OvaScience, Inc.
Form 10-K
March 02, 2017

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, 2016
OR
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to
Commission File Number: 001-35890
OVASCIENCE, INC.
(Exact name of registrant as specified in its charter)

Delaware	45-1472564
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
9 Fourth Avenue Waltham, Massachusetts	02451
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 500-2802
Securities registered pursuant to Section 12(b) of the Act:

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

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes o No ý
Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ý
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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, 2016 (the last day of the registrant's second fiscal quarter of 2016) was: $168.7 million.

As of February 27, 2017, there were 35,641,505 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 2017 Annual Meeting of Stockholders and are hereby incorporated by reference into this report.

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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, that involve substantial risks and uncertainties. All statements, other than statements related to present facts, current conditions or historical facts, contained in this Annual Report on Form 10-K, including but not limited to statements regarding our strategy, future operations, future financial position, future revenues, projected costs, anticipated pricing of our fertility treatments, prospects, plans and objectives of management are forward-looking statements. Such statements relate to, among other things, the timing of development and commercialization of our current and potential fertility treatments. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

There are a number of important risks and uncertainties that could cause our actual results to differ materially from the results discussed in the forward-looking statements. Factors that could cause actual results to differ materially from those in the forward-looking statements, include, but are not limited to, the risks implicit in the development process of preparing bovine and human eggs for fertilization; regulatory risks associated with obtaining authorization to fertilize human EggPC^{SM} cells for research; the possibility that international in vitro fertilization (“IVF”) clinics that we work with may determine not to provide or continue providing the AUGMENT treatment or OvaPrime treatment, or to delay providing such treatments, or to limit the population of patients receiving the treatments based on clinical efficacy, safety or commercial, logistic, economic, available data, regulatory or other reasons; challenges associated with enrolling and completing clinical trials, the science underlying our treatments (including the AUGMENT, OvaPrime and OvaTure treatments), which is unproven; scientific and regulatory challenges associated with characterizing and fertilizing an EggPC cell-derived egg; our ability to obtain regulatory approval or licenses where necessary for our treatments; our ability to develop our treatments on the timelines we expect, if at all; our ability to commercialize our treatments on the timelines we expect, if at all, as well as other risks described under "Risk Factors" and elsewhere in this Annual Report on Form 10-K and other filings with the Securities and Exchange Commission, or SEC. As a result of these and other factors, we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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PART I

Item 1. Business

Overview

OvaScience is a global fertility company developing proprietary potential treatments for female infertility based on scientific discoveries about the existence of egg precursor, or EggPC℠, cells. The current standard of treatment for infertility is in vitro fertilization ("IVF"), IVF, however, has a 73% average failure rate per cycle based on a 2014 report from the Center for Disease Control and Prevention (CDC). A woman is born with a set number of eggs that die over time. EggPC cells have the ability to mature into new healthy eggs, thereby enabling new fertility treatment options. Our patented technology is based on these newly discovered EggPC cells and represents a new fertility treatment option.

These EggPC cells are immature egg cells found in the protective outer lining of a woman's own ovaries. These immature egg cells have the ability to grow into fresh, young, healthy eggs. Our portfolio of fertility treatment options uses our patented technology including proprietary methods to identify and isolate EggPC cells from a patient's own ovarian tissue. By applying our EggPC technology platform in unique ways, we have commercialized one fertility treatment and are developing new fertility treatment options that are designed to improve egg health and revolutionize the fertility treatment landscape.

More women around the world are waiting until later in life to start families and are in need of new fertility treatment options. As of 2016, approximately 9% of women of reproductive age (20-42 years) worldwide are estimated to be infertile, or about 83 million women. Fertility decreases with age. The main cause of age related infertility is poor egg health, which is linked to a reduction in the number of functioning mitochondria. Unfortunately, many women cannot undergo IVF as they do not want or cannot have hormone treatment, or they make an insufficient number of eggs - or no eggs at all. The EggPC cell technology can potentially offer new options to those women.

The OvaTure℠ treatment is a potential next-generation fertility treatment that could help a woman produce healthy, young, fertilizable eggs without the need for hormone injections. The OvaTure treatment seeks to mature a woman’s own EggPC cells into eggs outside her body. This potential treatment may be an option for women with compromised eggs, who are unable to make eggs, or who may be unwilling or unable to undergo hormone hyperstimulation.

The OvaPrime℠ treatment is a potential fertility treatment that could enable a woman to increase her egg reserve. Approximately thirty-two percent of assisted reproductive technology (ART) cycles are performed on women with diminished ovarian reserve based on a 2014 report from the CDC. The OvaPrime treatment is designed to replenish a woman’s egg reserve by transferring a patient’s EggPC cells from the protective ovarian lining back into the patient’s own ovaries where they may mature into fertilizable eggs during the IVF process.

Our first commercial treatment, the AUGMENT℠ treatment, is specifically designed to improve egg health by supplementing a mitochondrial deficiency which may, in turn, offer the potential for enhanced IVF success rates. With the AUGMENT treatment, energy-producing mitochondria from a woman’s own EggPC cells are added to the woman’s mature eggs during the IVF process to supplement the existing mitochondria.

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

Increasing live birth rates and reducing the number of IVF cycles. By improving egg health, we believe we may increase the percentage of live births and reduce the number of IVF cycles required.

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

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

Replenishing the ovary for women who make too few or no eggs. Our OvaPrime treatment is designed to replenish a woman’s egg reserve by transferring a patient’s EggPC cells from the protective ovarian lining back into the patient’s own ovaries where they may mature into fertilizable eggs.

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

Developing new treatments for diseases. OvaXon[SM] is a joint venture with Intrexon, which is focused on developing significant improvements in human and animal health using our EggPC cell technology and Intrexon's synthetic biology and high throughput platform for applications.

Global Fertility Market

In 2013, 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%. Based on our company estimate, there were 2.6 million IVF (intracytoplasmic sperm injection, or ICSI) cycles performed globally in 2016, and the number of women seeking treatment for infertility is growing in certain regions (Figure 1). ESHRE estimates that 1 in 6 couples worldwide experience some form of infertility. Female infertility contributes to 65-80% of all cases. According to a 2016 report from Grand View Research, the global IVF market in 2014 was valued at $11.5 billion, and projected to grow to $27.8 billion by 2022.

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IVF Treatment and Success

IVF is one of the most common procedures in use today to address infertility.

An IVF procedure (Figure 2) typically begins with hyperstimulation of the woman's ovaries by a combination of fertility hormones. Then one or more eggs are taken from the woman's ovarian follicles and fertilized in vitro with either standard insemination, or ICSI, in which a single sperm is injected by needle into the egg. If the egg is healthy and has enough energy, it will start to divide, and the resulting embryo can be transferred into the woman's uterus 3-5 days after ICSI. These steps typically occur over several months.

Fertility decreases with age because of a decline in both egg health and embryo quality. A key factor for egg health and embryo quality is the energy level in the egg. Figure 3 demonstrates that IVF success declines with age if a woman is using her own egg. The IVF procedure also may be performed using eggs donated from another woman (donor egg). When a woman chooses to use a younger woman's donor egg, studies show that success rates are similar to a younger woman's.

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

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

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As shown in the following chart, according to a 2014 Centers for Disease Control report, IVF pregnancy success rates for women over age 35 remain relatively flat, regardless of the woman's age, when using donor eggs.

The Discovery of Egg Precursor Cells

In 2004, one of our scientific founders, Jonathan Tilly, Ph.D. (who at that point in time was the co-founder and Director of the Vincent Center for Reproductive Biology at Harvard Medical School and the Massachusetts General Hospital ("MGH"), and is currently the Chair of Northeastern Department of Biology), discovered the existence of EggPC cells within the ovaries of adult mice. Subsequent research by Dr. Tilly demonstrated that these EggPC cells also exist in human ovaries and have the potential to mature into eggs and, therefore, to replenish a woman's egg supply. This research demonstrated that these EggPC cells might provide a source of fresh cellular components, such as mitochondria, that could potentially be used to enhance the health of existing eggs.

Dr. Tilly discovered the existence of mouse EggPC cells by staining the outer cell layer of the ovary using an antibody that binds specifically to a protein found on EggPC cells called mouse VASA homologue. Following publication of this discovery in Nature Medicine in 2004, Dr. Tilly performed additional research, beginning in 2005, which demonstrated the existence of human EggPC 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 EggPC cells. Dr. Tilly also conducted an experiment in which human EggPC 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 EggPC cells were published in the March 2012 issue of Nature Medicine. These findings have been corroborated by multiple independent laboratories. We hold an exclusive license from MGH to multiple issued patents as well as various patent applications directed to methods of identifying and isolating EggPC cells, compositions comprising EggPC cells and methods of using EggPC cells to treat infertility and related disorders.

The OvaTure Treatment

The OvaTure^{SM} treatment is a potential next-generation fertility treatment that could help a woman produce healthy, young, fertilizable eggs without the need for hormone injections. The OvaTure treatment seeks to mature a woman’s own EggPC cells into eggs outside her body. This potential treatment may be an option for women with compromised eggs, who are unable to make eggs, or who are unable or unwilling to undergo hormone hyperstimulation. The OvaTure treatment would offer patients a treatment option who were not originally indicated for IVF.

In December 2013, we entered into a collaboration with Intrexon, a leader in synthetic biology, to accelerate development of OvaTure, which we refer to as the OvaTure Collaboration. The companies also formed OvaXon LLC, a joint venture designed to develop applications to prevent inherited human diseases and improve animal health.

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In 2016, the OvaTure Collaboration and OvaXon generated data supporting the characterization and developmental competence of human and bovine EggPC cell derived-eggs, respectively. Demonstrating developmental competence is a critical step towards successfully maturing an EggPC cell into a fertilizable egg, as it indicates an egg may potentially be fertilized and develop into an embryo. To demonstrate our current progress in growing EggPC cells into mature eggs, it is important to understand a concept known as gaining developmental competence, which is a series of changes that can be observed in a maturing egg as it prepares for fertilization and subsequent embryo development. In nature these steps towards gaining developmental competence happen in a defined sequence as the egg matures, and in the laboratory we use genetic and morphological criteria to measure the progress of our EggPC cell derived eggs.

The critical steps in defining developmental competence can be broken into two categories: cytoplasmic and nuclear maturation. Cytoplasmic maturation prepares the egg for fertilization by redistributing organelles and initiating post-transcriptional modification of mRNA; it is typically associated with an increase in cell volume. Mature eggs are the single largest cell in the body. In contrast, EggPC cells are quite small - less than 10 microns in both bovines and humans. We have made significant progress in demonstrating cytoplasmic maturation using our in vitro system. In the bovine models, we have observed growth from approximately 10 micron EggPC cells to approximately 120 micron eggs, while in human models, the EggPC cells have increased to approximately 100 micron eggs. We have also observed the formation of the zona pellucida in both human and bovine models; this is the thickened outer membrane that develops to protect the maturing egg and prevent fertilization from multiple sperm.

In conjunction with cytoplasmic maturation, nuclear maturation also prepares the egg for fertilization by organizing the genetic material. An immature egg has a germinal vesicle (GV), an enlarged nucleus that appears before meiotic division is completed. The next step in gaining developmental competence is nuclear maturation, which begins with the dissolution of the nuclear membrane, a process known as germinal vesicle breakdown (GVBD). The chromosomes then condense and align on the metaphase plate in preparation for their separation during metaphase II (MII). We have made great progress in demonstrating aspects of nuclear maturation using our in vitro system. In both bovine and human models, we have observed EggPC cell-derived eggs that have a GV- and we have also observed the condensed chromosomes reorganize and segregate into two sets of chromosomes. In addition, we have observed EggPC cell-derived eggs that have a polar body, one of the small cells produced during meiotic division of developing eggs that enable the correct number of chromosomes to end up in the fertilized zygote.

In addition to the genetic and morphological criteria, we performed functional tests to determine the eggs' status. One is a brilliant cresyl blue or BCB test. BCB is a blue dye which is metabolized by glucose-6-phosphate dehydrogenase. If you add BCB and the glucose-6-phosphate dehydrogenase metabolizes it, the cell is still growing and appears clear under a microscope. If the cell has stopped growing and is mature, it turns blue or BCB positive. Our research thus far has resulted in blue bovine and human eggs - an indication they are both mature.

Another functional test used to demonstrate developmental competence is parthenogenetic activation, which is the chemical induction of egg cleavage. It is used to determine if an egg is mature enough to be fertilized and is performed by chemically making the egg think that that sperm has entered it, and observing whether the egg divides. In bovine models, we have shown that the EggPC cell-derived eggs can be induced to divide into two cells, then into four cells, after parthenogenetic or chemical activation.

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The figure below outlines what we believe are the stages of development from EggPC cell to embryo:
The figure below outlines our progress in growing EggPC cells into mature eggs:

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The figure below outlines what we believe are key genetic and morphological criteria for an EggPC cell maturing into an egg:

The figure below outlines functional tests that we believe reinforce egg maturation:

In summary, as eggs mature in nature, they would begin to increase in size and develop a thickened zona pellucida. The nucleus would enlarge and form a germinal vesicle - which would then break down to allow the chromosomes to condense and separate, keeping half the genetic material and the majority of the cytoplasm in the egg and placing the remainder in the polar body for disposal. At this point the egg would be ready to fertilize. To date we have observed eggs at various stages of

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development that display the stage-appropriate hallmarks of a maturing egg and are pleased to have begun bovine fertilization studies. As we announced at the JP Morgan Healthcare Conference in 2017, we are working towards having a fertilized bovine egg by end of 2017; an embryo transfer by the end of the first quarter of 2018; and ultimately a bovine birth by the end of the first quarter of 2019.

Before we can fertilize human eggs for research purposes, we must have specific authorization. To that end, we are working with clinical partners to secure the appropriate authorization. In the meantime, we are working to make the maturation of human eggs a more repeatable, robust process so that we can increase the likelihood of success in our fertilization studies.

As we continue to progress both of these programs, we plan to approach regulatory authorities at the appropriate time to discuss our strategy moving forward.

The figure below outlines our clinical goals for our OvaTure treatment:

Our goals are forward looking statements, and there are a number of risks and uncertainties that could cause our actual results to differ materially from our forward looking statements. Please see the sections entitled “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors.”

Collaboration with Intrexon to Accelerate Development of OvaTure

In December 2013, we entered into the OvaTure Collaboration with Intrexon governing the use of Intrexon's synthetic biology technology platform for the accelerated development of our OvaTure platform. The OvaTure Collaboration provides that Intrexon will deliver laboratory and animal data to support OvaTure development. Upon the delivery of laboratory and animal data, we will incur an obligation to pay Intrexon a mid-single digit royalty on net sales of any OvaTure fertility treatment in the future, and the exact royalty will depend upon the timing of the completion of the milestone.

As a technology access fee, we (1) issued Intrexon 273,224 shares of our common stock worth approximately $2.5 million on the date of issuance upon the execution of the OvaTure Collaboration in December 2013, and (2) paid Intrexon $2.5 million cash in December 2014. We also agreed to a commercial milestone payment three months after the first commercial sale of OvaTure. The shares issued to Intrexon are subject to "piggy-back" registration rights that entitle Intrexon, unless waived, to have the shares included in any new registration statement filed in connection with an underwritten public offering, subject to underwriter cutback.

We may terminate the OvaTure Collaboration after ninety (90) days prior written notice, and either party may terminate after a material breach by the other party that is not cured within sixty (60) days. We may assign the OvaTure Collaboration in

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the event of a change of control transaction. In the event that we pursue the OvaTure program on its own after terminating the OvaTure Collaboration, the royalty will apply if Intrexon intellectual property is utilized.

OvaXon Joint Venture with Intrexon

In December 2013, we also entered into a joint venture with Intrexon to leverage Intrexon's synthetic biology technology platform and our technology relating to EggPC cells to pursue the development of potential fertility treatments within fields-of-use defined under the joint venture, which include prevention of genetic disease and animal health. The global animal genetics market is estimated at $3.7 billion as of 2016 and estimated to increase to $5.5 billion by 2021, a compounded annual growth rate of 8.4% for that time period.

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

We recorded our initial investment in OvaXon as an equity method investment in December 2013. As of December 31, 2015, OvaXon incurred expense in excess of the accumulated investment to-date. The additional expense incurred were included within accrued expenses on our balance sheet, as we had committed to provide additional funding in the future. We made additional contributions of $1.8 million in 2016. As of December 31, 2016, our equity investment in OvaXon was approximately $0.1 million.

The OvaPrime Treatment

The OvaPrime treatment is a potential fertility treatment that could enable a woman to increase her egg reserve. It is designed to replenish a woman’s egg reserve by transferring a patient’s EggPC cells from the protective ovarian lining back into the patient’s own ovaries where they may mature into fertilizable eggs during the IVF process. Approximately thirty-two percent of ART cycles are performed on women with diminished ovarian reserve. We reported large animal toxicology and small animal proof-of-concept studies relating to the OvaPrime treatment in 2014.

In August 2015, we also completed a good laboratory practices level toxicology study in cynomolgus monkeys which demonstrated the safety of the OvaPrime treatment method in a non-human primate model. All animals survived to the scheduled necropsy and no morbidity was observed. Additionally, no significant pre-to-post within-animal changes in hematology, serum chemistry, or urinalysis were observed, and all animals reestablished menstrual cycles within 69 days of egg precursor cell reintroduction. Ovarian follicular distribution at the final necropsy was comparable in the 3 dosage groups, suggesting that there was no disruption to normal ovarian physiology.

In December 2015, we agreed to an investigator sponsored study which continues in the UAE to assess the safety of the OvaPrime treatment. The primary objective of this study is to assess the use of OvaPrime in women undergoing IVF who are diagnosed with either Poor Ovarian Response (POI) (also known as premature ovarian failure (POF)), or Diminished Ovarian Response (DOR). The primary outcome of the clinical study is to assess the patient’s reproductive and fertility outcomes as assessed by egg quality, fertilization success and embryo quality; change in AMH, FSH and estradiol levels from baseline and change in the number of follicles from baseline in the treated ovary compared to the control ovary. This study is still ongoing.

In 2016, we received an IRB approval to begin an OvaPrime clinical trial in Canada. We have since begun enrolling and treating patients in our OvaPrime clinical trial, titled “A Single Center, Prospective, Controlled Pilot Study of OvaPrime Procedure”, which is being performed to evaluate the safety of the OvaPrime procedure in subjects with POI or DOR. Seventy subjects will be enrolled in this trial. Each subject will have one ovary exposed to the EggPC cells, while the other ovary is exposed to the EggPC vehicle as a means to have each subject serve as her own control. Results between the treatment and control ovary will be examined for relevant endpoints such as antral follicle counts. The primary study endpoint is to evaluate the safety of all subjects regardless of pregnancy outcome. The secondary study endpoint is to assess changes in women’s hormonal and follicular development and occurrence of pregnancy. We have completed enrollment of 50 patients under the original protocol of the study. We expect to enroll an additional 20 patients under the expanded protocol of the study, which was approved by the IRB, by the end of the

first half of 2017.

The current clinical milestones for our OvaPrime clinical study in Canada are as follows:

- complete enrollment for all 70 patients during the first half of 2017;

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- complete biopsies for all 70 patients during the second half of 2017;
- complete reintroductions for all 70 patients during the first half of 2018;
- complete embryo transfers for all patients in the first half of 2019; and
- last potential birth at the end of 2019.

In addition to the clinical milestones, data milestones for our OvaPrime clinical study in Canada include:

- initial readout: six months of post-EggPC[SM] reintroduction safety data for first 20 patients in the second half of 2017;
- initial presentation of six months post-EggPC reintroduction data for first 20 patients in the first half of 2018;
- initial data readout: six months of post-EggPC reintroduction safety data for all patients in the first half of 2019;
- initial readout: embryo transfers of all patients in the second half of 2019; and
- final readout during the second half of 2020.

The figure below outlines our clinical goals for our OvaPrime treatment:

Our goals are forward looking statements, and there are a number of risks and uncertainties that could cause our actual results to differ materially from our forward looking statements. Please see the sections entitled “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors.”

The AUGMENT Treatment

Our first treatment, the AUGMENT treatment, has been introduced in our clinic accounts outside of the United States. The AUGMENT treatment is not available in the United States. We plan to meet with the United States Food and Drug Administration, or FDA, in the first half of 2017, as part of our ongoing exploration of potential entry into the US market. An AUGMENT treatment cycle begins upon our receipt of the patient's ovarian tissue after biopsy, which is obtained through a biopsy performed by the patient's doctor prior to hormone stimulation. Our proprietary process identifies and isolates the patient’s own EggPC cells, and then the patient’s own mitochondria from these EggPC cells are further isolated. The patient’s own mitochondria are then injected into her egg at the time of ICSI. We expect to receive payment before processing the patient's tissue and defer revenue until we have met all of our treatment obligations, including the delivery of the mitochondria

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to the clinic. Based on our experience to date, the period from receipt of the patient's tissue to when we expect to record revenue is expected to range from 30 to 120 days or more. Within certain of our sales programs, revenue recognition may be further deferred.

