with our 2013 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 in the definitive proxy statement to be delivered to stockholders in connection with our 2013 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 2013 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.

| Exhibit No. | Exhibit |
|---|---|
| 3.1 | Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.3 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 3.2 | Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 3.3 | Restated Certificate of Incorporation of the Registrant to be effective upon the common stock trading on a national securities exchange (incorporated by reference to Exhibit 3.5 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 3.4 | Second Amended and Restated By-laws of the Registrant to be effective upon the common stock trading on a national securities exchange (incorporated by reference to Exhibit 3.6 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 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) |

Table of Contents

| Exhibit No. | Exhibit |
|---|---|
| 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 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# | Form of Amended and Restated Restricted Stock Agreement between the Registrant and each of David Sinclair and Jonathan Tilly (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.10# | 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) |
| 10.11 | 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) |
| 10.12 | 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) |
| 10.13 | Master Services Agreement, dated February 21, 2012, between the Registrant and Agenus Inc. (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.14 | 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) |
| 10.15# | 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) |

Table of Contents

| Exhibit No. | Exhibit |
|---|---|
| 10.16# | 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) |
| 10.17 | Consultation and Scientific Advisory Board Agreement, dated July 13, 2011, between the Registrant and Jonathan L. Tilly (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.18 | Consultation and Scientific Advisory Board Agreement, dated September 7, 2011, between the Registrant and David Sinclair (incorporated by reference to Exhibit 10.20 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, Thomas Malley, Harald Stock and Jonathan Tilly (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 Lock-Up Agreement between the Registrant and each of the Registrant's officers (incorporated by reference to Exhibit 10.24 to Amendment No. 1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on May 17, 2012) |
| 10.23 | 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) |
| 10.24*# | Letter Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp |
| 10.25*# | Letter Agreement, dated December 19, 2012, between the Registrant and Alison Lawton |
| 10.26*# | Restricted Stock Unit Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp |
| 10.27*# | Restricted Stock Unit Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp |
| 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 by Chief Executive Officer |
| 31.2* | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Principal Financial Officer |

Table of Contents

| Exhibit No. | Exhibit |
|---|---|
| 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 |
| 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.

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 25, 2013.

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 25, 2013 |
| /s/ CHRISTOPHER BLECK<br>Christopher Bleck | Treasurer (Principal financial and accounting officer) | February 25, 2013 |
| /s/ RICHARD ALDRICH<br>Richard Aldrich | Director | February 25, 2013 |
| /s/ JEFFREY D. CAPELLO<br>Jeffrey D. Capello | Director | February 25, 2013 |
| /s/ STEPHEN KRAUS<br>Stephen Kraus | Director | February 25, 2013 |
| /s/ THOMAS MALLEY<br>Thomas Malley | Director | February 25, 2013 |
| /s/ HARALD STOCK<br>Harald Stock Ph.D | Director | February 25, 2013 |

Table of Contents

| Signature | Title | Date |
|---|---|---|
| /s/ JONATHAN TILLY<br>Jonathan Tilly, Ph,.D | Director | February 25, 2013 |
| /s/ CHRISTOPH WESTPHAL<br>Christoph Westphal, M.D., Ph.D. | Director | February 25, 2013 |

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, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows for the year ended December 31, 2012, the period from April 5, 2011 (inception) to December 31, 2011 and the period from April 5, 2011 (inception) to December 31, 2012. 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, 2012 and 2011 and the consolidated results of its operations and its cash flows for the year ended December 31, 2012, the period from April 5, 2011 (inception) to December 31, 2011 and the period from April 5, 2011 (inception) to December 31, 2012, in conformity with U.S. generally accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 25, 2013