As part of the AUGMENT treatment, a woman's eggs are injected with mitochondria from her own EggPC cells into her egg during IVF. This has the potential to improve egg health. Improved egg health may offer the potential for enhanced IVF success rates.

On December 21, 2016, we announced a strategic shift whereby we will continue to make the AUGMENT treatment available to patients at our clinic accounts in Canada and Japan, but will slow commercial expansion of the AUGMENT treatment and reassess our ongoing and planned clinical studies of AUGMENT.

Our plans are forward looking statements, and there are a number of risks and uncertainties that could cause our actual results to differ materially from our forward looking statements. Please see the sections entitled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors."

Regulation of the AUGMENT Treatment

In those countries where we have introduced the AUGMENT treatment, we believe that the AUGMENT treatment is not subject to the traditional regulatory requirements (e.g., lengthy pre-market review and approval of an application for marketing authorization) that apply to drugs, biologics, medicinal products and medical devices. However, applicable regulatory bodies may disagree with our view. If they do, we and our clinic accounts may suffer significant delay or expense or may cease offering the treatment in such countries.

The countries where we are offering the AUGMENT treatment do, in some cases, have regulations that govern IVF and other fertility treatments, which vary country by country. Those regulations may apply to the AUGMENT treatment. In some countries, there are specific fertility regulatory authorities, such as the United Kingdom's Human Fertilisation and Embryology Authority ("HFEA"), which license IVF facilities and determine what procedures such establishments may perform. In other countries, the national health authority may delegate the review of a fertility treatment to an industry self-regulatory body, an institutional review board, or other body. For example, the approval of our clinic account's application to use the AUGMENT treatment in Japan was made by the Japan Society of Obstetrics and Gynecology ("JSOG"). Further, the investigator sponsored study of the AUGMENT treatment that is conducted by the IVI Group in Spain, was approved by La Comisión Nacional de Reproducción Humana Asistida ("CNRHA").

The United States does not have a fertility regulatory body separate and apart from the FDA. In September 2013, we received an "untitled" letter from the FDA advising us to file an IND application for the AUGMENT treatment. Following the receipt of the FDA letter, we chose to suspend the availability of the AUGMENT treatment in the United States. We plan to meet with the FDA in the first half of 2017, as part of our ongoing exploration of potential entry into the U.S. market.

We, together with our clinic accounts, plan to apply on a country by country basis for whatever licenses or approvals, if any, are required to offer the AUGMENT treatment. In some cases, there are no clear guidelines on what standards may apply to the AUGMENT treatment or what licenses or approvals may be required, and we therefore have engaged and will continue to engage in discussions with regulatory authorities in certain of the countries in which we have introduced the AUGMENT treatment. If we or our clinic accounts are unable to obtain any required licenses or approvals in a particular country, if the application process takes longer than expected, or if additional licenses or approvals are required to commercialize the treatment on a large scale, then our introduction of the AUGMENT treatment in such countries may be delayed, we may incur additional expenses, and we may determine not to provide the treatment in such countries.

The Role of Mitochondria in Egg Health

Fertility decreases with age, and the energy levels in the egg are believed to play a major role in this decline (Figure 3). 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 supplemented, and the success of embryo development improved, by the injection of mitochondria from the woman's own EggPC cells into her egg at the time of fertilization.

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

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

These clinical case reports 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 clinical reports, many scientists and clinicians questioned the long-term safety of the use of third party donor mitochondria in humans because mitochondria contain DNA. Mitochondria produce energy in all cells of the body. Unlike nuclear DNA, contained in the nucleus, which is inherited from two different people, half from the biological mother and half from the biological father, mitochondrial DNA is inherited solely from the mother. As a result, while the process appeared to be safe with respect to the fertilized egg and the patient, scientists and clinicians questioned whether the presence of mitochondria, and therefore mitochondrial DNA, from two different women might adversely impact a child's health later in life. In response to these concerns, the FDA stated 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.

Our Approach. The approach we are using with the AUGMENT treatment builds on these reports but uses a woman's own mitochondria from her own EggPC cells to improve her fertility instead of third-party donor mitochondria. While all cells contain mitochondria, we believe the mitochondria from cells involved in reproduction, known as germline cells, as opposed to other cells in the body, known as somatic cells, are the ideal source of mitochondria for transfer to improve egg health. This is because somatic cells are exposed to environmental toxins and cell waste products that may cause mutations or deletions in mitochondrial DNA that can be passed on during cell division. 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 health.

The approach we are using with the AUGMENT treatment is to use germline mitochondria from the patient's own EggPC cells to improve the quality of the patient's eggs. By using mitochondria from the woman's own EggPC cells, instead of from a third party donor, the AUGMENT treatment does not involve the transfer of third-party genetic material.

Publication of AUGMENT Treatment Experience in Peer-Reviewed Journal. In August 2015, the first published analysis comparing the AUGMENT treatment to standard IVF within the same woman within the same cycle was included in the peer-reviewed Journal of Fertilization: In Vitro- IVF-Worldwide Reproductive Medicine, Genetic & Stem Cell Biology. The analysis demonstrated statistically significant higher rates of embryo selection and transfer with the AUGMENT treatment based on standard embryo quality measures, including preimplantation genetic diagnosis/screening, resulting in statistically significant higher rates of pregnancy.

AUGMENT Treatment Steps

We designed the AUGMENT treatment to use mitochondria from a woman's own EggPC cells in IVF procedures to improve the energy and health of the woman's eggs. The following is a summary of the process that we are using to prepare the patient's own mitochondria for injection into one of her own mature eggs during IVF:

- Obtain Ovarian Tissue: Ovarian surface tissue is obtained by the IVF clinic prior to the AUGMENT treatment.
- Identify and Isolate EggPC Cells: We receive the ovarian tissue and perform all AUGMENT related proprietary procedures needed to isolate the EggPC cells. Ovarian tissue is washed, digested with enzymes, and mechanically dissociated to form a solution containing single cells. EggPC cells will be separated from the other cells in the single cell solution by a process known as fluorescence activated cell sorting, or FACS, and the use of our proprietary

monoclonal antibody. EggPC cells can then be processed for isolation of mitochondria (described below) or frozen and stored in vials until the day of egg fertilization in the IVF process.

- Prepare Mitochondria from EggPC Cells: We perform all AUGMENT related proprietary procedures needed to isolate the mitochondria from EggPC cells. EggPC cells will be disrupted mechanically and mitochondria isolated by differential centrifugation.

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- Inject EggPC Cell Mitochondria into Egg: An embryologist at a clinic, trained by us, receives the preparation of mitochondria and injects it into the egg, in a single injection alongside the sperm, during the ICSI step of 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 EggPC cells is performed using commercially available separation techniques. However, we have developed a proprietary monoclonal antibody to identify these cells, as the commercially available antibodies have been shown to be far less than optimal. The proprietary antibody has enabled us to establish a reliable and consistent method to readily identify and isolate the EggPC cells. Because the EggPC technology serves as the basis for all of our fertility treatments, including those on the market and in development, our proprietary monoclonal antibody and proprietary process by which EggPC cells are identified and isolated, together with a number of issued and pending patents, provides a strong intellectual property foundation.

We have established current Good Tissue Practices ("cGTP")-compliant facilities and currently perform the steps in the process ourselves in our laboratories either within or contiguous to the IVF clinics in which the AUGMENT treatment is offered.

Research and Development Spending

During the years ended December 31, 2016, 2015 and 2014 we spent approximately $21.6 million, $18.4 million and $21.8 million, respectively, on our research and development activities.

Manufacturing

We have established cGTP-compliant laboratories to perform the necessary steps for AUGMENT and OvaPrime either within or contiguous to the international IVF clinics in which our fertility treatments are offered.

In addition, we have contracted with a third-party supplier to perform the identification and isolation of EggPC cells and the preparation of mitochondria steps in the AUGMENT process in the event we decide to undertake offsite manufacturing. Our supplier has significant experience in tissue and cell therapy manufacturing. In regions outside of the United States, we may contract with third parties, through partnerships, out-licenses or other arrangements, to process and manufacture our potential fertility treatments.

Marketing and Sales

During 2016, we continued to expand our global sales and marketing team in anticipation of a commercial launch of our AUGMENT treatment in regions outside of the United States. In December 2016, we announced a corporate restructuring based on a strategic decision to slow our commercial expansion, which included a reduction of our workforce, including our global sales and marketing team.

UK Headquarters and Foreign Subsidiaries

We have established international headquarters in the United Kingdom to coordinate our international commercial efforts. We have also established subsidiaries in certain key regions where we will offer our fertility treatments. These subsidiaries are part of an international legal entity structure through which we plan to (and have, in some cases) license the ex-US commercial rights to the AUGMENT treatment, as well as the OvaPrime treatment, OvaTure treatment and any other potential future products or treatments. This arrangement would allow any potential value enhancement and future profits for the assets to be shared between us and the subsidiaries.

Intellectual Property

We believe we have a strong and growing intellectual property portfolio. We aggressively strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover our treatments 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.

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Patents and Patent Applications

As of February 24, 2017, we own or have exclusively licensed 58 issued patents in 44 countries and jurisdictions and have more than 150 applications pending in more than 130 countries (including applications directly filed in countries and applications filed in regional patent offices), with three of the pending applications currently in allowance.

One family of patents and applications that we own by way of assignment from our own inventors provides protection into 2035 and is directed to a plurality of monoclonal antibody compositions and methods of using those compositions to isolate EggPC cells, a step common to each one of our AUGMENT, OvaPrime and OvaTure treatments. This family includes two issued U.S. patents, one pending U.S. application, and approximately fifty patent applications pending or in the process of being filed in nearly 130 foreign countries.

We have exclusively licensed a portfolio of patent applications owned or co-owned by The General Hospital Corporation, the corporate entity of MGH, pursuant to an agreement that is summarized below. As of February 24, 2017, we held an exclusive license under this agreement to seven issued U.S. patents owned by MGH, three pending U.S. non-provisional patent applications owned by MGH, forty-four patents issued by patent offices outside of the United States which are owned by MGH, sixty-eight applications pending with patent offices outside of the United States which are owned by MGH, two pending U.S. non-provisional applications co-owned by MGH and The President and Fellows of Harvard College, or Harvard, and seventeen applications pending in patent offices outside of the United States which are co-owned by MGH and Harvard.

One family of patents and applications that we have licensed from MGH is directed to female germline stem cells, including methods of isolating such female germline stem cells and various uses for such female germline stem cells, including methods for IVF, methods for egg production, methods to treat infertility and methods to restore ovarian function. This family includes issued patents in the U.S., Canada and 30 European countries, all of which will expire in May 2025. We believe that some of the patents of this family provide protection for therapeutic compositions comprising EggPC cells, which are referred to in the patents as female germline stem cells, and that some of the patents of this family provide protection for elements of the manufacturing process for obtaining such therapeutic compositions.

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

A third family of patent applications that we have licensed from MGH is directed to methods and compositions for autologous germline mitochondrial energy transfer. A total of eighteen patents have issued in this family as of February 24, 2017, including three in the U.S., two in each of Australia and South Africa, and one in each of Canada and Japan and nine other countries/jurisdictions. Further, over fifty applications are pending in the U.S. and foreign patent offices. These applications provide opportunity for obtaining patents not only in the countries/jurisdictions in which at least one patent has already issued, but also in nearly 120 others. The issued patents, and any additional patents claiming priority to the underlying provisional applications, will expire in April 2032 unless patent term extension is granted. We believe that these patents, and any patents issuing from this family, provide protection for the AUGMENT treatment and several important aspects thereof.

A fourth family of patent applications that we have licensed from MGH and Harvard is directed to methods and compositions for enhancing the bioenergetic status in oocytes or EggPCs. This family includes two pending U.S. non-provisional patent applications, and eighteen applications that are pending with patent offices outside of the United States. The applications in this family provide opportunity for obtaining patents in more than sixty countries/jurisdictions. Any patents claiming priority to the underlying provisional application would expire in April 2032 unless patent term extension is granted. We believe that patents issuing from this family may provide protection for aspects of the AUGMENT procedure, as well as culture media that we may develop in the future.

In our efforts to improve the AUGMENT treatment, we invented a method of isolating mitochondria from EggPCs and concentrating the mitochondria in the picoliter-scale volume required for injection into oocytes as part of the AUGMENT treatment. We own this patent family, with applications currently pending in the U.S., Argentina and

Taiwan, and opportunity to file in nearly 150 other countries remaining preserved into the second quarter 2017. Additionally, we own one issued U.S. patent and one pending U.S. non-provisional patent application, with all issued patents expiring in June 2026. We believe that patents issued or issuing from this family may provide protection for an alternative method of producing healthy eggs.

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

Exclusive License Agreement with Massachusetts General Hospital

In June 2011, we entered into an exclusive license agreement with MGH under which we acquired an exclusive, worldwide, royalty-bearing license to specified patent rights owned by MGH and a non-exclusive license under specified know-how to make, use and sell products and processes and to develop and perform services covered by the licensed patent rights or which employ or are based on the licensed know-how in certain specified licensed fields. The license further included the grant to us under certain patent rights co-owned by MGH and Harvard to make, use and sell products and processes and to develop and perform services covered by such patent rights for use in ex vivo human female fertility treatments.

Pursuant to amendments dated September 2011, July 2013, September 2013, November 2013, December 2013 and August 2016, we agreed to expand the licensed field of the patent rights solely owned by MGH to include all uses, including human female fertility, the treatment or prevention of inherited (including mitochondrial) diseases or defects in all animals, including humans, assisted and/or artificial reproductive technology in all non-human animals, the artificial creation of food, research animals and/or animal products, the treatment of menopause and all diagnostics. Under the terms of this license agreement, as amended, we have agreed to pay MGH upfront license fees, annual license fees and an annual maintenance fee and agreed to reimburse MGH for certain patent related fees and costs incurred by MGH and Harvard, including past patent fees and costs totaling approximately $0.4 million in the aggregate. We also agreed to pay MGH milestone payments of up to an aggregate of approximately $10.9 million upon the achievement of specified developmental and commercialization milestones. We are also obligated under this license agreement to make a payment to MGH upon our consummation of certain specified liquidity events, subject to a specified cap. To date, we have we paid MGH an aggregate of $0.5 million in connection with our consummation of public offerings that fall within the definition of a liquidity event for purposes of this license agreement.

We are further obligated under this license agreement to pay MGH a royalty in the low single digits based on net sales of licensed products and processes that we commercialize under the agreement. Net sales are defined under this license agreement to exclude any amounts billed to patients by clinics and medical practices that use licensed products or perform licensed services for patients, but to include the amounts paid to us by such clinics and medical practices. Our obligation to pay royalties for each licensed product and process expires on a country-by-country basis on the date of expiration of the licensed patent rights that cover that licensed product or process in that country except that, solely with respect to the license under certain patent rights co-owned by MGH and Harvard for ex vivo human fertility treatments, our obligation to pay a royalty will continue at a reduced rate for a period of three (3) years after the expiration of such patent rights if the licensed patent rights covered the licensed product or process in that country prior to expiration. Royalty rates are subject to reduction in any country if we are required to obtain a license from any third party to the extent the licensed patent rights infringe the third party’s patent rights if such payments are in excess of one percent (1.0%) of net sales. If we enter into a sublicense under this license agreement, we will be obligated to pay MGH a percentage of certain consideration paid to us by the sublicensee.

We are required to use commercially reasonable efforts to develop and commercialize licensed products and licensed processes under this license agreement. In particular, we are required to achieve specified development and commercialization milestones in certain countries by specified dates, which dates may be subject to extension by us

upon making certain specified payments to MGH.

Under the terms of the agreement, MGH and Harvard have retained the right to practice the licensed patent rights within the licensed fields for research and educational purposes only.

We have the right to terminate the agreement for any reason upon at least 90 days' prior written notice. MGH has the right to terminate the agreement if we fail, subject to a specified cure period, to pay any amounts due and payable under the agreement to MGH, we otherwise materially breach the agreement and fail to cure such breach within a specified cure period, we fail to maintain insurance coverage as required under the agreement, we enter bankruptcy proceedings or make an

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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 potential fertility treatments. Some of these treatments, similar to our current and future fertility treatments, are designed to address the shortcomings of IVF.

In particular, we are aware of a number of companies and laboratories that are currently developing potential fertility treatments intended to identify high quality embryos for use in IVF and a university study of the transfer of granulosa cell mitochondria into eggs. We are also aware of a university study of induced pluripotent stem cells, or iPS, showing that iPS cells can be generated from somatic cells and programmed to become differentiated cells, which can include germline cells such as oocytes. However, we believe it is unlikely this approach would have clinical applications because these are non-germline, pluripotent cells. Novocellus Ltd. is developing an embryo viability test, using culture media, to aid in the selection of embryos used in IVF. We believe that culture media is complementary to our fertility treatment options. FertiliTech and Auxogyn, Inc. are developing hardware and software that analyzes embryo development against cell division timing parameters to help identify the highest quality embryo within a group of embryos. If successfully developed, these products could improve outcomes and alleviate some of the other shortcomings of traditional IVF, thereby decreasing the need for our potential fertility treatments. Fertility Focus, along with strategic partner Norgenix, are developing a fertiloscope for the early diagnosis of, and immediate corrective surgery for, the physical causes of infertility. Molecular diagnostic companies like Reprogenetics are developing novel preimplantation genetic diagnosis and screening methods to detect chromosomal and genetic disorders of embryos prior to transfer back to the women. Testing embryos in this manner may increase the likelihood of pregnancy, reduce the chances of pregnancy loss, and improve the odds of delivery.

There can be no assurance that we will be able to compete effectively. Our competitors may develop and commercialize new technologies before we do, allowing them to offer products, services or solutions that are superior to those that we may offer or that establish market positions before the time, if any, at which we are able to bring potential fertility treatments to the market. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. Our competitors' products may be more effective, or more effectively marketed and sold, than any treatment we may commercialize and may render our potential fertility treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our potential fertility treatments. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available. We also face competition from standard IVF clinics.

For the AUGMENT treatment and OvaPrime treatment, our ability to gain market acceptance will depend on, among other things, our ability to demonstrate improved IVF success rates, thereby reducing the number of cycles required to produce a live birth, our ability to reduce multiple births, and our ability to treat patients that face particular challenges with traditional IVF, such as patients with diminished ovarian reserve. Our ability to gain market acceptance for the OvaTure treatment, if and when introduced, 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 for all our fertility treatment options. At this time, we cannot evaluate how our potential fertility treatments, if successfully developed and commercialized, would compare technologically, clinically or commercially to any other potential products being developed or to be marketed by competitors.

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Government Regulation

Government authorities around the world regulate, among other things, the development, testing, manufacture, quality, approval, distribution, labeling, packaging, storage, record keeping, sale, marketing, import, export and promotion of drugs, biologics and medical devices, as well as other types of medical products and procedures. Most countries also have rules relating to procurement and use of human tissues or cells, and rules relating to assisted human reproduction. Although the specific rules vary country by country, in general different levels of regulation are applicable depending on the nature of the treatment, the level of risk involved, and/or its intended uses. Some classes of products (e.g., treatments regulated as drugs or biologics in the United States, or treatments regulated as medicinal products in the EU) require extensive preclinical testing, clearance to conduct clinical trials, successful completion of clinical trials, and submission and approval of an application for marketing authorization before the therapy can be commercially marketed. Such products also are subject to significant post-marketing requirements.

Many countries also specify various classes of therapies that are exempt from the above-mentioned pre-market review and approval requirements. In these jurisdictions, the development and marketing of such therapies generally do not require the conduct of clinical trials or pre-review and approval of a marketing application by the relevant regulatory authority. In addition, although many such therapies are still subject to post-marketing requirements, these requirements typically are substantially reduced as compared to the requirements for drugs, biologics, medicinal products or medical devices.

There can be no assurance that regulatory authorities in countries where we have introduced, or will introduce, the AUGMENT treatment or the OvaPrime treatment will agree with our determinations that these fertility treatments are exempt from pre-market review and approval as a drug, biologic, medicinal product or medical device. If the regulatory authorities in a given country disagree with our determination, then we likely will be required to cease commercial marketing of that fertility treatment in that country, and may not be able to resume commercial marketing without first demonstrating safety and efficacy through clinical trials, submitting an application for marketing authorization, and receiving approval from the relevant regulatory authorities. In these circumstances, we are likely to be significantly delayed in our ability to commercialize our fertility treatments in such country, or we may elect to cease our commercialization activities in that country altogether. From time to time, we engage in discussions regarding the AUGMENT treatment and our potential fertility treatments with regulatory authorities in certain of the countries in which we have launched or plan to introduce our fertility treatments. We expect to have ongoing dialogue with these regulatory authorities.

With regard to the United States, we commenced a clinical study of the AUGMENT treatment in the United States in 2012. We did so without an IND on the basis of our determination that the AUGMENT treatment was exempt from pre-market review and approval in the United States and did not require an IND to conduct clinical testing. In 2013, however, we received an "untitled" letter from the FDA questioning our determination of exempt status and advising us to file an IND for the potential fertility treatment. We have since discontinued our clinical study and are focused on commercializing our fertility treatments outside of the United States. We plan to meet with the FDA in the first half of 2017, as part of our ongoing exploration of potential entry into the U.S. market.

European Union Requirements

Regulation of Medicinal Products

If the authorities in certain EU countries were to determine that any of our potential treatments are subject to regulation as medicinal products, including as advanced therapy medicinal products, they would be subject to extensive pre- and post-market regulation by regulatory authorities at both the EU and national levels. Advanced therapy medicinal products include 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.

Clinical Trials. Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations and the International Conference on Harmonization, or ICH, guidelines on Good Clinical Practices, or GCP. Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the competent authority, and a positive opinion from an independent ethics committee. Currently, clinical trial authorization applications must be submitted to the competent authority in each EU member state in which the trial

will be conducted. Under the new Regulation on Clinical Trials, which is expected to take effect in October 2018, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

During the development of a medicinal product EMA, and national medicines regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human

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Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned. To date, we have not initiated any scientific advice procedures or other discussions with the EMA or any national regulatory authorities in the EU.

Marketing Authorizations. After completion of the required clinical testing, we must obtain a marketing authorization before we may place a medicinal product on the market in the EU. There are various application procedures available, depending on the type of product involved. All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and non-clinical and clinical trial information. There is an increasing trend in the EU towards greater transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the non-clinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. Clinical study reports will also be posted on the EMA's website following the grant, denial or withdrawal of a marketing authorization application, subject to procedures for limited redactions and protection against unfair commercial use.

The centralized procedure gives rise to marketing authorizations that are valid throughout the EU and, by extension (after national implementing decisions), in Norway, Iceland and Liechtenstein, which, together with the EU member states, comprise the European Economic Area, or EEA. Applicants file marketing authorization applications with the EMA, but the marketing authorization itself is granted by the European Commission. The centralized procedure is compulsory for medicinal products that (1) are derived from biotechnology processes, (2) contain a new active substance (approved after November 20, 2005) indicated for the treatment of certain diseases, (3) are orphan medicinal products or (4) are advanced therapy medicinal products, such as cell therapy medicines. 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 (i) the medicine concerned contains a new active substance (approved after November 20, 2005), (ii) the medicine is a significant therapeutic, scientific, or technical innovation, or (iii) if its authorization under the centralized procedure 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 applications to the national medicines regulators through one of three procedures: (1) a national procedure, which results in a marketing authorization in a single EU member state; (2) the decentralized procedure, in which applications are submitted simultaneously in two or more EU member states; and (3) the mutual recognition procedure, which must be used if the product has already been authorized in at least one other EU member state, and in which the EU member states are required to grant an authorization recognizing the existing authorization in the other EU member state, unless they identify a serious risk to public health.

The EU medicines rules expressly permit the member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal product containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells. Thus, it is possible that the national laws in certain EU member states may prohibit or restrict us from commercializing our fertility treatments, even if they have been granted an EU marketing authorization.

Data Exclusivity. Marketing authorization applications for generic medicinal products do not need to include the results of pre-clinical and clinical trials, but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate pre-clinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

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Post-Approval Controls. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, or QPPV, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new marketing authorization applications must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. Risk management plans and PSURs are routinely available to third parties requesting access, subject to limited redactions.

All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another.

Medicinal products may only be manufactured in the EU, or imported into the EU from another country, by the holder of a manufacturing authorization from the competent national authority. The manufacturer or importer must have a qualified person, or QP, who is responsible for certifying that each batch of product has been manufactured in accordance with EU standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the EU or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Regulation of Medical Devices

If European regulatory authorities were to determine that any of our potential treatments are subject to regulation as a medical device, the following requirements would apply. A medical device may be placed on the market within the EEA if it conforms to certain "essential requirements". These are general in nature and broad in scope. The most fundamental essential requirement, for example, is that a 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 or other persons. Other essential requirements include that the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner, and any undesirable side effect must constitute an acceptable risk when weighed against the performances intended.

The manufacturer is obliged to demonstrate that the device conforms 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: the length of time the device is in contact with the body, the degree of invasiveness, and the extent to which the device affects the anatomy. Class I (low risk) devices are those that do not enter or interact with the body. Class IIa and IIb (medium risk) devices are invasive or implantable or interact with the body. Class III (high risk) devices are those that affect the vital organs.

Conformity assessment procedures for all but the lowest risk classification of device involve a notified body. Notified bodies are entities licensed to provide independent certification of certain classes of medical device. Most notified bodies are private commercial entities, but some are state bodies and others are structured as private non-profit organizations.

EU regulatory bodies are not involved in the pre-market approval of medical devices, with only very limited exceptions (such as medical devices that incorporate a medicinal product as an ancillary substance). The onus of ensuring a device is safe enough to be placed on the market is ultimately the responsibility of the manufacturer and the notified body.

As part of the conformity assessment procedure, the manufacturer will need to conduct a clinical evaluation of the device. This clinical evaluation may consist of an analysis of the scientific literature relating to similar devices, new clinical investigations of the device, or a combination of the two. For class III devices, the conduct of clinical investigations is mandatory. Such studies must adhere to the Declaration of Helsinki, which requires appropriate

ethics committee approval of the study.

Once the appropriate conformity assessment procedure for a medical device has been completed, the manufacturer must draw up a written declaration of conformity and affix the CE mark to the device. The device can then be marketed throughout the EEA.

Manufacturers must put in place a device vigilance system that allows them to review relevant post-marketing experience and take corrective actions where necessary. As part of that system, manufacturers must report to the competent regulatory

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authorities any adverse incident related to a medical device that leads or might lead, directly or indirectly, to the death of a patient, user or other person or to a serious deterioration in their state of health. They must also report any recalls or other field safety corrective actions.

Human Cells and Tissues

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 pre-market review and approval, nor do they require extensive preclinical and clinical testing. However, there are EU rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are advanced therapy medicinal products. These rules also cover the processing, preservation and distribution of human cell 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. More detailed rules may exist at the national level.

IVF Treatment

While the procurement, processing and distribution of gametes and embryos for use in IVF and other assisted reproduction treatments falls within the scope of the EU rules governing human cells and tissues, there are no harmonized EU requirements for the performance of IVF and other medical treatments. Instead, the practice of medicine is regulated entirely at the national level in the individual member states. In some EU countries, there are specific regulatory authorities, such as the United Kingdom’s HFEA, which license IVF facilities and determine what procedures such establishments may perform. In other EU countries, the national health authority may review or delegate the review of a fertility treatment to an industry self-regulatory body, an institutional review board, or other body. For example, the investigator sponsored study of the AUGMENT treatment that is conducted by the IVI Group in Spain, was approved by La Comisión Nacional de Reproducción Humana Asistida ("CNRHA").

We believe that neither the AUGMENT treatment nor, when introduced and available, the OvaPrime treatment are subject to regulation as a medicinal product or a medical device in the EU, and instead is subject to the less rigorous regulations that apply to use of human cells and tissues that are intended for human applications and to any national rules that govern IVF treatment. When we proceed with the introduction of our treatments into certain countries within the EU on this basis, there is a risk that European or national regulatory authorities may reach a different conclusion.

United States Requirements

The FDA regulates human cell, tissue, or cellular or tissue-based products ("HCT/Ps") according to a tiered, risk-based approach. Under this approach, some HCT/Ps are regulated as biological products or as drugs or devices under the Public Health Service Act, or PHSA, the Federal Food, Drug, and Cosmetic Act, or FDCA, and the agency’s implementing regulations. Section 351 of the PHSA prohibits the introduction of a biological product into interstate commerce without an FDA-approved application for marketing authorization under that section. For pioneer products, the typical application under section 351 of the PHSA is the biologics license application ("BLA").

Biological products, including certain HCT/Ps, that are regulated under section 351 of the PHSA are subject to significant pre and post-market regulation. Section 351 of the PHSA prohibits the introduction of a biological product into interstate commerce without an FDA-approved biologics license application ("BLA"). After approval, a BLA product is subject to significant requirements relating to, among other things, manufacturing, adverse event reporting, advertising and promotion, distribution, packaging, labeling, import/export, and record keeping.

Certain HCT/Ps, however, are regulated solely under section 361 of the PHSA, which authorizes the FDA to promulgate regulations to prevent the spread of communicable diseases. Such products are referred to as "section 361 HCT/Ps." The FDA will regulate an HCT/P as a section 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:

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- the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function, or
- the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function and
(a) is for autologous use,
(b) is for allogeneic use in a first or second degree blood relative, or
(c) is for reproductive use.

HCT/Ps that meet all of these requirements are deemed are regulated exclusively under section 361 of the PHSA and the FDA's implementing regulations at 21 C.F.R. Part 1271. These regulations impose requirements for registration and listing, donor screening and testing, and good tissue practices, among other things. They do not, however, impose the IND requirements or the pre-market review and approval requirements described above for biologics regulated under section 351 of the PHSA.

Some HCT/Ps may be exempt from the requirements for section 351 biologics and section 361 HCT/Ps. For example, establishments that remove HCT/Ps from a donor and return them to the same donor during a single surgical procedure are exempt from the requirements for both section 351 biologics and section 361 HCT/Ps.

It is not certain how FDA would regulate any of our current or potential fertility treatments. As discussed above, in 2012 we commenced a clinical study of the AUGMENT treatment in the United States, but subsequently received from the FDA an "untitled" letter questioning the status of the AUGMENT treatment as a section 361 HCT/P, and advising us to file an IND for the potential fertility treatment, following which we suspended our commercialization efforts in the United States. We believe that the AUGMENT treatment could meet the criteria for regulation as a section 361 HCT/P, but there is no guarantee that FDA would agree with our classification of the AUGMENT treatment or any of our potential fertility treatments. We plan to meet with the FDA in the first half of 2017, as part of our ongoing exploration of potential entry into the U.S. market.

Other Healthcare Laws and Compliance Regulations

Both in and outside of the United States, our activities may be subject to regulation by various federal, state and local authorities in addition to the FDA or EMA. In the United States, this likely includes the Centers for Medicare and Medicaid Services ("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, and ex-US equivalents. Our operations in the relevant jurisdictions must comply with all of these applicable requirements or we may be unable to conduct our business or may face civil or criminal sanctions.

We are also subject to varying anti-corruption laws that exist both in the United States, where we are based, and the various countries in which we operate or otherwise offer our fertility treatments. For example, the Foreign Corrupt Practices Act ("FCPA"), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The Securities and Exchange Commission (SEC) is involved with enforcement of the books and records provisions of the FCPA. Failure to comply with the FCPA or similar laws in other countries where we operate could subject us to significant penalties that could have a material impact on our business.

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 the OvaTure treatment, the OvaPrime treatment, the AUGMENT treatment, or other potential fertility treatments we may attempt to commercialize. Thus, it is likely that IVF clinics and physicians will be able to use the AUGMENT treatment, the OvaPrime treatment, the OvaTure treatment and our other potential fertility treatments

only if the patient can afford and is willing to pay for our treatment out of pocket. The cost of the AUGMENT treatment, the OvaPrime treatment, the OvaTure treatment, and our other potential fertility treatments may be beyond the means of many patients.

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Third party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a treatment or procedure may be separate from the process for setting the price or reimbursement rate that the payor will pay for the treatment or procedure. Even if third party payors were to provide some minimal level of coverage and reimbursement for the AUGMENT treatment, the OvaPrime treatment, the OvaTure treatment or our other potential fertility treatments, such third party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness, in addition to the safety and efficacy, of medical products and procedures.

In the EU and elsewhere, governments influence the price of medical products and procedures through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of consumers' medical costs. Some jurisdictions operate positive and negative list systems under which treatments or procedures may be marketed only after a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of our particular treatments or procedures to currently available therapies. Other countries allow medical companies to fix their own prices, but monitor and control company profits. The downward pressure on healthcare costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new treatments and procedures.

Employees

As of December 31, 2016, we had 118 full-time employees. On December 21, 2016, we announced a corporate restructuring in which we would be reducing our workforce by approximately 30%. The majority of the reduction in workforce occurred in January 2017. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Our Corporate Information

We were incorporated under the laws of the State of Delaware in April 2011 under the name Ovastem, Inc. and changed our name to OvaScience, Inc. in May 2011. Our principal executive offices are located at 9 Fourth Avenue, Waltham, Massachusetts 02451, 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 SEC, on the Investors section of our website at www.ovascience.com or by contacting our Corporate Communications department at (617) 500-2802. The contents of our website are not incorporated by reference into this report and you should not consider information provided on our website to be part of this report.

Item 1A. Risk Factors

RISK FACTORS

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We commenced active operations in April 2011. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential fertility treatments, researching and developing the OvaTure, OvaPrime and AUGMENT treatments, introducing the AUGMENT treatment in

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select international IVF clinics, and determining the development and regulatory paths for our fertility treatments. 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.

We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by young businesses in new and rapidly evolving fields. For example, to execute our business plan, we will need to be successful in a range of challenging activities, including pursuing clinical trials of the OvaPrime treatment and introducing that treatment into international IVF clinics, completing development and optimization of the OvaTure treatment, continuing to make the AUGMENT treatment available in select international markets, obtaining any required approvals, manufacturing, marketing and selling those potential fertility treatments that we successfully develop, and addressing the challenges of foreign operations.

In addition, as a young business with a short operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We recently announced a change in our corporate strategy, including a shift to focus on the development of OvaPrime and OvaTure. We cannot assure you that this shift will be successful.

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 $82.3 million for the year ended December 31, 2016. As of December 31, 2016, we had an accumulated deficit of $250.2 million. We have recorded limited revenues to date and have financed our operations primarily through equity financings. We have devoted significant efforts to research and development, acquiring our technology, researching and developing the OvaPrime, OvaTure and AUGMENT treatments and building out our international infrastructure.

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

- advance the clinical development of the OvaPrime treatment, including through ongoing clinical trials as well as any AUGMENT clinical trials;
- Pursue OvaTure fertilization studies;
- continue advancing the preclinical development of the OvaTure treatment, both internally and in collaboration with Intrexon, including the maturation of an EggPC cell-derived egg, and the development of other potential fertility treatments, and ultimately introduce the OvaTure treatment;
- educate physicians and embryologists regarding the use of the OvaTure, OvaPrime and AUGMENT treatments;
- in the long term, establish a domestic and international sales, marketing, manufacturing and distribution infrastructure to commercialize our fertility treatments;
- initiate any additional clinical trials of our fertility treatments;
- collaborate with Intrexon through the OvaXon joint venture to develop significant improvements in human and animal health using our EggPC cell technology and Intrexon's synthetic biology and high throughput platform for applications;
- seek any required approvals from the FDA or similar regulatory agencies outside of the United States, which we refer to as Foreign Regulatory Authorities, for our potential fertility treatments that require such approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional scientific, clinical, quality control and management personnel internationally and in the United States to support our fertility treatment development efforts;
- seek to identify additional potential fertility treatments; and
- develop, acquire or in-license other potential fertility treatments and technologies.

To become and remain profitable, we must develop and eventually commercialize our potential fertility treatments with significant market potential, including the OvaTure treatment and the OvaPrime treatment and continue to offer the AUGMENT treatment commercially, and determine strategies to scale our treatments commercially. This will require us to be successful in a range of challenging activities, completing preclinical and clinical trials for our treatments, obtaining any

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necessary regulatory approvals and successfully commercializing, either alone or with partners. 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. If we do achieve profitability, we may not be able to sustain 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 fertility treatment development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development and commercialization of our fertility treatments. We are focused on developing the OvaTure and OvaPrime treatments and have introduced the AUGMENT treatment in IVF clinic accounts outside of the United States. We expect to incur significant expenses with respect to our continued development and optimization of the OvaTure treatment and our clinical trials for our fertility treatments. Any clinical trials that we are required to conduct for these fertility treatments will be costly. Furthermore, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate some or all of our research and development programs or commercialization efforts.

We believe that our cash and cash equivalents and short-term investments of approximately $114.4 million at December 31, 2016, will be sufficient to fund our current operating plan for at least the next 24 months. There can be no assurances, however, that the current operating plan will be achieved or that additional funding, if needed, will be available on terms acceptable to us, or at all.

Our future capital requirements will depend on many factors, including:

- the clinical development of the OvaPrime treatment and the AUGMENT treatment, and subsequent adoption by international IVF clinics;
- the costs associated with preclinical development and subsequent clinical trials of the OvaTure treatment and other potential fertility treatments;
- the costs associated with establishing a domestic and international sales, marketing, manufacturing and distribution infrastructure to commercialize fertility treatments that we successfully develop, and to continue to sell the AUGMENT treatment;
- the pricing of the AUGMENT treatment and resulting revenues, as well as any future revenues we receive from our potential fertility treatments;
- the costs associated with the non-commercial preceptorship training programs and clinical studies and trials;
- the costs of continuing the optimization of the OvaTure treatment and preclinical development of that treatment, and our success in defining a clinical pathway;
- the costs involved in collaborating with Intrexon through the OvaXon joint venture to create new applications to prevent inherited diseases for human and animal health;
- following any applicable regulatory process in the United States and abroad, including the premarketing and marketing approval requirements, to which any of our potential fertility treatments may be subject;
- following any regulatory or institutional review board review of our potential fertility treatments that are subject to such review;
- preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- establishing collaborations and partnerships on favorable terms, if at all; and
- developing, acquiring or in-licensing other potential fertility treatments and technologies.

Identifying, developing and commercializing potential fertility treatments is a time consuming, expensive and uncertain process that takes years to complete. We may fail to achieve sufficient revenues from our fertility treatments to achieve profitability on our expected timelines or at all. 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.

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

Until the time, if ever, that we can generate sufficient revenues from our potential fertility treatments and from the AUGMENT treatment to become profitable, we plan to finance our cash needs through some combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or potential fertility treatments or grant licenses on terms that may not be favorable to us.

We are currently subject to a securities class action lawsuit, the unfavorable outcome of which may have a material adverse effect on our financial condition, results of operations and cash flows.

In October 2015, a purported class action lawsuit was filed against us, certain of our executive officers, the members of our board of directors and certain of the underwriters from our January 2015 follow-on public offering of our common stock by investors alleging violations of the Securities Act of 1933, as amended. On November 9, 2016, a second purported derivative action was filed against certain present and former officers and directors of the company alleging breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement and corporate waste for purported actions related to our January 2015 follow-on public offering. While we believe we have substantial legal and factual defenses to these claims in these lawsuits and we will vigorously defend the lawsuits, the outcome of litigation is difficult to predict and quantify, and the defense against such claims or actions can be costly and divert management resources. In connection with these lawsuits, we could incur substantial costs and such costs and any related settlements or judgments may not be covered by insurance.

We have limited experience in marketing and selling our fertility treatments, and if we are unable to successfully commercialize our fertility treatments, our business and operating results will be adversely affected.

We have limited experience marketing and selling our fertility treatments, and we have had limited success in our commercialization activities to date. We have introduced the AUGMENT treatment in partner IVF accounts outside the United States and will continue to offer the treatment to patients at clinic accounts in Canada and Japan. Our ability to generate revenue in the near term, however, will depend on continued enrollment at our clinic accounts, the number of commercial AUGMENT treatment cycles our clinic accounts perform and the treatment prices charged. In addition, we plan to continue clinical trials of the OvaPrime treatment, and preclinical development of the OvaTure treatment. However, these activities are at early stages and may not ever yield positive data or treatments that will become commercially available to patients.

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

We have recently changed our corporate strategy to focus on the OvaPrime treatment and the OvaTure treatment, each of which is at a substantially earlier stage of development than the AUGMENT treatment. As a result, it will take a longer period of time for us to commercialize a product that will generate meaningful revenues.

In December 2016, we announced that we would slow the commercial expansion of the AUGMENT treatment, reassess our ongoing and planned clinical studies of AUGMENT, and undertake a corporate restructuring. These changes will enable us to extend our cash position into the first quarter of 2019 and increase our focus on the development of OvaPrime and OvaTure. Both of those treatments are at a substantially earlier stage of development than the AUGMENT treatment is. Accordingly, we expect that it will take a longer period of time for us to generate revenues from the sale of our treatments than it would have had we continued to pursue the commercial expansion of the AUGMENT treatment in accordance with our previous corporate strategy. The process of developing OvaTure and OvaPrime is uncertain and may never yield products that allow us to achieve revenue from their sale.

The science underlying the OvaTure treatment, the OvaPrime treatment and the AUGMENT treatment is based on recent discoveries, and as a result the programs are subject to a higher level of risk than programs based on longer extablished science. Additionally, our OvaPrime treatment and OvaTure treatment are at early stages of clinical and preclinical development, respectively, and may never yield treatments that can be successfully commercialized.

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The OvaTure treatment, the OvaPrime treatment and the AUGMENT treatment are based on recent scientific discoveries relating to egg precursor cells. As a result, the programs are subject to a higher level of risk than programs based on longer established science.