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

**Consolidated Balance Sheets**

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

| | As of December 31, 2012 | As of December 31, 2011 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 14,776 | $ 4,541 |
| Short-term investments | 16,615 | |
| Prepaid expenses and other current assets | 574 | 44 |
| Total current assets | 31,965 | 4,585 |
| Property and equipment, net | 756 | |
| Other assets | 93 | |
| Total assets | $ 32,814 | $ 4,585 |
| **Liabilities, preferred stock and stockholders' equity (deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 875 | $ 276 |
| Accrued expenses and other liabilities | 1,211 | 399 |
| Total current liabilities | 2,086 | 675 |
| Other non-current liabilities | 7 | 87 |
| Total liabilities | 2,093 | 762 |
| Commitments and contingencies (Note 10) | | |
| Series A convertible preferred stock, $0.001 par value; 0 and 6,200,000 shares authorized, issued and outstanding as of December 31, 2012 and December 31, 2011, respectively (liquidation preference of $6,200 as of December 31, 2011) | | 6,200 |
| Preferred stock, $0.001 par value;5,000,000 shares authorized, no shares issued and outstanding | | |
| Common stock, $0.001 par value; 100,000,000 and 23,000,000 shares authorized at December 31, 2012 and December 31, 2011, respectively; 14,268,068 and 3,529,406 shares issued at December 31, 2012 and December 31, 2011, respectively; 12,622,919 and 1,209,752 shares outstanding at December 31, 2012 and December 31, 2011, respectively | 14 | 2 |
| Additional paid-in capital | 46,847 | 245 |
| Accumulated other comprehensive loss | (6) | |
| Deficit accumulated during the development stage | (16,134) | (2,624) |
| Total stockholders' equity (deficit) | 30,721 | (2,377) |
| Total liabilities, preferred stock and stockholders' equity (deficit) | $ 32,814 | $ 4,585 |

See accompanying notes.

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

**Consolidated Statements of Operations and Comprehensive Loss**

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

| | Year Ended, December 31, 2012 | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2012 |
|---|---|---|---|
| Operating expenses: | | | |
| Research and development | $ 6,323 | $ 1,170 | $ 7,493 |
| General and administrative | 7,206 | 1,454 | 8,660 |
| Total operating expenses | 13,529 | 2,624 | 16,153 |
| Loss from operations | (13,529) | (2,624) | (16,153) |
| Interest income | 19 | | 19 |
| Net loss | (13,510) | (2,624) | (16,134) |
| Accretion of convertible preferred stock to redemption value | $ | $ (101) | $ (101) |
| Net loss applicable to common stockholders | $ (13,510) | $ (2,725) | $ (16,235) |
| Net loss per share applicable to common stockholders basic and diluted | $ (2.33) | $ (3.00) | $ (4.35) |
| Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted | 5,810 | 909 | 3,734 |
| Net loss | $ (13,510) | $ (2,624) | $ (16,134) |
| Other comprehensive loss: | | | |
| Unrealized losses on available-for-sale securities | (6) | | (6) |
| Comprehensive loss | $ (13,516) | $ (2,624) | $ (16,140) |

See accompanying notes.

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

**Consolidated Statements of Stockholders' Equity (deficit)**

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

| | Series A convertible preferred stock | | Series B convertible preferred stock | | Common stock | | Additional paid-in capital | Accumulated other comprehensive loss | Deficit accumulated during the development stage | Totals stockholders' equity (deficit) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | | | | |
| Balance at April 5, 2011 (inception) | | $ | | $ | | $ | $ | $ | $ | $ |
| Sale of common stock to founders | | | | | 526,443 | 1 | | | | 1 |
| 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 | | | | | | | 346 | | | 346 |
| Net loss | | | | | | | | | (2,624) | (2,624) |
| Balance at December 31, 2011 | 6,200,000 | 6,200 | | | 1,209,752 | 2 | 245 | | (2,624) | (2,377) |
| Vesting of restricted 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 in a private placement, net of issuance costs of $898 | | | | | 897,554 | 1 | 4,038 | | | 4,039 |
| Stock options exercised | | | | | 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 | $ 14 | $ 46,847 | $ (6) | $ (16,134) | $ 30,721 |

See accompanying notes.