We are continuing to develop the OvaTure treatment. While we have observed key criteria of developmental competence in EggPC cell-derived eggs in both human and bovine models, we will not know if we have successfully developed fertilizable, mature eggs until we have successfully fertilized them. We may find that there are important criteria for developmental competence that we are not observing, or that elements of the criteria for maturity that we have observed are inadequately developed for fertilization. While we have developed a limited number of human EggPC cell-derived eggs demonstrating criteria of maturity, we need to develop a robust and repeatable process to develop mature eggs. Further, we will require authorization from regulatory bodies outside of the United States to fertilize a human Egg PC cell-derived egg before we can test any eggs that we do mature. Fertilization studies may fail when we are able to start them. Therefore, there are significant aspects of the OvaTure treatment that will require additional innovation for us to continue its development. The recent nature of the scientific discoveries underlying the OvaTure treatment, the need for additional innovation and the absence of information about egg precursor cell technology from human clinical trials all increase the risks associated with this potential fertility treatment. In any event, we believe that it will be costly and time consuming to develop and successfully commercialize the OvaTure treatment.

The OvaPrime treatment has only recently been used in humans in our ongoing OvaPrime clinical study in the UAE and our ongoing OvaPrime clinical trial in Canada. The preclinical data we have generated for this treatments under development may not be replicated in humans.

We have limited patient experience with the AUGMENT treatment and our experience with the AUGMENT treatment to date may not be representative of what women will experience in the future. We continue to develop and optimize the AUGMENT treatment process and such modifications may lead to outcomes that are different from historical results. If results from clinics are unfavorable, the AUGMENT program could be delayed or abandoned. Further, international IVF clinics that we work with may determine not to provide or continue providing the AUGMENT treatment based on clinical efficacy, safety or commercial, logistic, regulatory or other reasons, or they may not expand their use of AUGMENT sufficiently for it to be a viable commercial offering.

We may not be able to successfully develop the OvaTure treatment, the OvaPrime treatment or other potential fertility treatments, and we may not successfully commercialize any of our treatments.

In December 2015 a study of OvaPrime was initiated in the UAE and in 2016, a clinical trial of OvaPrime was initiated in Canada. We plan to utilize the results of these studies during 2017 to assess the safety profile of OvaPrime and to help define the patient population most likely to derive the greatest benefit from treatment. The successful enrollment of patients in these clinical studies and their results, including whether and by how much the OvaPrime treatment boosts egg reserves, will impact our ability to further introduce and generate revenues from sales of the OvaPrime treatment. If the results are unfavorable, the OvaPrime treatment may not be viable or significant additional time and expense could be required before we are able to commercialize this potential fertility treatment. In December 2016, we announced that we are reassessing our ongoing and planned clinical studies of AUGMENT, including our planned multi-center clinical trial and the ongoing IVI-sponsored study in Valencia, Spain, and slowing our commercial expansion of AUGMENT.

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

Patient enrollment is affected by other factors, including:

- timing and capacity of tissue processing facilities and third party manufacturers;
- novelty of the potential fertility treatments being tested;

- form of infertility or severity of the condition being treated;
- eligibility criteria for the study in question;
- rates of success of competitive fertility treatments;

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- perceived risks and benefits of the potential fertility treatments under study;
- known side effects of the potential fertility treatments under study, if any;
- efforts of IVF clinics to facilitate enrollment in studies or clinical trials;
- patient referral practices of physicians;
- ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials for the OvaPrime treatment our other fertility treatments would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our potential fertility treatments, which would cause the value of our company to decline and limit our ability to obtain additional financing. Further, our inability to ramp up use of the AUGMENT treatment by clinics offering the treatment commercially may delay commercial acceptance of the treatment.

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

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

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

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

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

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

Regulatory review agencies, committees and advisory groups and any new requirements and guidelines they promulgate may lengthen the regulatory review process, require OvaXon to perform additional studies, increase OvaXon's development costs, which we share with Intrexon, lead to changes in regulatory positions and

interpretations, delay or prevent approval and commercialization of these treatment candidates or lead to significant post-approval limitations or restrictions. As OvaXon advances its potential new treatments in human and animal health, it will be required to consult with these regulatory and advisory groups and comply with applicable requirements and guidelines. If OvaXon fails to do so, we may be required to

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delay or discontinue development of its potential fertility treatments. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential fertility treatment to market could decrease our ability to generate sufficient revenue to maintain our business.

Development of our fertility treatments may not be successful. If we are unable to commercialize our fertility treatments or experience significant delays in doing so, our business will be materially harmed.

We intend to continue to invest a significant portion of our efforts and financial resources in the identification, development and commercialization of fertility treatments. Our ability to generate revenues will depend heavily on the successful development and eventual commercialization of our fertility treatments. For example, our plans to develop the OvaTure treatment will depend upon the regulatory pathways applicable to the OvaTure treatment in regions of the world that we target.

Regulatory authorities may conclude that certain of our fertility treatments qualify for a class of products exempt from pre-market review and approval. In some countries where we have introduced the AUGMENT treatment or may in the future plan to the AUGMENT treatment or the OvaPrime treatment, we believe that the AUGMENT treatment and OvaPrime treatment are not subject to regulatory requirements for extensive pre-market review and approval of an application for marketing authorization that apply to drugs, biologics, medicinal products and medical devices. However, applicable regulatory bodies may disagree with our view, and if they do, we and our clinic accounts may suffer significant delay or expense or may cease offering the treatment in such countries. In some jurisdictions where traditional pre-market approval such as that required for drugs, biologics, medicinal products and medical devices is not required for our treatments, we or our clinic accounts may be required to obtain special approval of or licenses from local institutions to study or use the AUGMENT treatment or OvaPrime treatment and/or license to offer such treatments. For example, in Spain, the IVI clinic commenced an investigator sponsored study of the AUGMENT treatment after receiving approval from the La Comisión Nacional de Reproducción Humana Asistida (CNRHA) and our clinic account in Japan has commenced a non-commercial preceptorship training program after receiving approval from the Japan Society of Obstetrics and Gynecology (JSOG). In some cases, there are no clear guidelines on what standards may apply to the AUGMENT treatment or OvaPrime treatment or what licenses or approvals may be required, and we therefore have engaged and will continue to engage in discussions with regulatory authorities in certain of the countries in which we have introduced or plan to introduce the AUGMENT treatment or OvaPrime treatment. If we or our clinic accounts are unable to obtain any required licenses or approvals in a particular country, if the application process takes longer than expected, or if additional licenses or approvals are required to commercialize the treatment on a large scale, then our introduction of the AUGMENT treatment or OvaPrime treatment in such countries may be delayed, we may incur additional expenses, and/or we may determine not to provide the treatment in such countries. Further, some or even all regulatory authorities may determine to classify the AUGMENT treatment, the OvaPrime treatment or our potential fertility treatments as drugs, biologics, medicinal products or medical devices. Any such regulation would mean, among other things, that we would have to conduct extensive clinical trials and would not be able to market such potential fertility treatments until we have received approval of an application for marketing authorization from the applicable regulatory authority. Other than as identified above, we have not applied for or received approval to market any fertility treatments from regulatory authorities in any jurisdiction. We have only limited experience in conducting preclinical testing and clinical trials and filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties, including contract research organizations, to assist us in this process.

If we are required to conduct traditional pre-market approval clinical trials in any of the countries where we seek to commercialize our potential fertility treatments, we would be subject to significant additional risk. Prior to initiating any necessary clinical trials of our potential fertility treatments that may be required in particular regions, we may need to submit clinical trial applications (such as an IND or foreign equivalent) to regulatory authorities, based on preclinical, animal and other tests. Upon submitting such an application, the regulatory authorities might determine that the risks involved in our potential fertility treatments are too great to justify proceeding with a clinical study and impose a partial or full clinical hold. They may require us to do significant and costly additional preclinical work before commencing our clinical trials or may not allow us to proceed with clinical trials at all. In addition, an ethics committee or IRB would be required to review and approve any clinical trial before we can commence that trial. The

ethics committee or 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. Our potential fertility treatments rely on new and complex technology that impacts human reproductive systems. Therefore, regulatory authorities and ethics committees may be especially cautious in reviewing and approving our clinical protocols for such potential fertility treatments.

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

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companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. The FDA, equivalent Foreign Regulatory Authorities or an IRB or ethics committee can suspend or terminate a clinical study at any time, for a number of reasons, including that continuing the study presents unreasonable risk to human subjects or that the rights of those subjects are not adequately protected.

We may experience numerous unforeseen events during, or as a result of, any clinical trials or studies if we choose to or are required to conduct them, which could delay or prevent our ability to achieve our stated goals for our fertility treatments or receive marketing approval for or commercialize our fertility treatments, including:

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

If we are unable to successfully complete any studies or clinical trials or other testing of our potential fertility treatments, if the results of these trials or tests are not positive or are insufficient to demonstrate safety or efficacy to applicable regulators, or if there are any safety concerns regarding our potential fertility treatments, we may:

- be delayed in obtaining marketing approval for our potential fertility treatments;
- not obtain marketing approval in countries where such approval may be required and therefore be unable to commercialize our fertility treatments;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;
- obtain approval with labeling that includes significant restrictions on distribution or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other regulatory requirements; or
- have the treatment removed from the market after obtaining marketing approval.

If serious adverse side effects are identified during the development or commercialization of the OvaTure treatment, OvaPrime treatment, AUGMENT treatment, or any other potential fertility treatments or with any procedures with which these fertility treatments are used, we may need to abandon or limit our development of those fertility treatments, which could have a material adverse effect on our business, results of operations or financial condition.

None of the OvaTure treatment, the OvaPrime treatment, the AUGMENT treatment nor any of our potential fertility treatments has been proven effective and safe in humans through clinical trials. We have limited patient experience with the AUGMENT treatment and our experience with the AUGMENT treatment to date may not be representative of what women will experience in the future. Further, we continue to develop the AUGMENT treatment, and changes to the treatment could result in future experiences with the treatment differing from past experience. It is impossible to predict when or if any of our

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fertility treatments will prove effective or safe in humans or, to the extent required, will receive marketing or other approval. If any of our current or potential fertility treatments are associated with undesirable side effects or have characteristics that are unexpected with respect to the mother or the child conceived using such treatment, we may need to abandon such treatments or limit their development and/or commercialization to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, if any of the procedures with which our potential fertility treatments are used is determined to be unsafe, we may be required to delay or abandon our fertility treatment development or commercialization. For example, we expect the AUGMENT treatment will be administered as part of the ICSI process and the OvaPrime treatment will be administered as part of the IVF process. To the extent physicians limit or abandon the use of ICSI, IVF or other procedures with which the AUGMENT treatment or the OvaPrime treatment is used, we may need to delay or abandon our development or commercialization of these treatments.

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

Even if we are able to continue the commercialization of the AUGMENT treatment or commercialize any of our potential fertility treatments, 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 the AUGMENT treatment, the OvaPrime treatment and the OvaTure treatment may affect market acceptance by physicians and patients. We have limited patient experience with the AUGMENT treatment and our experience with the AUGMENT treatment to date may not be representative of what women will experience in the future. Our ability to gain market acceptance of the AUGMENT treatment will depend on the experience women have with this treatment option over time. If our potential fertility treatments do not achieve an adequate level of acceptance, we may not generate significant treatment revenues and we may not become profitable. The degree of market acceptance of our fertility treatments, after receipt of any necessary licenses or approvals, will depend on a number of factors, including:

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

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

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

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To achieve commercial success for any potential fertility treatment, we must either develop a sales and marketing team or outsource these functions to third parties.

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 the introduction of any fertility treatment. If the commercial introduction or expansion of our treatments 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. For example, we incurred restructuring costs in connection with the corporate restructuring that we announced in December 2016.

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

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

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

- there may be evidence that such candidates may have harmful side effects;
- preclinical studies may put into question the efficacy of such candidates;
- we may determine that such candidates are unlikely to achieve marketing approval or market acceptance; or
- such candidates may be too costly to manufacture or market.

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

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

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

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

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

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

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

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

Competitors may develop new infertility drugs, assisted reproductive technology, or ART, therapies, devices and techniques that could render obsolete our potential fertility treatments. There are a number of pharmaceutical companies, biotechnology companies, universities and research organizations actively engaged in research and development of potential fertility treatments. Like our treatments, some of these potential fertility treatments are designed to address the shortcomings of IVF. In particular, we are aware of a number of companies and laboratories that are currently developing potential fertility treatments intended to identify high quality embryos for use in IVF, a university study of the transfer of granulosa cell mitochondria into eggs, a university study using pronuclear transfer for improvement in IVF success rates and a university study of induced pluriopotent stem cells, or iPS, shows that iPS cells can be generated from somatic cells and programmed to become differentiated cells, which can include germ line cells such as oocytes. Novocellus Ltd. is developing an embryo viability test, using culture media, to aid in the selection of embryos used in IVF. FertiliTech and Auxogyn, Inc. are developing hardware and software that analyzes embryo development against cell division timing parameters to help identify the highest quality embryo within a group of embryos. If successfully developed, these potential fertility treatments could improve outcomes and alleviate some of the other shortcomings of traditional IVF, thereby decreasing the need for our potential fertility treatments. Fertility Focus, along with its strategic partner Norgenix, are developing a fertiloscope for the early diagnosis of, and immediate corrective surgery for, the physical causes of infertility. Molecular diagnostic companies like Reprogenetics are developing novel preimplantation genetic diagnosis and screening methods to detect chromosomal and genetic disorders of embryos prior to transfer back to the women. Testing embryos in this manner may increase the likelihood of pregnancy, reduce the chances of pregnancy loss, and improve the odds of delivery. At this time, we cannot evaluate how our potential fertility treatments, if successfully developed and commercialized, would compare technologically, clinically or commercially to any other potential fertility treatments being developed or to be marketed by competitors. There can be no assurance that we will be able to compete effectively. OvaXon is engaged in gene editing, which is a rapidly evolving field. OvaXon could potentially have competitors in both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Some of the pharmaceutical and biotechnology companies we expect OvaXon to compete with include GlaxoSmithKline plc, Sangamo BioSciences Inc., HemaQuest Pharmaceuticals, Inc., Merck & Co., Inc., and Novartis AG.

Our competitors may develop and commercialize new technologies before we do, allowing them to offer potential fertility treatments, services or solutions that are superior to those that we may offer or which establish market positions before the time, if any, at which we are able to bring potential fertility treatments to the market. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of potential fertility treatments, obtaining FDA and other regulatory approvals of potential fertility treatments and the commercialization

of those treatments. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. Our competitors' potential fertility treatments may be safer, more effective or more effectively marketed and sold than any treatment we may commercialize and may render our potential fertility treatments obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our potential fertility treatments. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

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

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

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

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

- decreased demand for any potential fertility treatment that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards or payments to trial participants or patients;
- loss of revenue;
- the diversion of management's resources; and
- the inability to commercialize any potential fertility treatments that we may develop.

We obtained product liability insurance coverage when we initiated our AUGMENT treatment study in the United States and introduced the AUGMENT treatment in select IVF centers outside of the United States. We will need to maintain product liability insurance coverage as we continue to offer the AUGMENT treatment outside of the United States, introduce the OvaPrime and OvaTure treatments, and/or conduct clinical trials for our current or potential fertility treatments. Such insurance is increasingly expensive and difficult to procure. In the future, such insurance may not be available to us at all or 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 our current or potential fertility treatments. If we are not able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, our business could be harmed, possibly materially.

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

Various countries where we are seeking or may seek to introduce our fertility treatments have standards set by regulatory authorities and/or non-governmental bodies that govern IVF procedures and the procurement, storage and processing of gametes and embryos for use in IVF procedures. In the UK, for example, the HFEA has adopted a Code of Practice, as well as supplementary guidance documents, with which licensed IVF clinics are obliged to comply. Similarly, the UK's Association of Clinical Embryologists has adopted a series of best practice guidelines for its

members. Even where these standards are voluntary, 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 potential fertility treatments of companies that meet these standards. Similarly, physicians or IVF clinics may be less likely to endorse or use procedures or potential fertility

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treatments that fail to comply with such standards. In addition, failure to meet the standards could subject us to negative media attention.

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

Our potential plans to commercialize the AUGMENT treatment in certain regions outside of the United States, to introduce the OvaPrime treatment in selected regions outside of the United States, and to continue to define the clinical pathway for development of the OvaTure treatment depend upon these treatments meeting the requirements of a class of products or a type of practice or treatment exempt from pre-market review and approval of applications for marketing authorizations in such regions. Determinations by regulators in the markets we target that these treatments do not meet the requirements for a class of products exempt from pre-market review and approval could significantly delay or prevent commercialization of those products. Failure to obtain marketing approval in international regions, to the extent required, would prevent our potential fertility treatments from being marketed in such regions. Additionally, our plans to continue to define the clinical pathway for the OvaTure treatment will depend upon the regulatory pathway applicable in regions of the world that we target.

Our plans to continue the commercialization of the AUGMENT treatment outside of the United States, to introduce the OvaPrime treatment in select regions outside of the United States, and to continue to define the clinical pathway for development of the OvaTure treatment depend upon the treatments meeting the requirements of a class of products or a type of practice or treatment exempt from pre-market review and approval of applications for marketing authorizations in such regions. There can be no assurance that this will be the case in any particular jurisdiction, or that applicable Foreign Regulatory Authorities will agree with our determinations that our treatments meet these requirements. If the Foreign Regulatory Authorities in a given country disagree with our determination that our treatments are exempt from pre-market review and approval of applications for marketing authorizations required for drugs, biologics, medicinal products and medical devices, then we likely will be required to cease commercial marketing of that fertility treatment in that country, and may not be able to resume commercial marketing without first demonstrating safety and efficacy through clinical trials, submitting an application for marketing authorization, and receiving approval from the relevant regulatory authorities. In these circumstances, we are likely to be significantly delayed in our ability to commercialize our fertility treatments in such country, or we may elect to cease our commercialization activities in that country altogether. In 2012, we commenced a clinical study of the AUGMENT treatment in the United States relying on our conclusion that the AUGMENT treatment met the requirements for a section 361 HCT/P, and therefore did not require an IND. In September 2013, however, we received an "untitled" letter from the FDA questioning the status of the AUGMENT treatment as a section 361 HCT/P and advising us to file an IND for the AUGMENT treatment. As a result, we chose to suspend enrollment in our AUGMENT study in the United States. We are scheduled to speak with the FDA in the first half of 2017 as part of our ongoing exploration of potential entry into the U.S. market. However, we cannot provide any assurance as to the outcome of that meeting. We will be unable to complete the development of OvaTure if we do not obtain authorization to fertilize an Egg PC cell-derived egg. Additionally, our plans to continue to define the clinical pathway for the OvaTure treatment will depend upon the regulatory pathway available in regions of the world that we target. From time to time, we engage in discussions regarding our fertility treatments with Foreign Regulatory Authorities in certain of the countries in which we have introduced or plan to introduce such fertility treatment or potential fertility treatment. We expect to have ongoing dialogue with these regulatory authorities. If any of our fertility treatments are subject to pre-market approval in a particular region, failure to obtain such required marketing approval in international regions would prevent us from marketing such fertility treatment in such regions, which could have a material adverse effect on our business, results of operations or financial condition.

Further, if Foreign Regulatory Authorities in a particular region determine that our fertility treatments do not meet the requirements of a class of products that is exempt from pre-market approval of applications for marketing authorization , then in order to market and sell our potential fertility treatments in that region, we or our third party collaborators may need to obtain separate marketing approvals and will need to comply with numerous and varying regulatory requirements, as described above. Additionally, study or license requirements vary among countries and may cause delays of or suspension of the approval process and can involve additional testing. The time required to obtain approval in foreign regions can be lengthy, and may differ substantially from region to region. The regulatory

approval process outside the United States may be subject to risks like those associated with obtaining FDA approval. In addition, in many countries, a treatment must be approved for reimbursement before the treatment can be approved for sale in that country. Furthermore, some countries have restrictions particular to IVF and/or other fertility treatments, which may impose additional regulatory barriers for market entry for our potential fertility treatments. If required, we may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA for marketing in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

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By way of example, regulators could determine that the OvaPrime treatment, the OvaTure treatment or the AUGMENT treatment, and/or any other potential fertility treatments, do not meet the requirements for a class of products exempt from pre-market review and approval. In that case, they could be regulated as medicinal products (including advanced therapy medicinal products), as medical devices or as human tissues and cells intended for human applications. For example, 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 potential fertility treatment's safety, efficacy and quality. Following review of the marketing authorization application the EMA will issue an opinion, which the European Commission will take into account when deciding whether or not to grant a marketing authorization. If we are required to follow this regulatory pathway for the OvaPrime treatment, OvaTure treatment, AUGMENT treatment or our potential fertility treatments, this may significantly delay or preclude commercialization of these treatments. Similar determinations in other markets outside of the United States could have the same impact.

Even if regulators in regions outside of the United States, such as the EU, deem our treatments to be exempt from pre-market review and approval of an application for marketing authorization as required of drugs, biologics, medicinal products and medical devices, other regulatory requirements may nevertheless be applicable. For example, medical treatments and processes, such as IVF, may be regulated at the national level, which is the case in the EU. Such national regulations may restrict the extent to which the eggs used in IVF treatments may be manipulated and so may prevent us from commercializing our treatments in that country. Alternatively, such regulations may require the IVF facilities to be licensed by the national regulatory authority to perform specific IVF procedures or require us or our clinic accounts to obtain special approval of or licenses from national regulatory bodies to introduce our treatments in that country. For example, there are specific fertility regulatory authorities, such as the United Kingdom’s HFEA, which license IVF facilities and determine what procedures such establishments may perform. In other countries, the national health authority may delegate the review of a fertility treatment to an industry self-regulatory body, an institutional review board, or other body. For example, the approval of our clinic account’s application to use the AUGMENT treatment in Japan was made by the JSOG. Further, the investigator sponsored study of the AUGMENT with the IVI Group in Spain, was approved by the CNRHA. However, in some countries, there are no clear guidelines on what standards may apply to our treatments or what licenses or approvals may be required. While we have engaged and will continue to engage in discussions with regulatory authorities in certain of the countries in which we have introduced or plan to introduce our fertility treatments, if we or our clinic accounts are unable to obtain any required licenses or approvals in a particular country, if the application process takes longer than expected, or if additional licenses or approvals are required to commercialize the treatment on a large scale, then our introduction of our fertility treatments in such countries may be delayed, we may incur additional expenses, and we may determine not to provide the treatment in such countries.

It is unclear what regulatory pathway FDA will ultimately require for the AUGMENT treatment, the OvaPrime treatment, the OvaTure treatment or any other potential fertility treatments we may develop.

In 2012, we commenced a clinical study of the AUGMENT treatment in the United States. We did so without an IND on the basis of our conclusion that FDA would regulate the AUGMENT treatment as a section 361 HCT/P. On September 6, 2013, however, we received an "untitled" letter from the FDA questioning the status of the AUGMENT treatment as a section 361 HCT/P and advising us to file an IND.

We are scheduled to speak with the FDA in the first half of 2017 as part of our ongoing exploration of potential entry into the U.S. market for our fertility treatments. We believe that the AUGMENT treatment meets the regulatory definition of a section 361 HCT/P or is a procedure that can be performed as part of the practice of medicine - and in either case, is exempt from pre-market approval. The AUGMENT treatment involves isolation of mitochondria from egg precursor cells, and injection of those mitochondria into the same woman's egg, which we believe constitutes minimal manipulation of both the mitochondria and the egg. We believe the AUGMENT treatment involves only homologous use, does not combine the oocyte with an article that raises now safety concerns, and involves tissues for reproductive use. We therefore believe that the AUGMENT treatment meets all four of the criteria for a section 361

HCT/P set forth in FDA's regulation. If FDA ultimately agrees with our conclusions, the AUGMENT treatment will not be required to conduct clinical trials pursuant to an IND, nor will it be required to seek FDA pre-market review and approval of an NDA or BLA. However, both the AUGMENT treatment, the OvaPrime treatment and our potential fertility treatments constitute new technologies, the proper regulatory characterization of which likely constitute matters of first impression for FDA. Particularly because the AUGMENT treatment, the OvaPrime treatment and our potential fertility treatments are intended to result in the creation of human life, there can be no assurance that FDA will agree with our views as to the proper regulatory characterization of the AUGMENT treatment, the OvaPrime treatment or any of our potential fertility treatments. FDA may conclude that the AUGMENT treatment, the OvaPrime treatment and/or potential fertility treatments constitute drugs, biologics, or medical devices. If FDA makes such a determination for AUGMENT, the OvaPrime treatment or any of our potential fertility treatments, we may be required to conduct clinical trials under an IND (or investigational device exemption for a medical device) and seek FDA pre-market

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review and approval of an NDA or BLA (or premarket approval for a medical device). In that event, we may abandon pursuing that potential fertility treatment in the United States, or suffer significant delays and expense seeking to obtain any necessary approval.

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

If we ultimately do not need to submit the AUGMENT treatment to the FDA for preapproval due to the FDA regulating the treatment as a section 361 HCT/P, we still must generate adequate substantiation for claims we make in our marketing materials. Both the U.S. Federal Trade Commission (FTC) and the states retain jurisdiction over the marketing of products for which advertising and promotion are not regulated by the FDA, and require certain standards of evidence to support claims made in marketing materials. Many countries outside of the United States have similar regulatory authorities that regulate the marketing of products. We intend to generate such adequate substantiation for any claims we make about the AUGMENT treatment. If, however, after we commence marketing of the AUGMENT treatment in the United States, the FTC or one or more states or foreign authorities conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties or may be forced to alter or cease our marketing of the AUGMENT treatment in one or more jurisdictions. Any of this could materially harm our business. In addition, if our promotion of the AUGMENT treatment suggests that the AUGMENT treatment is intended for uses that are not consistent with a section 361 HCT/P, the FDA or equivalent Foreign Regulatory Authorities might consider the potential fertility treatment to be a new drug or biologic. We will therefore be limited in the promotional claims that we could make about the AUGMENT treatment.

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 government sanctions.

Various countries where we are seeking or may seek to introduce our fertility treatments have standards set by regulatory authorities and/or non-governmental bodies that govern IVF procedures and the procurement, storage and processing of gametes and embryos for use in IVF procedures. In the UK, for example, the HFEA has adopted a Code of Practice with which licensed IVF clinics are obliged to comply, as well as supplementary guidance documents. Similarly, the UK's Association of Clinical Embryologists has adopted a series of best practice guidelines for its members. Even where these standards are voluntary, 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 potential fertility treatments of companies that meet these standards. Similarly, physicians or IVF clinics may be less likely to endorse or use procedures or potential fertility treatments that fail to comply with such standards.

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. If we begin commercialization of our fertility treatments in the United States, we will have to comply with these state requirements. Failure to comply with these state requirements could subject us to significant sanctions.

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

Some regions or countries may determine that certain of our potential fertility treatments, or certain aspects of such treatments, such as the innovative culture media solution that we are planning to develop, should be regulated as

medical devices. In such cases, we will need to seek approval or clearance from the appropriate regulatory authorities in such countries.

In the EU, for example, we will need to complete a conformity assessment procedure, to demonstrate that our fertility treatments conform to the essential requirements set out in EU law, and only then may we apply the CE mark to the products, which would allow the products to be marketed throughout the EU. In other countries, such products may be subject to pre-market review and approval by regulatory authorities or some other form of regulatory clearance. We cannot guarantee that we will be able to complete the necessary conformity assessment procedures or obtain the necessary regulatory clearances of pre-

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market approvals of these medical devices. In addition, any modifications to medical devices that we successfully bring to market, if any, may require new conformity assessment procedures, regulatory clearances or pre-market approvals. Marketing a medical device without the necessary CE mark, clearance or approval could result in a warning letter, fines, injunctions, product seizures or other civil or criminal penalties. Delays in our receipt of CE marking, regulatory clearance or pre-market approval will cause delays in our ability to sell our potential fertility treatments, which will have a negative effect on our ability to generate and grow revenues.

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

We are currently subject to risks associated with doing business internationally as a result of our commercialization of the AUGMENT treatment and the clinical development of the OvaPrime treatment outside of the United States. If we succeed in commercializing internationally, then our business will be subject to additional 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 currently have a limited international infrastructure including, without limitation, sales, manufacturing and distribution capabilities. Establishing and expanding commercial activities and complying with laws in foreign jurisdictions may be costly and could disrupt our operations.

Even if our fertility treatments are not subject to pre-market review and approval, they may be subject to certain ongoing regulation in some regions. We could be subject to significant civil or criminal penalties if we fail to comply with these requirements, and we may be unable to commercialize our potential fertility treatments.

If regulatory authorities allow our fertility treatments to be offered to patients in any of the countries we seek to access, we will still be subject to numerous post-market requirements. Post-marketing requirements applicable to such products vary by region and by country. For example, in the United States, section 361 HCT/Ps are subject to several regulatory requirements, including those related to registration and listing, record keeping, labeling, cGTPs, donor eligibility and other activities. HCT/Ps that do not meet the definition of a section 361 HCT/P and, therefore, are approved via an NDA or BLA, are also subject to these and additional ongoing obligations. If we fail to comply with these requirements, or similar requirements in foreign jurisdictions, we could be subject to warning letters, product seizures, injunctions or civil and criminal penalties.

Moreover, even if the FDA or equivalent Foreign Regulatory Authorities allow our fertility treatments to be marketed without pre-market approval, the regulatory authorities could still seek to take enforcement action, which could include serving a written order that an HCT/P be recalled or destroyed, taking possession of the HCT/P, requiring cessation of manufacturing, or otherwise seeking to withdraw the potential fertility treatment from the market for a variety of reasons, including if the regulatory authority develops concerns regarding the safety of the potential fertility treatment or its manufacturing process

Any fertility treatment for which we are required to obtain marketing approval, and for which we obtain such marketing approval, will be subject to continuing regulation after approval. We may be subject to significant penalties if we fail to comply with these requirements.

Any potential fertility treatment, including any potential fertility treatment developed by our OvaXon joint venture, for which we obtain approval or clearance of an application for marketing authorization, will be subject to continuing regulation by the FDA or equivalent Foreign Regulatory Authorities. Specific requirements will vary by country

and/or region. In general, however, such requirements will include those relating to, among other things, submission of safety and other post-marketing information and reports, registration and listing, manufacturing, packaging, quality control, storage, distribution, quality assurance and corresponding maintenance of records and documents, labeling, advertising and promotional activities, distribution of samples to physicians and recordkeeping. Even if marketing approval or clearance of a potential fertility

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treatment is granted, the approval or clearance may be subject to limitations on the uses for which the potential fertility treatment may be marketed, be subject to restrictions on distribution or use, or contain requirements for costly post-marketing testing to further evaluate the safety or efficacy of the potential fertility treatment. The FDA and equivalent Foreign Regulatory Authorities closely regulate the post-approval marketing and promotion of drugs, biologics and medical devices to ensure such products are marketed only for the approved indications or cleared uses and in accordance with the provisions of the approved labeling. The FDA and equivalent Foreign Regulatory Authorities impose stringent restrictions on manufacturers' communications regarding off-label use and if we market our potential fertility treatments for uses other than for their approved indications, we may be subject to enforcement action.

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

- restrictions on the labeling or marketing of potential fertility treatments;
- restrictions on distribution or use of potential fertility treatments;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters from the FDA or equivalent Foreign Regulatory Authorities;
- withdrawal of potential fertility treatments from the market;
- refusal to approve pending applications or supplements to approved applications;
- recall of potential fertility treatments;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our potential fertility treatments;
- product seizure;
- injunctions; or
- the imposition of civil or criminal penalties.

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

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

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

- reducing reimbursement rates;
- challenging the prices charged for medical potential fertility treatments or services;
- further limiting potential fertility treatments and services covered;

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- challenging whether potential fertility treatments or services are medically necessary;
- taking measures to limit utilization of potential fertility treatments and services;
- negotiating prospective or discounted contract pricing;
- adopting capitation strategies; and
- seeking competitive bids.

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

In March 2010, Congress enacted healthcare reform legislation known as the Affordable Care Act. The Affordable Care Act has substantially changed the way that healthcare is financed by both governmental and private insurers and significantly affected 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 our potential fertility treatments, if the FDA regulates those treatments as a biologic. The fee, which is not deductible for federal income tax purposes, is based on the manufacturer's market share of sales of branded drugs and biologics, excluding orphan drugs, to, or pursuant to coverage under, specified U.S. government programs. In addition, the law subjects most medical devices to a 2.3% excise tax, beginning on January 1, 2013. The implementation of the Affordable Care Act may have a material adverse effect on our results of operations and financial condition. However, it is also possible that the Affordable Care Act will be repealed and/or replaced, given recent changes in the federal administration in the United States. We are unable at this time to determine the outcome or impact on us of this uncertainty.

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

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

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

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

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

To the extent that the AUGMENT treatment, the OvaTure treatment, the OvaPrime treatment or other future potential fertility treatments or services are treated as laboratory or pathology services for purposes of reimbursement, these laws may make it difficult for us to market those potential fertility treatments and services to IVF clinics and physicians in some states

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and may also require us to restructure our business model before we can expand into certain markets. To the extent that our IVF clinic and physician customer base anticipates seeking Medicare reimbursement, these laws may require a comprehensive restructuring of our business model, and therefore adversely impact our ability to market our potential fertility treatments. Any additional legislation or regulation in this area could also adversely affect our ability to market our potential fertility treatments.

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

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

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal Stark law prohibits physicians from referring patients to hospitals, laboratories, and other types of entities in which they or their immediate family members have a financial interest, if the referral is for a select list of Medicare or Medicaid-covered services, including most clinical laboratory services, and also prohibits entities that furnish the covered services subsequent to a prohibited referral from billing Medicare or Medicaid for the services provided and from receiving payment from a federal healthcare program for those services;
- the federal False Claims Act imposes civil penalties, often through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- HIPAA (Health Insurance Portability and Accountability Act), 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, as well as the Foreign Corrupt Practices Act (FCPA), may apply to sales or marketing arrangements and interactions with physicians in countries outside the United States.

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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 similar criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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

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

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

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

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

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

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

In the course of performing our business, we will obtain, from time to time, confidential patient health information. For example, we may learn patient names and be exposed to confidential patient health information when we provide training on the AUGMENT treatment, the OvaPrime treatment, the OvaTure treatment and other future potential fertility treatments and services to the staff at IVF clinics and physicians' offices. United States federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information and privacy and security rules under HIPAA. At this time, we are not a HIPAA covered entity. However, our current and future business associate or other confidentiality agreements with covered entities contain commitments to protect the privacy and security of patients' health information and, in some instances,

may require us to indemnify the covered entity for any claim, liability, damage, cost or expense arising out of or in connection with a breach of the agreement by us. If we were to violate one of these agreements, we could lose customers and be exposed to liability or our reputation and business could be harmed. In addition, the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted in February 2009, expands the HIPAA privacy and security rules, including imposing many of the requirements of those rules directly on business associates and making business associates directly subject to HIPAA civil and criminal enforcement provisions and associated penalties. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements. Our failure to comply may result in criminal and civil liability.

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

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

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to the Manufacturing of Our Potential Fertility Treatments

We currently rely on on-site manufacturing at or near to the IVF clinics in which the AUGMENT treatment is offered. We may rely on third parties for the manufacture of our potential fertility treatments for development and commercialization to the extent that we do not rely on on-site manufacturing. This reliance on third parties may increase the risk of failing to provide manufacturing capacity to meet our potential fertility treatments at an acceptable cost. Lack of direct control of manufacturing capacity, costs and regulatory compliance could delay, prevent or impair our development and commercialization efforts.

We currently manufacture on-site or near to international IVF clinics where we have introduced commercial AUGMENT treatments and clinical programs for our OvaPrime treatment using our own equipment and employees. We entered into a master services agreement with a third party manufacturer to execute a technology transfer program to potentially provide services for the manufacture of the AUGMENT and OvaPrime treatments in the event that we decide to outsource our manufacturing operations for clinic or commercial activities. In addition, if we utilize centralized off-site manufacturing, we may also enter into similar master service agreements with other third party manufacturers to perform the processing steps for our AUGMENT and OvaPrime treatments. While we believe that our third party manufacturer has the capabilities to undertake the manufacturing activities in accordance with all applicable rules and regulations, there can be no assurance that they will be able to do so successfully or be capable of maintaining consistent quality standards. We seek to maintain high standards by working with high quality clinics, providing our own manufacturing equipment and personnel, and conducting regular training and quality audits, however there can be no assurance that such clinics will maintain consistent quality standards for activities outside of our control.

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

- reliance on the third party for regulatory compliance and quality assurance;
- reliance on the third party for establishment of and maintenance of its redundancy and disaster recovery plans
- possible changes by third party manufacturers and laboratories of business strategies or operating models that are incongruent with maintaining our relationship with such third parties;

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- the possible breach of the manufacturing or service agreement by the third party;
- the possible delay in obtaining, interruption of or withdrawal of required licenses;
- the possible delay, disruption or termination of service due to sanctions, regulations, or travel bans imposed by the site of third party manufacturer to patients or clinics outside the region where the manufacture is located;
- the possible disruption or availability of supplies, equipment, or properly qualified and trained staff;
- the possible exposure of trade secrets to unintended parties; and
- the possible interruption, or termination, or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

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

While we have identified and may continue to identify contractors with suitable regulatory experience and expertise, they may not be able to comply with cGTP regulations or similar regulatory requirements expected from global regulatory bodies in countries where we plan to offer our fertility treatments. Any performance failure on the part of our existing or future manufacturers and service providers could delay clinical development or marketing approval or adversely affect or impede commercial sales. Our failure, or the failure of our third party manufacturers and service providers, to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our potential fertility treatments and harm our business and results of operations.

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

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

Our potential future dependence upon others for the manufacture of our potential fertility treatments, were we could cease relying on on-site manufacturing, may adversely affect our future profit margins and our ability to commercialize the AUGMENT and OvaPrime treatments or any future potential fertility treatments that we seek to market on a timely and competitive basis.

In the future, we may build and equip a cGTP-compliant facility for the processing of the AUGMENT treatment. 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 the AUGMENT and OvaPrime treatment. We believe that such a facility may be important to our ability to meet demand for these on a cost-effective basis. The leasing, build-out and equipping of this facility will require substantial capital expenditures. In addition, it will be costly and time consuming to recruit necessary additional personnel for the operation out of the facility. We may continue to rely on on-site or third party manufacturing during the build-out of the facility and possibly retain third party manufacturing along with our own cGTP-compliant facility for a period of time to ensure uninterrupted service which will require additional capital.

Furthermore, we do not have experience running a manufacturing facility, which includes international tissue shipping and handling to meet local regulations. There is a risk that failure to maintain adequate quality controls and assurance for AUGMENT and OvaPrime processing facilities, associated support services and maintenance of equipment could impact the quality of our treatments, in terms of effectiveness and patient safety, which could lead to regulatory actions that could adversely impact commercialization of our fertility treatment business.

There is no assurance that we will secure necessary permits and license to build and equip a cGTP-compliant facility in the intended country, nor manufacture commercial products, nor do we currently have funding available for any of

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purposes. If we are unable to successfully construct and equip a commercial manufacturing facility in compliance with regulatory requirements, and hire additional necessary personnel appropriately, our revenues from the AUGMENT treatment, and the profitability of such revenues, may be adversely affected.

In addition, if treatment volumes projected to initiate the build of such a facility do not materialize, the cost burden on AUGMENT and OvaPrime treatments could be significantly increased and could negatively impact the profitability of the business.

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

Providing the AUGMENT treatment 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 biopsy sample to the cGTP-compliant facility responsible for the next steps in the AUGMENT treatment process and we will need to coordinate with them to ship treatment products, the patient's egg precursor cells or mitochondria, to the appropriate clinic or physician. Such coordination involves a number of risks that may lead to failures or delays in processing and providing our AUGMENT treatments, including:

- difficulties in the timely shipping of patient-specific materials to us, or shipping of our potential fertility treatments to the treating physicians due to errors by third party carriers, transportation restrictions or delays or other reasons
- destruction of, loss of, or damage to, patient-specific materials or our potential fertility treatments during the shipping process due to improper handling by third party carriers, hospitals, physicians
- destruction of, loss 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, loss of, or damage to, patient-specific materials or our potential fertility treatments during storage at our facilities
- destruction of, loss of, or damage to, patient-specific materials or our potential fertility treatments stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians
- failure to maintain precise patient records sufficient to ensure the chain of custody procedures are followed, either by clinicians, hospital, physicians, carriers or by ourselves
- failure to ensure adequate quality control and assurances in the AUGMENT treatment process as we increase production quantities
- failure to establish or maintain sufficient manufacturing capacity, whether through third party manufacturers or internally, and
- failure to establish or maintain sufficient manufacturing supplies, whether through third party manufacturers or internally.

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

We are reliant on single sourcing of materials and equipment for our potential fertility treatments which could put us at risk for continuity of supply in the event that any of our suppliers are unable to supply us in part or in full

We also are reliant on single sourcing for the majority of our raw materials, consumables and processing equipment, including but not limited to our proprietary antibody and Fluorescence-Activated Cell Sorting equipment. At this point in time we do not have the capacity or intent to source alternative or secondary suppliers of materials or processing equipment.

There is a risk that if we are required to find alternative suppliers, for whatever reason, this could delay supply of our fertility treatments for clinical or commercial purposes and could add an additional, unplanned financial burden on the company. Qualification of alternative suppliers could be a costly and timely process that would need to be driven through our Quality Management System to confirm and document that all the testing and validation activities are in

place to ensure that like-for-like changes do not impact the performance and safety of our potential fertility treatments.