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

**Consolidated Statements of Cash Flows**

**(In thousands)**

| | Year Ended December 31, 2012 | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2012 |
|---|---|---|---|
| **Cash flows from operating activities:** | | | |
| Net loss | $ (13,510) | $ (2,624) | $ (16,134) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 93 | | 93 |
| Accretion of discount on debt securities | 77 | | 77 |
| Stock-based compensation expense | 1,382 | 346 | 1,728 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current assets | (530) | (44) | (574) |
| Accounts payable | 599 | 276 | 875 |
| Accrued expenses and other liabilities | 733 | 486 | 1,219 |
| Net cash used in operating activities | (11,156) | (1,560) | (12,716) |
| **Cash flows from investing activities:** | | | |
| Purchases of property, plant, and equipment | (849) | | (849) |
| Purchases of short-term investments | (16,698) | | (16,698) |
| Increase in restricted cash | (93) | | (93) |
| Net cash used in investing activities | (17,640) | | (17,640) |
| **Cash flows from financing activities:** | | | |
| Proceeds from issuance of preferred stock, net of issuance costs | 34,992 | 6,099 | 41,091 |
| Net proceeds from issuance of common stock | 4,039 | 2 | 4,041 |
| Net cash provided by financing activities | 39,031 | 6,101 | 45,132 |
| Increase in cash and cash equivalents | 10,235 | 4,541 | 14,776 |
| Cash and cash equivalents at beginning of period | 4,541 | | 0 |
| Cash and cash equivalents at end of period | $ 14,776 | $ 4,541 | $ 14,776 |
| Supplemental disclosure of non-cash financing activity | | | |
| 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 and basis of presentation**

OvaScience, Inc. (the "Company"), incorporated on April 5, 2011 as a Delaware corporation, is a life science company developing proprietary products to improve the treatment of female infertility based on recent scientific discoveries about the existence of egg precursor cells. The Company's operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates, planning and conducting a marketing study in humans for its most advanced product candidate and undertaking preclinical studies of certain product candidates. The Company has commenced its planned principal operations but has not generated any significant revenues to date. Accordingly, the Company is considered to be in the development stage.

The Company is 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 of preclinical testing or clinical trials, the need to obtain marketing approval for certain of its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of the Company's products and protection of proprietary technology. If the Company does not successfully commercialize any of its product candidates, it will be unable to generate product revenue or achieve profitability. As of December 31, 2012 the Company had a deficit accumulated during the development stage of approximately $16.1 million.

Unless otherwise indicated, all information in these financial statements gives retrospective effect to the one-for-2.023 reverse stock split of the Company's common stock (the "Reverse Stock Split") that was effected on March 28, 2012 (see Note 5).

***Liquidity***

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

The Company believes that its cash resources of approximately $31.4 million at December 31, 2012 will be sufficient to allow the Company to fund its current operating plan and continue as a going concern through at least December 31, 2013. The Company will be required to obtain additional funding in order to continue to fund its operations after 2013. 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 the Company, or at all.

**2. Significant accounting policies**

***Principles of Consolidation***

The Company's consolidated financial statements include the Company's accounts and the accounts of the Company's wholly-owned subsidiary, OvaScience Securities Corporation. All intercompany transactions have been eliminated.

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**2. Significant accounting policies (Continued)**

**Use of estimates**

The preparation of the Company's financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from such estimates.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair market value of its common stock as determined by the board of directors contemporaneously at the date such grants were made, with input from management. The fair value of common stock at certain of the grant dates was adjusted in connection with the Company's retrospective fair value assessment for financial reporting purposes. The board of directors has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector, the prices at which the Company sold shares of preferred stock and common stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company.

The Company utilized various valuation methodologies in accordance with the framework of the 2004 American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. The methodologies included a probability analysis including both a potential public trading scenario and potential sale scenario. For the sale scenario, the Company used the reverse backsolve method and in the public trading scenario the Company assumed that all of its shares of convertible preferred stock would convert into common stock. Valuation methodologies include estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of the Company's AUGMENT marketing study in humans and the time to complete a public trading scenario or sale. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

**Segment and geographic information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing product candidates dedicated to the treatment of female infertility, and the Company operates in only one geographic segment.

**Comprehensive loss**

In June 2011, the Financial Accounting Standards Board issued revised guidance on the presentation of comprehensive income and its components in the financial statements. As a result of this guidance, companies are now required to present the components of net income and other

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**2. Significant accounting policies (Continued)**

comprehensive income either as one continuous statement or as two consecutive statements, eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders' equity. This update does not change the items that must be reported in other comprehensive income, how such items are measured or when they must be reclassified to net income. The Company adopted this new guidance on January 1, 2012 and elected to present comprehensive income (loss) in one continuous statement as part of the financial statements.