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Risks Related to Our Dependence on Third Parties

We currently rely and will in the future rely on selected international IVF clinics to continue to conduct clinical trials, commercialize, gain experience and generate data on the AUGMENT treatment and the OvaPrime treatment. We will also rely on other third parties to conduct clinical trials for our fertility treatments. Such third parties may not perform satisfactorily, including failing to meet volume expectations, quality standards or deadlines for the completion of such studies or trials.

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

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

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

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

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

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

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

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collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and could devote fewer resources to our potential fertility treatments than we expect them to;

- a collaborator with marketing and distribution rights to one or more other potential fertility treatments may not commit sufficient resources to the marketing and distribution of our potential fertility treatments;
- collaborators may not pursue development and commercialization of our potential fertility treatments or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the

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collaborator's strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a potential fertility treatment or repeat or conduct new clinical trials;
- collaborators could independently develop, or develop with third parties, potential fertility treatments that compete directly or indirectly with our potential fertility treatments;
- collaborators may create intellectual property that we need to in-license, may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our potential fertility treatments or that result in costly litigation or arbitration that diverts management's attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable potential fertility treatments.

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

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

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, if any, the likelihood of approval by the FDA or similar regulatory authorities outside the United States or the availability of an exemption for the need or pre-marketing review or approval of our potential fertility treatment, the potential market for such potential fertility treatment, the costs and complexities of manufacturing and delivering the potential fertility treatment to patients, the potential and relative cost of competing fertility treatments, uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative potential fertility treatments or technologies for similar indications or conditions that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our potential fertility treatment. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of business combinations among pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators. Collaborations are complex and time consuming to negotiate, document and manage. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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Moreover, in recent years, the Supreme Court and the U.S. Court of Appeals for the Federal Circuit have rendered decisions in several patent cases such as Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I), BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., (Myriad II), Mayo Collaborative Services v. Prometheus Laboratories, Inc., and Alice Corporation Pty. Ltd. v. CLS Bank International, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, in the Myriad I case, the U.S. Supreme Court held that certain claims to naturally occurring substances are not patentable. We cannot predict how future decisions by the courts, the U.S. Congress, or the U.S. Patent and Trademark Office, USPTO, may impact the value of our patents. In addition to increasing uncertainty with regard to our and our licensors' or collaborators' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents and patents that we may obtain in the future.

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

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

We may be required to 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 potential fertility treatments and use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our potential fertility treatments and technology, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our potential fertility treatments and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby

giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or treatment. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our potential fertility treatments or force us to cease some of our business operations, which could materially harm our business. Claims that we have wrongfully appropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

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

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

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

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

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

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on Dr. Dipp, our executive chair, and Christophe Couturier, our chief financial officer, as well as the other principal members of our management and scientific teams. Following the change in our corporate strategy announced in December 2016, we are also engaged in a search for a permanent chief executive officer. Although we have entered into employment arrangements with Dr. Dipp and Mr. Couturier providing for certain benefits, including severance in the event of a termination without cause, these arrangements 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.

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

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other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

We may encounter difficulties in managing our organizational changes and successfully adjusting our operations.

As we seek to transition from a company focused on in-licensing and research to a company capable of developing multiple potential fertility treatments and supporting commercial activities, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize our therapeutic candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development and commercialization efforts and hire, train and integrate additional management, administrative and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

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

We expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of research and development, and potentially in the future, 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. Our management team may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. 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. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business plans. Our future financial performance and our ability to commercialize fertility treatments will depend, in part, on our ability to effectively manage the future development and expansion of our company. Accordingly, any inability to manage growth could delay the execution of our business plans or disrupt our operations.

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

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

Risks Associated with Our Capital Stock

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

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

- sales or potential sales of substantial amounts of our common stock;
- the delay or failure to execute our plans for the OvaTure treatment, OvaPrime treatment or AUGMENT treatment;
- results of preclinical testing or clinical trials of our potential fertility treatments, including the OvaTure treatment, or those of our competitors;
- the cost of our development programs;

- the success of competitive potential fertility treatments or technologies;

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- the success of our OvaXon joint venture with Intrexon;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals, new potential fertility treatment introductions and commercial results;
- the recruitment or departure of key personnel;
- developments concerning our licensors or manufacturers;
- the results of our efforts to discover, acquire or in-license additional potential fertility treatments;
- litigation and other developments relating to our issued patents or patent applications or other proprietary rights or those of our competitors or other material litigation;
- disagreement by the FDA or equivalent Foreign Regulatory Authorities regarding the regulatory pathway applicable to the OvaPrime treatment, the OvaTure treatment or the AUGMENT treatment;
- 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 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.

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;
- limit who may call stockholder meetings;
- prohibit actions by our stockholders by written consent;
- require that stockholder actions be effected at a duly called stockholders meeting;

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- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or by-laws.

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

We will continue to incur increased costs as a result of operating as a public company and complying with the Sarbanes-Oxley Act, and our management continues to be required to devote substantial time to new compliance initiatives.

As a public reporting company, we have incurred significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and the NASDAQ Global Market (NASDAQ) have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel have devoted a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and may make some other activities more time consuming and costly.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. In addition, because we are no longer an emerging growth company status under the Jumpstart our Business Startups (JOBS) Act enacted in April 2012, we are required to have our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting beginning with this Annual Report on Form 10-K. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. If we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources.

Our ability to successfully implement our business plan and comply with Section 404 requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls, may cause our operations to suffer and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an unqualified report on internal controls from our auditors as required under Section 404 of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on trading prices for our common stock, and could adversely affect our ability to access the capital markets.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. We are required, under Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of

annual or interim financial statements will not be prevented or detected on a timely basis. Section 404 also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. Now that we no longer qualify as an emerging growth company as defined in the JOBS Act, we are no longer exempted from certain requirements, such as the independent registered public accounting firm attestation.

Our compliance with Section 404 requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and

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process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently occupy approximately 25,200 square feet of office and laboratory space in Waltham, Massachusetts. This facility is under a lease agreement that expires in November 2020 that can be extended for an additional five-year term. We believe our facility is sufficient to meet our current needs and that suitable additional space will be available if and when needed. In December 2016, we executed a lease agreement for approximately 950 square feet of office space in Oxford, United Kingdom that is month-to-month and cancellable by either us or the landlord with one month's written notice.

We maintain office space in Tokyo, Japan under a lease agreement that expires in April 2017. We also maintain lab space in Toronto, Canada under a lease agreement that is cancellable by either us or the landlord with 60 days' written notice.

Item 3. Legal Proceedings

On October 9, 2015, a purported class action lawsuit was filed in the Suffolk County Superior Court in the Commonwealth of Massachusetts against us, several of our officers and directors and certain of the underwriters from our January 2015 follow-on public offering of our common stock. The plaintiffs purport to represent those persons who purchased shares of our common stock pursuant or traceable to our January 2015 follow-on public offering. The plaintiffs allege, among other things, that the Company defendants made false and misleading statements and failed to disclose material information in the Company’s January 2015 Registration Statement and incorporated offering materials. Plaintiffs allege violations of Sections 11, 12 and 15 of the Securities Act of 1933, as amended, and seek, among other relief, unspecified compensatory damages, rescission, pre-and post-judgment interest and fees, costs and disbursements. On December 7, 2015, the OvaScience defendants filed a notice of removal with the Federal District Court for the District of Massachusetts. On December 30, 2015, plaintiffs filed a motion to remand the action to the Superior Court. Oral argument on the motion to remand was held on February 19, 2016. On February 23, 2016, the District Court granted plaintiffs' motion to remand the action to the Superior Court. On February 26, 2016, a second putative class action suit was filed in the Suffolk County Superior Court in the Commonwealth of Massachusetts against the Company, several of our officers and directors and certain of the underwriters from the January 2015 follow-on public offering. The complaint is substantially similar to the complaint filed in October 2015. The two actions subsequently were consolidated and plaintiffs filed a First Amended Class Action Complaint on June 17, 2016. Defendants filed motions to dismiss the complaint. Those motions were denied by order dated December 22, 2016. The parties currently are engaged in discovery. We believe that the complaint is without merit and intend to defend against the litigation. There can be no assurance, however, that we will be successful. A resolution of this lawsuit adverse to the Company or the other defendants could have a material effect on our consolidated financial position and results of operations in the period in which the lawsuit is resolved. At present, we are unable to estimate potential losses, if any, related to the lawsuit.

On November 9, 2016, a purported shareholder derivative action was filed in the Business Litigation Session of the Suffolk County Superior Court in the Commonwealth of Massachusetts against certain of our present and former officers and directors alleging breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement and corporate waste for purported actions related to the January 2015 follow-on public offering. On February 23, 2017, the court approved the parties' joint stipulation to stay all proceedings in the action until further notice. The court has calendared a status conference for December 2017. We believe that the complaint is without merit and intend to defend against the litigation. There can be no assurance, however, that we will be successful. A resolution of this lawsuit adverse to the Company or the other defendants could have a material effect on our consolidated financial position and results of operations in the period in which the lawsuit is resolved. At present, we are unable to estimate potential losses, if any, related to the lawsuit.

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

Item 4. Mine Safety Disclosures

Not Applicable.

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PART II

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

Market Information

Our common stock is traded on the NASDAQ Global Market ("NASDAQ") under the symbol "OVAS."

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

Year Ended December 31, 2016	High	Low
Fourth Quarter 2016	$7.63	$1.34
Third Quarter 2016	$8.86	$4.96
Second Quarter 2016	$11.26	$4.76
First Quarter 2016	$10.58	$5.10

Year Ended December 31, 2015	High	Low
Fourth Quarter 2015	$15.39	$8.11
Third Quarter 2015	$31.72	$7.90
Second Quarter 2015	$39.29	$23.75
First Quarter 2015	$55.69	$34.44

On February 27, 2017, the closing price of a share of our common stock on the NASDAQ was $1.55.

Holders

As of February 27, 2017, there were 35,641,505 shares of common stock outstanding, which were held by approximately 80 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.

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Performance Graph

The graph below compares the cumulative total stockholder return on our common stock, the NASDAQ Composite Index and the NASDAQ Biotechnology Index assuming the investment of $100.00 on November 12, 2012, the day our stock began trading publicly, with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.

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Item 6. Selected Financial Data

The selected financial data set forth below is derived from our audited consolidated financial statements and may not be indicative of future operating results. The following selected consolidated financial data should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and the notes thereto included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of our future results.

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except per share amounts)				
Consolidated Statements of Operations Data:					
Revenues	$653	$277	$—	$—	$—
Total costs and expenses (excluding restructuring)	76,265	72,276	47,933	29,134	13,529
Restructuring	5,400	—	—	—	—
Loss from operations	(81,012)	(71,999)	(47,933)	(29,134)	(13,529)
Net loss	$(82,260)	$(73,219)	$(49,520)	$(29,044)	$(13,510)
Net loss per share applicable to common stockholders—basic and diluted	$(2.56)	$(2.70)	$(2.19)	$(1.80)	$(2.33)
Weighted average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	32,148	27,085	22,647	16,160	5,810

	Year Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents, and short-term investments	$114,388	$126,662	$60,231	$44,427	$31,391
Total assets	122,543	138,613	65,572	47,545	32,814
Total current liabilities	13,209	11,243	10,074	5,774	2,086
Total long-term liabilities	1,116	520	73	70	7

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

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

Overview

OvaScience Inc., is a global fertility company developing proprietary potential treatments for female infertility based on scientific discoveries about the existence of egg precursor, or EggPC[SM], cells. The current standard of treatment for infertility is in vitro fertilization, or IVF. IVF, however, has a 73% average failure rate per cycle based on a 2014 report from the Center for Disease Control and Prevention (CDC). The discovery of EggPC[SM] cells countered a long-held medical belief that women are born with a set number of eggs, thereby enabling new fertility treatment options. Our patented technology is based on these newly discovered EggPC[SM] cells and represents a new fertility treatment option.

EggPC cells are immature egg cells found in the protective outer lining of a woman's own ovaries. These immature egg cells have the ability to grow into fresh, young, healthy eggs. Our portfolio of fertility treatment options uses our patented technology including proprietary methods to identify and isolate EggPC cells from a patient's own ovarian tissue. By applying

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our EggPC technology platform in unique ways, we have commercialized one fertility treatment and are developing new fertility treatment options that are designed to improve egg health and revolutionize the fertility treatment landscape.

More women around the world are waiting later in life to start families and are in need of new fertility treatment options. As of 2016, approximately 9% of women of reproductive age (20-42 years) worldwide are estimated to be infertile, or about 83 million women. Fertility decreases with age. The main cause of age related infertility is poor egg health, which is linked to a reduction in the number of functioning mitochondria.

The OvaTure℠ treatment is a potential next-generation fertility treatment that could help a woman produce healthy, young, fertilizable eggs without the need for hormone injections. The OvaTure treatment seeks to mature a woman's own EggPC cells into eggs outside her body. This potential treatment may be an option for women with compromised eggs, who are unable to make eggs, or who may be unwilling or unable to undergo hormone hyperstimulation.

The OvaPrime℠ treatment is a potential fertility treatment that could enable a woman to increase her egg reserve. Approximately thirty-two percent of assisted reproductive technology (ART) cycles are performed on women with diminished ovarian reserve based on a 2014 report from the CDC. The OvaPrime treatment is designed to replenish a woman's egg reserve by transferring a patient's EggPC cells from the protective ovarian lining back into the patient's own ovaries where they may mature into fertilizable eggs during the IVF process.

Our first commercial treatment, the AUGMENT℠ treatment, is specifically designed to improve egg health by supplementing a mitochondrial deficiency which may, in turn offer the potential for enhanced IVF success rates. With the AUGMENT treatment, energy-producing mitochondria from a patient's own EggPC cells are added to the patient's mature eggs during the IVF process to supplement the existing mitochondria.

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

Increasing live birth rates and reducing the number of IVF cycles. By improving egg health, we believe we may increase the percentage of live births and reduce the number of IVF cycles required.

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

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

Replenishing the ovary for women who make too few or no eggs. Our OvaPrime treatment is designed to replenish a woman's egg reserve by transferring a patient's EggPC cells from the protective ovarian lining back into the patient's own ovaries where they may mature into fertilizable eggs.

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

Developing new treatments for diseases. OvaXon℠ is a joint venture with Intrexon, which is focused on developing significant improvements in human and animal health using our EggPC cell technology and Intrexon's synthetic biology and high throughput platform for applications.

Strategic Alliances

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

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Collaboration with Intrexon to Accelerate Development of OvaTure

Scope

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

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

Technology Access Fee Payable to Intrexon

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

The shares issued to Intrexon are subject to "piggy-back" registration rights, unless waived, that entitle Intrexon to have the shares included in any new registration statement filed in connection with an underwritten public offering, subject to underwriter cutback.

Research and Development Funding and Potential Commercial Milestone

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

Termination Rights

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

Royalties

Upon the delivery of laboratory and animal data necessary to support the successful filing of an IND application, we will incur an obligation to pay Intrexon a mid-single digit royalty on net sales of any OvaTure fertility treatments.

Joint Venture

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

We recorded our initial investment in OvaXon as an equity method investment in December 2013. As of December 31 2015, OvaXon incurred expense in excess of the accumulated investment to-date. The additional expense incurred was included within accrued expenses on our consolidated balance sheet, as we had committed to provide additional funding in the future. We made additional contributions of $1.8 million in 2016. As of December 31, 2016, our equity investment in OvaXon was approximately $0.1 million.

Financial Operations Overview

Revenue

An AUGMENT treatment cycle begins upon our receipt of the patient's ovarian tissue after biopsy, which is obtained through a biopsy performed by the patient's doctor prior to hormone stimulation. Our proprietary process identifies and isolates the patient’s own EggPC cells, and then the patient’s own mitochondria from these EggPC cells are further isolated. The patient’s own mitochondria are then injected into her egg at the time of ICSI. We expect to receive payment before processing the patient's tissue and defer revenue until we have met all of our treatment obligations, including delivery of the mitochondria to the clinic. Based on our experiences to date, the period from receipt of the patient's tissue to when we expect to record revenue is expected to range between 30 and 120 days or more. Within

certain of our programs, revenue recognition may be

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further deferred. Our ability to generate revenue from sources other than the AUGMENT treatment, if ever, will depend upon the successful development and commercialization of the OvaPrime treatment, OvaTure treatment and any other future treatments.

Cost of Revenues

Cost of revenues includes all costs directly related to providing the AUGMENT treatment, which consists primarily of labor, material, facilities, warehousing and other overhead expenses. Cost of revenues also includes royalties paid or owed by us on our products and depreciation expense related to certain equipment used as part of the AUGMENT treatment.

Research and Development Expenses

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

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- fees for acquired technologies which have not yet reached technological feasibility and have no alternative use;
- costs of clinical trials for our potential fertility treatments;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, manufacturing organizations and consultants, including our scientific advisory board;
- license fees; and
- facilities, laboratory supplies and other allocated expenses.

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

We use our employee and infrastructure resources across multiple research and development projects. We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. We do not have actual external or total expenses by project for the years ended December 31, 2016, 2015 and 2014.

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our programs;
- the anticipated completion dates of our programs; or
- the period in which material net cash inflows are expected to commence, if at all, from our current programs and any potential future treatments.

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

- the scope and rate of progress of our clinical and preclinical studies and trials and other research and development activities from OvaPrime, OvaTure and any other potential fertility treatments;
- our ability to successfully introduce the OvaPrime treatment outside of the United States and to international IVF clinics;
- the scope, rate of progress and cost of any clinical trials that we may commence in the future;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our programs under development;

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- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our programs under development;
- our expectation that the AUGMENT treatment and OvaPrime treatment meet the requirements of a class of products exempt from pre-market review and approval under applicable regulations in certain countries where we plan to introduce the AUGMENT treatment and OvaPrime treatment;
- the cost and timing of any regulatory approvals required for the development and marketing of our treatments and the outcome of our planned discussions with the FDA;
- the cost of establishing clinical supplies of any treatments;
- the effect of competing technological and market developments.
- our reliance on our clinic partners to offer and use our treatments, and our development partner Intrexon to prioritize our human and bovine OvaTure programs; and
- our ability to conserve capital

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

Selling, General and Administrative Expenses

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

We expect selling, general and administrative expense to decrease as a result of the corporate restructuring announced in December 2016. We do not believe that our historical costs are indicative of the future costs associated with supporting our business activities nor do they represent what any other future programs we initiate may cost to support.

Interest Income

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

Income Tax Expense

Income tax expense includes taxes incurred in the U.S. and various state authorities as well as foreign jurisdictions in which we operate.

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

Revenue Recognition

To date, our revenues have consisted solely of sales of AUGMENT. We apply the revenue recognition guidance in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Subtopic 605, Revenue Recognition. We recognize revenue from AUGMENT sales when there is persuasive evidence that an arrangement

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exists, services have been rendered, the price is fixed or determinable, collectability is reasonably assured and we have no further performance obligations.

The AUGMENT treatment cycle begins upon our receipt of the patient's tissue. We expect to receive payment before processing the tissue and defer revenue until we meet all of our treatment obligations, including delivery of the mitochondria to the clinic. Based on our experiences to date, the period from receipt of the patient's tissue to when we expect to record revenue is expected to range between 30 and 120 days. Within certain of our programs, revenue recognition may be further deferred.

Accrued 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 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 and contract manufacturing 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

We expect to make additional stock option and restricted stock grants in the future, 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 FASB ASC Topic 718, Compensation—Stock Compensation, which we refer to as ASC 718. Determining the amount of stock-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. Stock-based compensation expense is recognized ratably over the requisite service period, which in most cases is the vesting period of the award. For awards with performance conditions, we estimate the likelihood of satisfaction of the performance criteria, which affects the awards expected to vest and the period over which the expense is recognized, and recognize the expense using the accelerated attribution model to the extent the condition is deemed probable. Calculating the fair value of stock-based awards requires that we make certain subjective assumptions, including estimating the expected term of the options issued and the estimated volatility of our stock price over the expected term. We used the Black-Scholes option pricing model to value our stock option awards.

The valuation assumptions were determined as follows:

- Risk-free interest rate: The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term of the awards.
- Expected annual dividend yield: The estimate for annual dividends is zero, because we have not historically paid a dividend and do not intend to do so in the foreseeable future.
- Expected stock price volatility: We determine the expected volatility by using a blend of our historical experience and a weighted average of selected peer companies.

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

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

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2016, 2015, and 2014 (dollars in thousands).

	Year Ended December 31,			2016 / 2015 Comparison Increase / (Decrease)		2015 / 2014 Comparison Increase / (Decrease)	
	2016	2015	2014	$	%	$	%
Revenues	$653	$277	$—	$376	136 %	$277	N/A
Costs of revenues	5,401	2,249	—	3,152	140 %	2,249	N/A
Research and development	21,641	18,433	21,784	3,208	17 %	$(3,351)	(15)%
Selling, general and administrative	49,223	51,594	26,149	(2,371)	(5)%	25,445	97 %
Restructuring	5,400	—	—	5,400	N/A	N/A	N/A
Interest income (expense), net	659	436	(126)	223	51 %	562	(446)%
Other (expense) income, net	(164)	(20)	122	(144)	720 %	(142)	(116)%
Loss from equity method investment	(1,542)	(1,561)	(1,583)	19	(1)%	22	(1)%
Income tax expense	(201)	(75)	—	(126)	168 %	(75)	N/A
Net loss	$(82,260)	$(73,219)	$(49,520)	$(9,041)	12 %	$(23,699)	48 %

Revenues

We commenced our first commercial AUGMENT treatment in December 2014, but did not record any revenue for the year ended December 31, 2014. We have recorded $653,000 and $277,000 of treatment revenues for the years ended December 31, 2016 and 2015, respectively. During 2016, additional clinic accounts began performing revenue generating AUGMENT treatment cycles, for which we received cash and have recognized revenue or have deferred the revenue and expect to recognize the associated revenue in future quarters. An AUGMENT treatment cycle begins upon our receipt of the patient's ovarian tissue after biopsy. We expect to receive payment before processing tissue and defer treatment revenues until we have met all of our treatment obligations, including delivery of the mitochondria to the clinic. Based on our experiences to date, the period from receipt of the patient's tissue to recording revenue is expected to range between 30 and 120 days. Within certain of our programs, revenue recognition may be further deferred. We had limited revenue and deferred revenue in 2016 and 2015. We have offered discounted treatments under various pilot pricing programs. These programs are designed to broaden the customer base knowledge and hands on experience with AUGMENT treatment. We may offer similar pricing programs in the future. Based on our decision to slow our commercial expansion, as announced in December 2016, we do not anticipate significant revenue in the near term. Our ability to generate additional revenue in the near term will depend on continued enrollment and use of the AUGMENT treatment in our clinic accounts.

Costs of Revenues

Costs of revenues for the year ended December 31, 2016 and 2015 was $5.4 million and $2.2 million, respectively. To make the AUGMENT treatment available in a specified international region, we need to establish laboratories and hire scientific personnel to process the patient tissue. Therefore, we expect that the cost of processing an AUGMENT treatment would decline if these fixed costs were allocated over a larger number of treatments. In 2016, we recorded charges of approximately $0.5 million related to the write-off of supplies, including $0.4 million in the fourth quarter due to the identification of excess inventory in connection with our change in corporate strategy relating to AUGMENT in December 2016. In 2015, we recorded charges of $0.9 million related to the write-off of supplies due

to expected expiration prior to commercial use and an anticipated change in our manufacturing process that made certain materials obsolete. We did not have costs of revenues for the year ended December 31, 2014.

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Research and Development Expenses

The $3.2 million, or 17%, increase in research and development expense for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily attributable to:

- a $3.9 million increase in employee compensation and related benefits driven by the hiring of additional research and development personnel;
- a $2.4 million increase in lab supplies and patient related costs associated with our ongoing clinical studies;
- a $0.1 million increase in facilities and other costs; and
- a $3.3 million decrease in stock-based compensation expense driven by certain mark-to-market adjustments of Founders' stock, which was fully expensed and vested in 2015 that did not recur in 2016, and stock-based compensation expense for certain executives that did not recur in 2016 as a result of executive leadership changes.

The $3.4 million, or 15%, decrease in research and development expense for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily attributable to:

- a $1.6 million decrease in stock-based compensation expense, including a $3.1 million decrease in expense for non-employee awards driven by Founders' shares being fully vested and expensed in the first quarter of 2015, compared to a full year of expense in 2014, partially offset by a $1.5 million increase in expense for employee awards driven by increased headcount in 2015 compared to 2014;
- a $0.9 million decrease in certain costs that have been transitioned to selling, general and administrative expense and to costs of revenues with the commercial launch of the AUGMENT treatment including costs associated with contract manufacturing; and
- a $0.8 million decrease in license fees, resulting from a decrease of $1.0 million for the milestone that became due upon completion of our public offering in the first quarter of 2014, which was offset by $0.2 million for a milestone incurred as a result of our first commercial AUGMENT treatment in the first quarter of 2015.

Selling, General and Administrative Expenses

The $2.4 million, or 5%, decrease in selling, general and administrative expense for the year ended December 31, 2016 compared to the year ended December 31, 2015 was primarily attributable to:

- a $7.2 million decrease in stock-based compensation expense related to pre-vest forfeitures as a result of the resignation of certain senior executives, as well as certain mark-to-market adjustments of Founders' shares, which was fully expensed and vested in the first quarter of 2015 that did not recur in 2016;
- a $4.2 million decrease in costs related to international expansion preparation, including the establishment of certain international legal entities and international infrastructure;
- a $4.3 million increase in employee compensation and related benefits driven by the hiring of additional selling, general and administrative personnel, including $0.3 million of severance related costs; and
- a $4.6 million increase in commercialization efforts and overall business growth, including increases of $2.6 million in marketing-related expenses, $0.7 million in legal expenses, and $1.3 million in accounting, tax and other related expenses.

The $25.4 million, or 97%, increase in selling, general and administrative expense for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily attributable to:

- a $13.7 million increase in employee compensation and related benefits, including stock-based compensation expense driven by the hiring of additional selling, general and administrative personnel in 2015 (a 62% headcount increase during the year);
- a $10.4 million increase to support our international growth and continued commercial development of the AUGMENT treatment including increases of $4.7 million in consulting, legal and marketing expenses, $2.7 million in specific AUGMENT commercialization costs, $1.7 million in travel and related costs, and $1.3 million associated with setting up labs at our clinic accounts;
- a $0.9 million increase in facilities expenses related to the relocation of our corporate headquarters to Waltham, MA; and

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- a $0.4 million increase in accounting, tax and other expenses.

Restructuring Expense

On December 21, 2016, we announced a corporate restructuring in which we reduced our workforce by approximately 30% as a result of our change in corporate strategy, primarily related to the commercialization strategy associated with our AUGMENT treatment. For the year ended December 31, 2016, we recognized restructuring charges totaling $5.4 million related to termination benefits and other related charges, including $1.4 million recorded as a one-time termination benefit, and $1.7 million recorded as a benefit under an ongoing benefit plan. The remaining 2016 restructuring charges primarily relate to a $2.0 million impairment of our laboratory and clinical site equipment. No such activities occurred for the years ended December 31, 2015 and 2014.

Interest Income (Expense), net

Interest income (expense) for the years ended December 31, 2016, 2015 and 2014 relates to interest earned on the average balances on our cash equivalents and short-term investments, offset in 2014 by $0.3 million of interest expense recorded to accrete the Intrexon technology access fee to its fair value through December 2014.

Loss from Equity Method Investment

Loss from equity method investment for each of the years ended December 31, 2016, 2015 and 2014 was $1.6 million. These losses resulted from our OvaXon joint venture established in December 2013.

Liquidity and Capital Resources

We have generated limited AUGMENT treatment revenue to date. We have relied on the proceeds from sales of equity securities to fund our operations. Our short-term investments primarily trade in liquid markets, and the average days to maturity of our portfolio as of December 31, 2016 are less than twelve months. Because our fertility treatments are in various stages of development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our fertility treatments, or whether or when we may achieve profitability.

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

	December 31, 2016	December 31, 2015
Cash, cash equivalents and short-term investments	$ 114,388	$ 126,662
Working capital	103,235	118,618

	Year Ended December 31,		
	2016	2015	2014
Cash (used in) provided by:			
Operating activities	$(61,734)	$(50,286)	$(30,588)
Investing activities	8,292	(38,290)	(32,788)
Capital expenditures (included in investing activities above)	(2,586)	(5,229)	(2,804)
Financing activities	54,148	125,386	51,712

Cash Flows

Cash used in operating activities for the years ended December 31, 2016, 2015 and 2014 was primarily driven by our net loss. Cash flows from operations can vary significantly due to various factors, including changes in the net loss and the timing of disbursements made for accounts payable and accruals.

Cash provided by investing activities for the year ended December 31, 2016 was primarily driven by the proceeds from maturities and sales of short-term investments. Cash used in investing activities for the years ended December 31, 2015 and 2014 included the purchase of and proceeds from maturities and sale of short-term investments, as well as purchases of property and equipment. Capital expenditures for the year ended December 31, 2016, 2015 and 2014 consisted primarily of laboratory equipment and leasehold improvements.

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Cash provided by financing activities for all periods presented included the proceeds from public offerings and stock option exercises. In June 2016, we issued and sold in an underwritten public offering an aggregate of 8,222,500 shares of our common stock at $7.00 per share which resulted in $53.9 million of net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us. In January 2015, we issued and sold in a public offering an aggregate of 2,645,000 shares of our common stock at $50.00 per share, which resulted in $124.1 million of net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us.

We will need substantial additional funds to support our planned operations and commercialization strategy. We expect our existing cash, cash equivalents and short-term investments of $114.4 million at December 31, 2016, will enable us to fund our current operating plan for at least the next 12 months. 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 fertility treatments, and the extent to which we may enter into collaborations with third parties for development and commercialization of our fertility treatments, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current treatments in development. Our future capital requirements will depend on many factors, including:

- the clinical development of the OvaPrime treatment and the AUGMENT treatment, and their subsequent adoption by international IVF clinics;
- the costs associated with preclinical development and subsequent clinical trials of the OvaTure treatment and other potential fertility treatments;
- the costs associated with establishing a domestic and international sales, marketing, manufacturing and distribution infrastructure to commercialize fertility treatments that we successfully develop, and to continue to sell the AUGMENT treatment;
- the pricing of the AUGMENT treatment and resulting revenues, as well as any future revenues we receive from our potential fertility treatments;
- the costs associated with the non-commercial preceptorship training programs and clinical studies and trials;
- the costs of continuing the optimization of the OvaTure treatment and preclinical development of that treatment, and our success in defining a clinical pathway;
- the costs involved in collaborating with Intrexon through the OvaXon joint venture to create new applications to prevent inherited diseases for human and animal health;
- following any applicable regulatory process in the United States and abroad, including the premarketing and marketing approval requirements, to which any of our potential fertility treatments may be subject;
- following any regulatory or institutional review board review of our potential fertility treatments that are subject to such review;
- preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- establishing collaborations and partnerships on favorable terms, if at all; and
- developing, acquiring or in-licensing other potential fertility treatments and technologies.

Until such time, if ever, as we can generate sufficient revenues from our fertility treatments to become profitable, 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. In addition, we may elect to raise additional funds even before we need them if the conditions for raising capital are favorable. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or treatments or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit,

reduce or terminate our fertility treatment development or future commercialization efforts or grant rights to develop and market treatments that we would otherwise prefer to develop and market ourselves.

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Off-Balance Sheet Arrangements

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

Contractual Obligations

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Operating leases	3,855	986	1,945	924	—
	$3,855	$986	$1,945	$924	$ —

RecentAccounting Standards

In November 2016, the FASB issued ASU No. 2016-18, Statement of Cash Flows (Topic 230) - Restricted Cash. ASU 2016-18 require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. This update is for entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years using a retrospective transition method to each period presented. Early adoption is permitted. We do not believe the adoption of ASU 2016-18 will have a material impact on our consolidated financial statements and footnote disclosures thereto.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 requires changes in the presentation of debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies and distributions received from equity method investees. This update is effective for annual and interim periods beginning after December 15, 2017 using a retrospective transition method to each period presented. Early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Based Compensation, which simplifies several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 also provides the option to either continue to estimate the number of awards that are expected to vest or to account for forfeitures as they occur. The amendment is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods, early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which is intended to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new standard, a lessee will be required to recognize assets and liabilities for both operating and financing leases with lease terms of more than 12 months. In addition, ASU 2016-02 requires the use of the modified retrospective method, which will require adjustment to all comparative periods presented in the consolidated financial statements. The amendment is effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. We are currently assessing the impact that adopting this new accounting standard will have on our consolidated financial statements and footnote disclosures thereto.

In November 2015, FASB ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, which simplifies the presentation of deferred taxes. ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent on the balance sheet. The amendment is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We elected early adoption of this ASU prospectively as of December 31, 2015. We maintain full valuation allowances on all deferred tax balances, and therefore, the adoption had no impact to current or prior period reporting.

In August 2015, the FASB issued ASU No. 2015-14, which defers the effective date of ASU No. 2014-09 by one year. ASU 2014-09 amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. This guidance is now effective for fiscal years beginning after December 15, 2017 with early adoption permitted for annual periods beginning after December 15, 2016. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. We have

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not yet determined whether we will utilize the full retrospective or modified retrospective method upon adoption of the new revenue standard. We are currently in the process of determining the impact the adoption of ASU 2015-14 will have on our consolidated financial statements but due to the limited revenues we have generated for the periods presented, we do not believe the adoption of ASU 2015-14 will have a material impact on our consolidated financial statements and footnotes disclosures thereto.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements—Going Concern. ASU 2014-15 requires management of public and private companies to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. We are also be required to evaluate and disclose whether our plans alleviate that doubt. This guidance is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. We adopted ASU 2014-15 for the year ending December 31, 2016. The adoption of ASU 2014-15 did not have a material impact on our consolidated financial statements and related disclosures.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since a significant portion of our investments are in money market funds and corporate obligations. We do not enter into investments for trading or speculative purposes. We maintain our cash, cash equivalents and short-term investments with a high quality, accredited financial institution. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase.

A hypothetical 100 basis point increase in interest rates would result in a decrease in the fair value or our investments of approximate $0.3 million and $0.5 million as of December 31, 2016 and 2015, respectively. We have the ability to hold our fixed income investments until maturity and, therefore, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

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.

Item 8. Financial Statements and Supplementary Data

The information required by Item 8 is contained on pages F-1 through F-27 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 of Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2016. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d- 15(e) under the Securities Exchange Act of 1934, 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 our 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, 2016, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, as amended. Our internal control system was

designed to

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provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its 2013 Internal Control—Integrated Framework. Based on our assessment we believe that, as of December 31, 2016, our internal control over financial reporting is effective based on those criteria. The effectiveness of our internal control over financial reporting as of December 31, 2016 has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their report which appears below in this section.

Changes in Internal Controls

No change in our internal control over financial reporting, identified in connection with the evaluation of such internal control, that occurred during the fourth quarter ended December 31, 2016 has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm
The Board of Directors and Stockholders of OvaScience, Inc.

We have audited OvaScience, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). OvaScience, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, OvaScience, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of OvaScience, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016 of OvaScience, Inc. and our report dated March 2, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
March 2, 2017

Item 9B. Other Information

As announced initially on December 21, 2016, we determined to change our corporate strategy in December 2016, including a workforce reduction to better align our workforce to our revised corporate strategy and to carefully manage our cash burn.

For the year ended December 31, 2016, we recognized restructuring charges totaling $5.4 million related to termination benefits and other related charges, including $1.4 million recorded as a one-time termination benefit, and $1.7 million recorded as a benefit under an ongoing benefit plan. The remaining 2016 restructuring charges relate to a $2.0 million impairment of our fixed assets. We anticipate that we will incur an additional $1.4 million to $2.8 million in restructuring charges during 2017.

Cash expenditures related to the actions resulting from this corporate restructuring are estimated to total between $5.7 million and $6.5 million over 2017 and 2018.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by Item 10 of Form 10-K may be found under the captions "Corporate Governance" and "Ownership of our Common Stock—Section 16(a) Beneficial Ownership Reporting Compliance" in the definitive proxy statement to be delivered to stockholders in connection with our 2017 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 under the captions "Executive Compensation," "Director Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report" in the definitive proxy statement to be delivered to stockholders in connection with our 2017 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

The information required by Item 12 of Form 10-K may be found under the captions "Ownership of our Common Stock—Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under our Equity Compensation Plans" in the definitive proxy statement to be delivered to stockholders in connection with our 2017 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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

The information required by Item 13 of Form 10-K may be found under the captions "Certain Relationships and Related Transactions" and "Corporate Governance" in the definitive proxy statement to be delivered to stockholders in connection with our 2017 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by Item 14 of Form 10-K may be found under the caption "Audit-Related Matters" in the definitive proxy statement to be delivered to stockholders in connection with our 2017 Annual Meeting of Stockholders. Such information is incorporated herein by reference.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) The following financial statements are filed as part of this report:

(a)(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.

(a)(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File / Registration Number
3.1	Restated Certificate of Incorporation of the Registrant		Form 8-K (Exhibit 3.1)	April 30, 2013	001-35890
3.2	Third Amended and Restated By-laws of the Registrant		Form 8-K (Exhibit 3.1)	December 23, 2016	001-35890
4.1	Specimen Stock Certificate evidencing shares of Common Stock		Form S-1 (Exhibit 4.1)	August 29, 2012	333-183602
4.2	Amended and Restated Investors' Rights Agreement, dated March 29, 2012, by and among the Registrant and the other parties thereto		Form 10 (Exhibit 4.4)	April 11, 2012	000-54647
4.3	Registration Rights Agreement, dated August 13, 2012, by and among the Company and the persons party thereto		Form 8-K (Exhibit 10.2)	August 14, 2012	000-54647
10.01#	2011 Stock Incentive Plan		Form 10 (Exhibit 10.1)	April 11, 2012	000-54647
10.02#	Forms of Incentive Stock Option Agreement under the 2011 Stock Incentive Plan		Form 10 (Exhibit 10.2)	May 17, 2012	000-54647

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10.03#	Forms of Nonstatutory Stock Option Agreement under the 2011 Stock Incentive Plan	Form 10 (Exhibit 10.3)	May 17, 2012	000-54647
10.04#	Form of Restricted Stock Agreement under the 2011 Stock Incentive Plan	Form 10 (Exhibit 10.4)	May 17, 2012	000-54647
10.05#	2012 Stock Incentive Plan	Form 10 (Exhibit 10.5)	April 11, 2012	000-54647
10.06#	Form of Incentive Stock Option Agreement under the 2012 Stock Incentive Plan	Form 10-K (Exhibit 10.6)	March 16, 2015	001-35890
10.07#	Form of Nonstatutory Stock Option Agreement under the 2012 Stock Incentive Plan	Form 10-K (Exhibit 10.7)	March 16, 2015	001-35890
10.08†	Exclusive License Agreement, dated June 27, 2011, between the Registrant and The General Hospital Corporation	Form 10-Q (Exhibit 10.2)	May 11, 2015	001-35890
10.09†	Amendment No. 1 to the Exclusive License Agreement, dated September 7, 2011, between the Registrant and The General Hospital Corporation	Form 10-Q (Exhibit 10.3)	May 11, 2015	001-35890
10.10†	Amendment No. 2 to the Exclusive License Agreement, dated July 30, 2013, between the Registrant and The General Hospital Corporation	Form 10-K (Exhibit 10.12)	February 27, 2014	001-35890
10.11	Amendment No. 3 to the Exclusive License Agreement, dated September 9, 2013, between the Registrant and The General Hospital Corporation	Form 10-K (Exhibit 10.13)	February 27, 2014	001-35890
10.12†	Amendment No. 4 to the Exclusive License Agreement, dated November 14, 2013, between the Registrant and The General Hospital Corporation	Form 10-K (Exhibit 10.14)	February 27, 2014	001-35890
10.13†	Amendment No. 5 to the Exclusive License Agreement, dated December 18, 2013, between the Registrant and The General Hospital Corporation	Form 10-K (Exhibit 10.15)	February 27, 2014	001-35890
10.14†	Amendment No. 6 to the Exclusive License Agreement by and between OvaScience, Inc. and The General Hospital Corporation.	Form 10-K (Exhibit 10.3)	November 3, 2016	001-35890

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10.15†	Intellectual Property License Agreement, dated December 18, 2013, between the Registrant and OvaXon, LLC	Form 10-K (Exhibit 10.34)	February 27, 2014	001-35890
10.16†	Exclusive Channel Collaboration Agreement, dated December 18, 2013, between the Registrant and Intrexon Corporation and OvaXon, LLC	Form 10-K (Exhibit 10.35)	February 27, 2014	001-35890
10.17	Exclusive Channel Collaboration Agreement, dated December 18, 2013, between Intrexon Corporation and OvaXon, LLC	Form 10-K (Exhibit 10.36)	February 27, 2014	001-35890
10.18	Lease Agreement, dated May 22, 2015, by and between Nine Fourth Avenue LLC and the Registrant	Form 10-Q (Exhibit 10.1)	August 10, 2015	001-35890
10.19	Form of Indemnification Agreement between the Registrant and each of Richard Aldrich and Michelle Dipp	Form 10 (Exhibit 10.21)	April 11, 2012	000-54647
10.20#	Form of Indemnification Agreement between the Registrant and each of Jeffrey Capello, Mary Fisher, John Howe, Marc Kozin, Thomas Malley, John Sexton and Harald Stock	Form 10 (Exhibit 10.22)	April 11, 2012	000-54647
10.21#	Amended and Restated Non-Employee Director Compensation Policy of the Registrant (effective 2016)	Form 10-K (Exhibit 10.34)	March 16, 2015	001-35890
10.22#	Amended and Restated Letter Agreement, dated December 9, 2014, between the Registrant and Michelle Dipp	Form 10-K (Exhibit 10.21)	March 16, 2015	001-35890
10.23#	Time-Based Restricted Stock Unit Agreement, dated December 9, 2014, between the Registrant and Michelle Dipp	Form 10-K (Exhibit 10.22)	March 16, 2015	001-35890
10.24#	Performance-Based Restricted Stock Unit Agreement, dated December 9, 2014, between the Registrant and Michelle Dipp	Form 10-K (Exhibit 10.23)	March 16, 2015	001-35890
10.25#	Stock Option Agreement, dated December 9, 2014, between the Registrant and Michelle Dipp	Form 10-K (Exhibit 10.24)	March 16, 2015	001-35890