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss for the year ended December 31, 2012, the periods from April 5, 2011 (inception) to December 31, 2011 and April 5, 2011 (inception) to December 31, 2012 comprised net loss and net unrealized losses on investments.

**Organizational costs**

All organizational costs have been expensed as incurred.

**Cash and cash equivalents**

The Company considers all highly liquid investment instruments with an original or remaining maturity of three months or less at the date of purchase to be cash equivalents. Investments qualifying as cash equivalents primarily consist of money market funds. The carrying amount of cash equivalents approximates fair value. The amount of cash equivalents included in cash and cash equivalents was approximately $13.3 million at December 31, 2012. There were no cash equivalents as of December 31, 2011.

**Fair value of financial instruments**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

| | |
|---|---|
| Level 1 inputs | Quoted prices in active markets for identical assets or liabilities |
| Level 2 inputs | Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly |
| Level 3 inputs | Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability |

Effective January 1, 2012, the Company adopted, on a prospective basis, ASU No. 2011-04, "Fair Value Measurement (Topic 820)" ("ASU No. 2011-04"), which updates the existing fair value measurement guidance currently included in the ASC to achieve common fair value measurement and

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**2. Significant accounting policies (Continued)**

disclosure requirements in U.S. generally accepted accounting principles and International Financial Reporting Standards. ASU No. 2011-04 is generally consistent with the Company's previous fair value measurement policies but includes additional disclosure requirements, particularly for assets and liabilities that require the use of Level 3 inputs to measure fair value. The adoption of ASU No. 2011-04 did not have a material impact on the Company's financial position or results of operations.

**Concentrations of credit risk and off-balance sheet risk**

Cash, cash equivalents and marketable securities are the only financial instruments that potentially subject the Company to concentrations of credit risk. The Company maintains its cash with a high quality, accredited financial institution and, accordingly, such funds are subject to minimal credit risk. The Company also has established guidelines relating to diversification and maturities that allow the Company to manage risk. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

**Research and development costs**

The Company expenses 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 therapeutic product candidates and advances in the field of infertility. The Company accounts 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 when the service has been performed rather than when the payment is made. 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 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.

**Stock-based compensation**

The Company expenses the fair value of employee stock options on a straight-line basis over the requisite service period, which is the vesting period. Compensation expense is measured using the fair value of the award at the grant date, net of estimated forfeitures, and is adjusted annually to reflect actual forfeitures. The fair value of each stock option is estimated using the Black-Scholes option pricing model.

Stock-based awards issued to non-employees, including directors for non-board related services, are accounted for based on the fair value of such services received or of the equity instruments issued,

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**2. Significant accounting policies (Continued)**

whichever is more reliably measured. These stock-based option awards are revalued at each vesting date using the fair value method.

**Income taxes**

The Company determines its deferred tax assets and liabilities based on the differences between the financial reporting and tax bases of assets and liabilities. The deferred tax assets and liabilities are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered.

The Company applies 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. During the years ended December 31, 2012 and December 31, 2011, the Company had no material unrecognized tax benefits and no adjustments to its deferred tax assets. The Company recognizes any material interest and penalties related to unrecognized tax benefits in income tax expense.

The Company files income tax returns in the United States federal jurisdiction and multiple state jurisdictions. The Company currently is not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

**Property and equipment**

Property and equipment is stated at cost. Expenditures for repairs and maintenance are recorded to expense as incurred, whereas major betterments are capitalized as additions to property and equipment. Depreciation is calculated over the following estimated useful lives of the assets:

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

Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

The Company reviews its long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying value of assets may not be fully recoverable and that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If impairment is indicated, the asset will be written down to its estimated fair value. To date, no such impairment losses have been recorded.

**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. The Company's potentially dilutive shares, which include preferred stock, outstanding stock options and restricted stock, are considered to be

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**2. Significant accounting policies (Continued)**

common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

**3. Fair value of financial instruments**

The tables below present information about the Company's assets that are measured at fair value on a recurring basis as of December 31, 2012 and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value, which is described further within Note 2, *Summary of Significant Accounting Policies*. As of December 31, 2011, the Company did not have any financial assets that have been recorded at fair value on a recurring basis.

The Company's financial assets have been initially valued at the transaction price and subsequently valued at the end of each reporting period, typically utilizing third-party pricing services or other market observable data. The pricing services utilize industry standard valuation models, including both income and market based approaches, and observable market inputs to determine value. These observable market inputs include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices provided by its third-party pricing services by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active. The Company did not adjust or override any fair value measurements provided by its pricing services as of December 31, 2012.

The Company reviews 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, the Company considers the intent to sell, or whether it is more likely than not that the Company 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 the Company's investment policy, the severity and the duration of the impairment and changes in value subsequent to year end. As of 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.

There have been no transfers of assets between the fair value measurement classifications.

The following tables set forth the Company's financial assets that were recorded at fair value at December 31, 2012 (in thousands):

| Description | Balance as of December 31, 2012 | Quoted Prices in Active Markets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Other Unobservable Inputs (Level 3) |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents | $ 13,268 | $ 13,268 | $ | $ |
| Marketable securities: | | | | |
| Corporate debt securities | 16,615 | | 16,615 | |
| Total | $ 29,883 | $ 13,268 | $ 16,615 | $ |

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

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

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

| As of 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 |
| Marketable securities | 16,621 | 5 | (11) | 16,615 |
| Total | $ 31,397 | $ 5 | $ (11) | $ 31,391 |

**5. Convertible preferred stock**

In July 2011, the Company sold 6,200,000 shares of Series A Preferred Stock at a price of $1.00 per share for gross proceeds of $6,200,000. The Company incurred approximately $101,000 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, the Company sold 6,770,563 shares of Series B Preferred Stock at a price of $5.50 per share for gross proceeds of approximately $37,238,000. The Company incurred approximately $2,246,000 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 the Company's common stock (see Note 5), the Company's 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.

The Company 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)**

**5. 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 6).

**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 the Company's 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 the Company 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. The Company 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 $35,000,000 of gross proceeds to the Company and the Company's common stock is listed for trading on a national securities exchange, (b) the closing of certain private placement or registered offerings of the Company's 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.

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**5. Convertible preferred stock (Continued)**

**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 Company, unless holders of at least 70% of the outstanding shares of Series A Preferred Stock and Series B Preferred Stock, including certain of the Company's 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 the Company 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 the Company's major investors, voting together on an as-converted to common stock basis, was required to amend the Company's 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 the Company's material intellectual property, effect a significant change in the Company's business, create indebtedness in excess of $250,000, 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 the Company's organizational documents, increase the number of shares of Series B Preferred Stock, undertake change of control transactions or exclusively license any of the Company's 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 the Company's common stock, Series A

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**5. Convertible preferred stock (Continued)**

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.

**6. Common stock**

On March 28, 2012, the Company's board of directors and stockholders approved, and the Company filed, a restated certificate of incorporation effecting a Reverse Stock Split of the outstanding shares of the Company's common 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, the Company 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 $4,039,000. As a result of the completion of the private placement, on August 13, 2012, the Company's 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, the Company 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. The Company 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, the Company amended its certificate of incorporation and by-laws to divide the Company's board of directors into three classes with staggered three year terms. In addition, the Company's 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 the Company's 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.

The Company has 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, 2012 | December 31, 2011 |
|---|---|---|
| Outstanding stock options | 1,218,153 | 617,633 |
| Outstanding restricted stock units | 192,308 | |

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**7. Stock-based compensation**

In March 2012, the Company's 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 the Company's 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 the Company 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 the Company's common stock outstanding on the first day of the year and an amount determined by the Company's board of directors. The Company began making grants under the 2012 Plan following June 11, 2012, the effective date of the Company's registration of securities on Form 10. The Company ceased granting options under the 2011 Plan following the effective date of the Company's registration of securities on Form 10.

**Founders' stock**

In April 2011, the Company 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 the Company, at its discretion, to repurchase unvested shares if the founder's relationship with the Company 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 the Company's restricted stock activity and related information is as follows:

| | Shares | Weighted-average purchase price per share |
|---|---|---|
| Unvested at December 31, 2011 | 2,319,646 | $ 0.002 |
| Granted | | |
| Vested | 674,505 | $ 0.002 |
| Unvested at December 31, 2012 | 1,645,141 | $ 0.002 |

The Company records 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)**

**7. 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, 2011 | 617,633 | 0.04 | 9.80 | $ 2,162 |
| Granted | 718,936 | 6.49 | | |
| Exercised | (5,792) | 0.04 | | |
| Forfeited | (112,624) | 0.26 | | |
| Outstanding at December 31, 2012 | 1,218,153 | 3.83 | 9.34 | 5,535 |
| Exercisable at December 31, 2012 | 175,814 | 0.44 | 8.84 | 1,394 |
| Vested and expected to vest at December 31, 2012 | 1,114,651 | 3.78 | 8.84 | 5,123 |

A summary of the Company's restricted stock unit activity and related information is as follows:

| | Shares | Weighted-average grant date fair value |
|---|---|---|
| Unvested at December 31, 2011 | | |
| Granted | 192,308 | $ 7.80 |
| Vested | | |
| Unvested at December 31, 2012 | 192,308 | $ 7.80 |

**Stock options**

The fair value of each employee stock-based award is estimated on the grant date using the Black-Scholes option pricing model.

The Company uses the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term for options granted to employees and utilizes the contractual term for options granted to non-employees. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options.

The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The representative group of companies consisted of BioSante Pharmaceuticals, Inc., Corcept Therapeutics Inc., Cardiome Pharmaceutical Corporation, Polymedix, Inc. and Sangamo Biosciences, Inc. As a result of being a development stage company in a

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**7. Stock-based compensation (Continued)**

very early stage of product development with no revenues, the representative group of companies has certain similar, but not all similar, characteristics to the Company. The Company believes the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of the Company.

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, 2012 | December 31, 2011 |
|---|---|---|
| Risk-free interest rate | 0.8% - 1.78% | 1.2% - 1.84% |
| Dividend yield | | |
| Volatility | 79% - 89% | 79% - 82% |
| Expected term (years) | 5.1 - 9.93 | 6.0 - 9.75 |

During the year ended December 31, 2012, the Company 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. There were 452,294 options granted during the period from April 5, 2011 (inception) to December 31, 2011.

The Company recognized total stock-based compensation expense for employee stock option grants of $346,000 for year ended December 31, 2012 and $26,000 for the period from April 5, 2011 (inception) to December 31, 2011.

During 2012, the Company granted 39,685 options to purchase common stock with an exercise price of $4.81 per share to non-employees. During 2011, the Company granted 165,339 options to purchase common stock with an exercise price of $0.04 per share to non-employees.

In November 2011, the Company issued and sold 19,772 shares of common stock pursuant to the 2011 Plan, at a price per share of $0.002, to a former employee, who served as an executive officer at the time of the Company's incorporation. These shares were fully vested at December 31, 2011.

Stock-based awards issued to non-employees, including directors for non-board related services, are accounted for using the fair value method. These stock-based option awards are revalued on each vesting and reporting date. The Company recognized total stock-based compensation of $999,000 for the year ended December 31, 2012 and $320,000 for the period from April 5, 2011 (inception) to December 31, 2011 for these non-employee awards.

At December 31, 2012, there was $7,118,000 of total unrecognized compensation cost related to non-vested stock options and restricted stock. The Company expects to recognize these costs over a remaining weighted average period of 2.9 years.

**Restricted Stock Units**

On December 5, 2012, the Company issued a total of 192,308 restricted stock units ("RSUs") to its Chief Executive Officer. This grant included 128,205 RSUs with time-based vesting as follows: 16,025 shares on March 31, 2013 and 16,025 shares each quarter thereafter until December 31, 2014. The grant also included 64,103 RSUs that will vest only upon the achievement of performance conditions as

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**7. Stock-based compensation (Continued)**

determined by the Company's board of directors. The weighted average exercise price is $0.001 per share for these awards. The fair value of the time-based RSUs is based on the closing price of the Company's 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. The Company recognized total stock-based compensation for the time-based awards of $36,000 for the year ended December 31, 2012.

The performance conditions for performance-based RSUs had not been established as of December 31, 2012. 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, 2012. The measurement date will occur upon the determination and communication of the performance criteria by the board of directors and stock-based compensation expense for these awards will only be recognized if and when it is deemed probable that the performance conditions will be met. A summary of the status of non-vested RSUs as of December 31, 2012 is as follows:

| | Restricted Stock Units | Weighted-Average Grant Date Fair Value | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Non-vested at December 31, 2011 | | $ | | |
| Granted | 192,308 | 7.80 | 2.00 | $ 1,500 |
| Vested | | | | |
| Cancelled | | | | |
| Non-Vested at December 31, 2012 | 192,308 | $ 7.80 | 2.00 | $ 1,500 |

As of December 31, 2012, there was $964,000 of total unrecognized stock-based compensation expense related to non-vested time based RSUs granted under the 2012 Plan. The expense is expected to be recognized over a weighted-average period of 2.0 years

**8. Property and equipment**

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

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| Laboratory equipment | $ 663 | $ |
| Furniture and equipment | 101 | |
| Computer equipment | 7 | |
| Leasehold improvements | 78 | |
| Less: accumulated depreciation | (93) | |
| | $ 756 | $ |

Depreciation expense for the year ended December 31, 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, 2012 was $93,000, $0 and $93,000, respectively.

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**9. Income taxes**

As of December 31, 2012, the Company had federal net operating loss carryforwards of approximately $14,100,000, and state net operating loss carryforwards of approximately $13,900,000, which are available to reduce future taxable income. As of December 31, 2012 and 2011, the Company had federal tax credits of approximately $45,000, and state tax credits of approximately $165,000, which may be used to offset future tax liabilities. The net operating loss ("NOL") and tax credit carryforwards will expire at various dates through 2031. 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 the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years.

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations follows:

| | 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% |
| State income taxes, net of federal benefit | 5.42% | 5.47% |
| Research and development tax credits | 0.00% | 1.70% |
| Permanent items | (2.78)% | (3.93)% |
| Change in the valuation allowance | (36.64)% | (37.24)% |
| | % | % |

The principal components of the Company's deferred tax assets are as follows (in thousands):

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 5,527 | $ 750 |
| Research and development credits | 153 | 67 |
| Stock-based compensation | 142 | 22 |
| Other | 106 | 138 |
| Gross deferred tax assets | 5,928 | 977 |
| Valuation allowance | (5,928) | (977) |
| Net deferred tax asset | $ | $ |

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**9. Income taxes (Continued)**

The Company has recorded a valuation allowance against its deferred tax assets at December 31, 2012 and December 31, 2011 because the Company's management believes that it is more likely than not that these assets will not be fully realized.

The Company follows the provisions of ASC 740 *Accounting for Income Taxes* and the accounting guidance related to accounting for uncertainty in income taxes. The Company's reserves related to taxes are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Upon adoption, the Company recognized no material adjustment for unrecognized income tax benefits. As of the adoption date and through December 31, 2012, the Company had no unrecognized tax benefits or related interest and penalties accrued. The Company has not, as yet, conducted a study of research and development ("R&D") credit carryforwards. Such a study, once undertaken by the Company, may result in an adjustment to the Company's 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 the Company's 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. The Company would recognize both accrued interest and penalties related to unrecognized benefits in income tax expense. The Company's uncertain tax positions are related to years that remain subject to examination by relevant tax authorities. Since the Company is in a loss carryforward position, the Company is generally subject to examination by the U.S. federal, state and local income tax authorities for all tax years in which a loss carryforward is available.

**10. Commitments and contingencies**

From April 2011 through April 2012, the Company leased office space from a significant stockholder. There was no formal lease arrangement with the stockholder.

On May 1, 2012, the Company entered into a commercial building lease agreement. The sixty month lease, which commenced on August 10, 2012, provides for the lease by the Company 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%.

Future minimum lease payments under this lease as of December 31, 2012 are as follows (in thousands):

| Year | |
|---|---|
| 2013 | 267 |
| 2014 | 275 |
| 2015 | 284 |
| 2016 | 292 |
| 2017 | 173 |
| | $ 1,291 |

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**10. Commitments and contingencies (Continued)**

Rent expense for the year ended December 31, 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, 2012 amounted to $176, 000, $41,000 and $217,000, respectively.

**11. Accrued expenses and other current liabilities**

Accrued expenses consist of the following (in thousands):

| | December 31, 2012 | December 31, 2011 |
|---|---|---|
| Professional and consultant fees | $ 441 | $ 140 |
| Compensation and related benefits | 471 | 83 |
| License and patent fees | 87 | 108 |
| Market research and consulting | 40 | 40 |
| Contract research organizations | 127 | 15 |
| Other expenses | 45 | 13 |
| | $ 1,211 | $ 399 |

**12. Net loss per share**

The following table reconciles net loss to net loss applicable to common stockholders (in thousands, except per share data):

| | Year Ended December 31, 2012 | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2012 |
|---|---|---|---|
| Net loss applicable to common stockholders | $ (13,510) | $ (2,725) | $ (16,235) |
| Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted | 5,810 | 909 | 3,734 |
| Net loss per share applicable to common stockholders basic and diluted | $ (2.33) | $ (3.00) | $ (4.35) |

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, 2012 | Period from April 5, 2011 (inception) to December 31, 2011 | Period from April 5, 2011 (inception) to December 31, 2012 |
|---|---|---|---|
| Series A Preferred Stock | | 3,065 | |
| Series B Preferred Stock | | | |
| Outstanding stock options and restricted stock units | 1,410 | 618 | 1,410 |
| Founders' stock | 1,645 | 2,319 | 1,645 |

Table of Contents

**OvaScience, Inc.**

**(A development stage company)**

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

**13. 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. In addition, the Company may in the future determine to compensate Dr. Dipp with cash or other compensation.

As discussed in Note 10, during 2011 and a portion of 2012, the Company leased office space from one of its principal stockholders.

**14. 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 year ended December 31, 2012 and for the period from April 5, 2011 (Inception) through December 31, 2012, the Company made contributions to the 401(k) Plan of $52,000. No contributions were made during 2011.

Table of Contents

**Exhibit Index**

| Exhibit No. | Exhibit |
|---|---|
| 3.1 | Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.3 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 3.2 | Amended and Restated By-laws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 3.3 | Restated Certificate of Incorporation of the Registrant to be effective upon the common stock trading on a national securities exchange (incorporated by reference to Exhibit 3.5 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 3.4 | Second Amended and Restated By-laws of the Registrant to be effective upon the common stock trading on a national securities exchange (incorporated by reference to Exhibit 3.6 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 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 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) |

Table of Contents

| Exhibit No. | Exhibit |
|---|---|
| 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# | Form of Amended and Restated Restricted Stock Agreement between the Registrant and each of David Sinclair and Jonathan Tilly (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.10# | 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) |
| 10.11 | 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) |
| 10.12 | 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) |
| 10.13 | Master Services Agreement, dated February 21, 2012, between the Registrant and Agenus Inc. (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.14 | 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) |
| 10.15# | 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) |
| 10.16# | 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) |
| 10.17 | Consultation and Scientific Advisory Board Agreement, dated July 13, 2011, between the Registrant and Jonathan L. Tilly (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on April 11, 2012) |
| 10.18 | Consultation and Scientific Advisory Board Agreement, dated September 7, 2011, between the Registrant and David Sinclair (incorporated by reference to Exhibit 10.20 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, Thomas Malley, Harald Stock and Jonathan Tilly (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) |

Table of Contents

| Exhibit No. | Exhibit |
|---|---|
| 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 Lock-Up Agreement between the Registrant and each of the Registrant's officers (incorporated by reference to Exhibit 10.24 to Amendment No. 1 to the Registration Statement on Form 10 (File No. 000-54647) filed by the registrant on May 17, 2012) |
| 10.23 | 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) |
| 10.24*# | Letter Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp |
| 10.25*# | Letter Agreement, dated December 19, 2012, between the Registrant and Alison Lawton |
| 10.26*# | Restricted Stock Unit Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp |
| 10.27*# | Restricted Stock Unit Agreement, dated December 5, 2012, between the Registrant and Michelle Dipp |
| 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 by Chief Executive Officer |
| 31.2* | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Principal Financial Officer |
| 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 |
| 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.