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10.26#	Letter Agreement, dated July 15, 2013, between the Registrant and Arthur Tzianabos	Form 10-Q (Exhibit 10.1)	November 13, 2013	001-35890
10.27#	Stock Option Agreement, dated September 10, 2013, between the Registrant and Arthur Tzianabos	Form 10-Q (Exhibit 10.2)	November 13, 2013	001-35890
10.28#	Offer Letter, dated July 22, 2014, between the Registrant and Jeffrey E. Young	Form 8-K (Exhibit 10.1)	September 18, 2014	001-35890
10.29#	Stock Option Agreement, dated September 18, 2014, between the Registrant and Jeffrey E. Young	Form 8-K (Exhibit 10.2)	September 18, 2014	001-35890
10.30#	Executive Agreement, dated January 5, 2016, between the Registrant and Michelle Dipp	Form 10-K (Exhibit 10.29)	February 26, 2016	001-35890
10.31#	Employment Agreement, dated January 5, 2016, between the Registrant and Harald Stock	Form 10-K (Exhibit 10.30)	February 26, 2016	001-35890
10.32#	U.K. Appointment Letter, dated January 5, 2016, between OvaScience Limited and Harald Stock	Form 10-K (Exhibit 10.31)	February 26, 2016	001-35890
10.33#	Incentive Stock Option Agreement between the Registrant and Harald Stock dated January 5, 2016.	Form 10-Q (Exhibit 10.4)	May 5, 2016	001-35890
10.34#	Nonstatutory Stock Option Agreement between the Registrant and Harald Stock dated January 5, 2016.	Form 10-Q (Exhibit 10.5)	May 5, 2016	001-35890
10.35#	Restricted Stock Unit Award Agreement between the Registrant and Harald Stock dated January 5, 2016.	Form 10-Q (Exhibit 10.6)	May 5, 2016	001-35890
10.36#	Employment Agreement, dated February 25, 2016, between the Registrant and Paul W. D. Chapman.	Form 10-Q (Exhibit 10.7)	May 5, 2016	001-35890
10.37#	Nonstatutory Stock Option Agreement between the Registrant and Paul W. D. Chapman dated March 3, 2016.	Form 10-Q (Exhibit 10.8)	May 5, 2016	001-35890
10.38#	Independent Consulting Agreement and Separation Agreement, dated March 31, 2016, between the Registrant and Arthur Tzianabos.	Form 10-Q (Exhibit 10.9)	May 5, 2016	001-35890

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10.39#	Offer Letter, dated September 6, 2016, by and between the Registrant and Christophe Couturier.	Form 8-K (Exhibit 10.1)	September 6, 2016	001-35890
10.40#	Nonstatutory Stock Option Agreement between the Registrant and Christophe Couturier dated September 6, 2016.	Form 10-Q (Exhibit 10.2)	November 3, 2016	001-35890
10.41#	Separation Agreement between the Registrant and Harald Stock dated December 21, 2016	X		
10.42#	Separation Agreement between the Registrant and Paul W.D. Chapman dated December 21, 2016	X		
10.43	Sales Agreement between the Registrant and Cowen and Company, LLC, dated November 3, 2016	Form S-3 (Exhibit 1.2)	November 3, 2016	333-214413
21.1	List of Subsidiaries of the Registrant	X		
23.1	Consent of Ernst & Young	X		
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X		
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X		
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	X		
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	X		
101.INS	XBRL Instance Document	X		
101.SCH	XBRL Taxonomy Extension Schema Document	X		
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X		
101.DEF	XBRL Taxonomy Extension Definition	X		

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101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X
101.PRE	XBRL Taxonomy Presentation Linkbase Document	X

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† Confidential treatment received as to portions of the exhibit. Confidential materials omitted and filed separately with the SEC.

# Indicates a management contract or compensatory plan.

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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 March 2, 2017.

OVASCIENCE, INC.

By: /s/ MICHELLE DIPP
Michelle Dipp, M.D., Ph.D.
Executive Chair

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 Michelle Dipp, M.D., Ph.D.	Executive Chair (Principal executive officer)	March 2, 2017
/s/ CHRISTOPHE COUTURIER Christophe Couturier	Chief Financial Officer (Principal financial and accounting officer)	March 2, 2017
/s/ RICHARD ALDRICH Richard Aldrich	Director	March 2, 2017
/s/ JEFFREY D. CAPELLO Jeffrey D. Capello	Director	March 2, 2017
/s/ MARY FISHER Mary Fisher	Director	March 2, 2017
/s/ JOHN HOWE John Howe, M.D.	Director	March 2, 2017
/s/ MARC KOZIN Marc Kozin	Director	March 2, 2017
/s/ THOMAS MALLEY Thomas Malley	Director	March 2, 2017
/s/ JOHN SEXTON John Sexton, Ph.D.	Director	March 2, 2017

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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. as of December 31, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. 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 audits 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as 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. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), OvaScience, Inc.’s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 2, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP
Boston, Massachusetts
March 2, 2017

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OvaScience, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share data)

	As of December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$43,930	$43,224
Short-term investments	70,458	83,438
Prepaid expenses and other current assets	2,056	3,002
Restricted cash	—	197
Total current assets	116,444	129,861
Property and equipment, net	5,572	8,313
Investment in joint venture	65	—
Restricted cash	439	439
Other long-term assets	23	—
Total assets	$122,543	$138,613
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$2,183	$3,352
Accrued expenses and other current liabilities	11,026	7,891
Total current liabilities	13,209	11,243
Other non-current liabilities	1,116	520
Total liabilities	14,325	11,763
Commitments and contingencies (Note 10)		
Stockholders' equity:		
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 shares authorized; 35,641,505 and 27,296,747 shares issued and outstanding at December 31, 2016 and 2015, respectively	36	27
Additional paid-in capital	358,419	294,910
Accumulated other comprehensive loss	(60)	(170)
Accumulated deficit	(250,177)	(167,917)
Total stockholders' equity	108,218	126,850
Total liabilities and stockholders' equity	$122,543	$138,613

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

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OvaScience, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Revenues	$653	$277	$—
Costs and expenses:			
Costs of revenues	5,401	2,249	—
Research and development	21,641	18,433	21,784
Selling, general and administrative	49,223	51,594	26,149
Restructuring	5,400	—	—
Total costs and expenses	81,665	72,276	47,933
Loss from operations	(81,012)	(71,999)	(47,933)
Interest income (expense), net	659	436	(126)
Other (expense) income, net	(164)	(20)	122
Loss from equity method investment	(1,542)	(1,561)	(1,583)
Loss before income taxes	(82,059)	(73,144)	(49,520)
Income tax expense	201	75	—
Net loss	$(82,260)	$(73,219)	$(49,520)
Net loss per share—basic and diluted	$(2.56)	$(2.70)	$(2.19)
Weighted average number of shares used in net loss per share—basic and diluted	32,148	27,085	22,647
Net loss	$(82,260)	$(73,219)	$(49,520)
Other comprehensive loss:			
Unrealized gain (loss) on available-for-sale securities	110	(144)	(36)
Comprehensive loss	$(82,150)	$(73,363)	$(49,556)

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

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OvaScience, Inc.
Consolidated Statements of Stockholders' Equity
(In thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Amount				
Balance at January 1, 2014	17,541,126	$ 18	$86,851	$ 10	$(45,178)	$41,701
Issuance of common stock under public offering, net of underwriters' discounts and issuance costs	5,518,630	5	51,728	—	—	51,733
Vesting of Founders stock	658,060	1	1	—	—	2
Exercise of stock options	308,150	—	163	—	—	163
Stock-based compensation expense	—	—	12,407	—	—	12,407
Vesting of restricted stock	58,671	—	(1,125)	—	—	(1,125)
Unrealized loss on investments	—	—	—	(36)	—	(36)
Net loss	—	—	—	—	(49,520)	(49,520)
Balance at December 31, 2014	24,084,637	$ 24	$150,025	$ (26)	$(94,698)	$55,325
Issuance of common stock under public offering, net of underwriters' discounts and issuance costs	2,645,000	3	124,060	—	—	124,063
Vesting of Founders stock	329,021	—	—	—	—	—
Issuance of common stock to board of directors	15,808	—	165	—	—	165
Exercise of stock options	208,734	—	1,440	—	—	1,440
Stock-based compensation expense	—	—	19,337	—	—	19,337
Vesting of restricted stock	13,547	—	(117)	—	—	(117)
Unrealized loss on investments	—	—	—	(144)	—	(144)
Net loss	—	—	—	—	(73,219)	(73,219)
Balance at December 31, 2015	27,296,747	$ 27	$294,910	$ (170)	$(167,917)	$126,850
Issuance of common stock under public offering, net of underwriters' discounts and issuance costs	8,222,500	9	53,916	—	—	53,925
Issuance of common stock to board of directors	42,047	—	154	—	—	154
Exercise of stock options	63,961	—	224	—	—	224
Stock-based compensation expense	—	—	9,215	—	—	9,215
Vesting of restricted stock	16,250	—	—	—	—	—
Unrealized gain on investments	—	—	—	110	—	110
Net loss	—	—	—	—	(82,260)	(82,260)
Balance at December 31, 2016	35,641,505	$ 36	$358,419	$ (60)	$(250,177)	$108,218

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

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OvaScience, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$(82,260)	$(73,219)	$(49,520)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,238	1,286	450
Impairment of property and equipment	147	—	—
Impairment of property and equipment related to restructuring	1,994	—	—
Amortization of premium on debt securities	659	1,116	871
Stock-based compensation expense	9,215	19,337	12,407
Issuance of common stock for board of directors fees	154	165	—
Net loss on equity method investment	1,542	1,561	1,583
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	946	(1,113)	(997)
Accounts payable	(1,178)	(171)	2,317
Accrued expenses, current and other non-current liabilities	4,809	752	2,301
Net cash used in operating activities	(61,734)	(50,286)	(30,588)
Cash flows from investing activities:			
Investment in joint venture	(1,750)	(1,500)	(1,500)
Purchases of property and equipment	(2,586)	(5,229)	(2,804)
Maturities of short-term investments	72,013	53,528	20,797
Sales of short-term investments	23,089	10,817	8,431
Purchases of short-term investments	(82,671)	(95,225)	(57,603)
(Decrease) increase in restricted cash	197	(681)	(109)
Net cash provided by (used in) investing activities	8,292	(38,290)	(32,788)
Cash flows from financing activities:			
Net proceeds from the issuance of common stock	53,925	124,063	51,733
Issuances of common stock under benefit plans, net of withholding taxes paid	223	1,323	(21)
Net cash provided by financing activities	54,148	125,386	51,712
Net increase (decrease) in cash and cash equivalents	706	36,810	(11,664)
Cash and cash equivalents at beginning of period	43,224	6,414	18,078
Cash and cash equivalents at end of period	$43,930	$43,224	$6,414
Supplemental disclosure of non-cash investing activity			
Additions of property and equipment included in accounts payable and accrued liabilities	$55	$1,003	$133

The accompanying notes are an integral part of these consolidated financial statement.

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OvaScience, Inc.
Notes to Consolidated Financial Statements
1. Organization
OvaScience, Inc., incorporated on April 5, 2011 as a Delaware corporation, is a global fertility company developing proprietary potential treatments to enhance female fertility based on scientific discoveries about the existence of egg precursor, or EggPC℠ cells. As used in these consolidated financial statements, the terms "OvaScience", "the Company", "we", "us", and "our" refer to the business of OvaScience, Inc. and its wholly owned subsidiaries. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential fertility treatments, developing the AUGMENT℠ treatment, preparing for the AUGMENT treatment in select international in vitro fertilization ("IVF") clinics, researching and developing the OvaTure℠ the OvaPrime℠ treatment and the treatment, and determining the development and regulatory path for our fertility treatments. We have only generated limited revenues to date, and do not anticipate significant revenues in the near term.
We are subject to a number of risks similar to other life science companies, including, but not limited to, the need to obtain adequate additional funding, possible failure to provide our fertility treatments to IVF clinics to gain clinical experience in select countries outside of the United States, the need to obtain regulatory and marketing approval for certain of our fertility treatments, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of our fertility treatments and protection of proprietary technology. If we do not successfully commercialize any of our fertility treatments, we will be unable to generate treatment revenue or achieve profitability. As of December 31, 2016 we had an accumulated deficit of approximately $250.2 million.
Liquidity
We have incurred annual net operating losses in each year since our inception. We have generated limited treatment revenues related to our primary business purpose and have financed our operations primarily through private placements of our preferred stock, which was subsequently converted to common stock, and public sales of our common stock and interest income earned on cash, cash equivalents, and short-term investments balances.
We have commercialized one fertility treatment, the AUGMENT treatment, in select international IVF clinics and have two potential treatments in development. We have devoted substantially all of our financial resources and efforts to research and development, raising capital and efforts to commercialize the AUGMENT treatment. We expect to continue to incur significant expenses and operating losses for at least the next several years.
We believe that our cash and cash equivalents and short-term investments of approximately $114.4 million at December 31, 2016, will be sufficient to fund our current operating plan for at least the next 12 months. There can be no assurances, however, that the current operating plan will be achieved or that additional funding, if needed, will be available on terms acceptable to us, or at all.
2. Summary of Significant Accounting Policies
Basis of Presentation
Our consolidated financial statements include the accounts of OvaScience, Inc. and our wholly-owned subsidiaries. All intercompany transactions have been eliminated in consolidation. The financial statements are presented in United States dollars, our functional currency.
These consolidated financial statements are presented in conformity with U.S. generally accepted accounting principles, which require management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments. We based our estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.
Cash Equivalents and Short-term Investments
Cash equivalents and short-term investments primarily consist of money market funds, corporate debt securities and government debt securities. Corporate debt securities include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government

agencies. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash

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equivalents, which consist of money market funds, are stated at fair value. They are also readily convertible to known amounts of cash and have such short-term maturities that each presents insignificant risk of change in value due to changes in interest rates.

The appropriate classification of short-term investments is determined at the time of purchase and reevaluated at each balance sheet date. We have classified all of our short-term investments at December 31, 2016 and 2015 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive loss, which is a separate component of stockholders' equity.

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

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

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

Fair Value Measurements

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

We value our short-term investments utilizing third party pricing services. The pricing services use observable market inputs to determine value, including benchmark yields, reportable trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, reference data, new issue data, and monthly payment information. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and confirming that those securities trade in active markets.

Restricted Cash

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

Concentrations of Risk

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

Segment Information

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

dedicated to the treatment of female infertility.

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Revenue Recognition

To date, our revenues have consisted solely of sales of AUGMENT. We apply the revenue recognition guidance in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Subtopic 605, Revenue Recognition. The Company recognizes revenue from AUGMENT sales when there is persuasive evidence that an arrangement exists, services have been rendered, the price is fixed or determinable, collectability is reasonably assured and we have no further performance obligations.

The AUGMENT treatment cycle begins upon our receipt of the patient's tissue. We expect to receive payment before processing the tissue and defer revenue until we have met all of our treatment obligations, including the delivery of the mitochondria to the clinic. Based on our experiences to date, the period from receipt of the patient's tissue to when we expect to record revenue is expected to range between 30 and 120 days or more. Within certain of our programs, revenue recognition may be further deferred.

Costs of Revenues

Cost of revenues includes all costs directly related to providing the AUGMENT treatment, which consists primarily of labor, material, facilities, warehousing and other overhead expenses. Cost of revenues also includes royalties paid or owed by us on our products and depreciation expense related to certain equipment used as part of the AUGMENT treatment.

Research and Development Costs

We expense research and development costs to operations as incurred. Research and development expenses consist of costs associated with research activities, including license payments paid to third parties for rights to intellectual property, the costs of development of treatments and advances in the field of infertility. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made. We also include as research and development expense access fees for technologies which have not yet reached technological feasibility and have no alternative use. Research and development expenses consist of:

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

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

Selling, general and administrative costs

We expense selling, general and administrative costs as incurred. Selling, general and administrative costs consist of ongoing costs to run our daily operations and internal costs to support the international availability of the AUGMENT treatment.

Stock-based Compensation

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

performance condition is deemed probable. We use the Black-Scholes valuation model in determining the fair value of stock options.

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Stock-based compensation expense is determined including estimated forfeitures, and is adjusted each period to reflect actual forfeitures and the outcomes of certain performance conditions.

Income Taxes

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

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

Due to the uncertainty surrounding the realization of the net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of December 31, 2016 and 2015.

Property and Equipment

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

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

Impairment of Long-Lived Assets

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

For the year ended December 31, 2016, as the result of our corporate strategy and restructuring announced in December 2016, we recorded a fixed asset impairment charge of $2.0 million. No fixed asset impairment charges were recorded for the years ended December 31, 2015 and 2014.

Net Loss per Share

Basic and diluted net loss per common share is calculated by dividing net loss by the weighted average number of shares outstanding during the period. Potentially dilutive shares, including outstanding stock options and unvested restricted stock, are only included in the calculation of diluted net loss per share when their effect is dilutive.

Consolidation of Variable Interest Entities

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

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New accounting pronouncements

In November 2016, the FASB issued Accounting Standard Update (ASU) No. 2016-18, Statement of Cash Flows (Topic 230) - Restricted Cash. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. This update is for entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years using a retrospective transition method to each period presented. Early adoption is permitted. We do not believe the adoption of ASU 2016-18 will have a material impact on our consolidated financial statements and footnote disclosures thereto.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. ASU 2016-15 requires changes in the presentation of debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance policies and distributions received from equity method investees. This update is effective for annual and interim periods beginning after December 15, 2017 using a retrospective transition method to each period presented. Early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Based Compensation, which simplifies several aspects of accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard also provides the option to either continue to estimate the number of awards that are expected to vest or to account for forfeitures as they occur. The amendment is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods, early adoption is permitted. We are evaluating this standard to determine if adoption will have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which is intended to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new standard, a lessee will be required to recognize assets and liabilities for both operating and financing leases with lease terms of more than 12 months. In addition, ASU 2016-02 requires the use of the modified retrospective method, which will require adjustment to all comparative periods presented in the consolidated financial statements. The amendment is effective for annual periods beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. We are currently assessing the impact that adopting this accounting standard will have on our consolidated financial statements and footnote disclosures thereto.

In November 2015, FASB ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes, which simplifies the presentation of deferred taxes. The new standard requires that deferred tax liabilities and assets be classified as noncurrent on the balance sheet. The amendment is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. We elected early adoption of this ASU prospectively as of December 31, 2015. We maintain full valuation allowances on all deferred tax balances, and therefore, the adoption had no impact to current or prior period reporting.

In August 2015, the FASB issued ASU No. 2015-14, which defers the effective date of ASU No. 2014-09 by one year. ASU 2014-09 amends the guidance for accounting for revenue from contracts with customers. This ASU supersedes the revenue recognition requirements in Accounting Standards Codification Topic 605, Revenue Recognition, and creates a new Topic 606, Revenue from Contracts with Customers. This guidance is now effective for fiscal years beginning after December 15, 2017 with early adoption permitted for annual periods beginning after December 15, 2016. Two adoption methods are permitted: retrospectively to all prior reporting periods presented, with certain practical expedients permitted; or retrospectively with the cumulative effect of initially adopting the ASU recognized at the date of initial application. We have not yet determined which adoption method we will utilize or the effect that the adoption of this guidance will have on our consolidated financial statements. We are currently in the process of determining the impact the adoption of ASU 2015-14 will have on our consolidated financial statements but due to the limited revenues we have generated for the periods presented, we do not believe the adoption of ASU

2015-14 will material impact on our consolidated financial statements and footnote disclosures thereto.
In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern. The new standard requires management of public and private companies to evaluate whether there is substantial doubt about the entity's ability to continue as a going concern and, if so, disclose that fact. We are also be required to evaluate and disclose whether our plans alleviate that doubt. This guidance is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. We adopted ASU 2014-15 for the year ending December 31, 2016. The adoption of ASU 2014-15 did not have a material impact on our consolidated financial statements and related disclosures.

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3. Business Agreements

Exclusive License Agreement with Massachusetts General Hospital

We acquired an exclusive, royalty-bearing, worldwide license pursuant to a license agreement, as amended, with Massachusetts General Hospital, or MGH and The President and Fellows of Harvard College, or Harvard to make, use and sell products covered by the licensed patent rights. These rights include the technology used as part of the AUGMENT treatment and our other fertility treatments.

Under the agreement, as amended, we agreed to pay MGH upfront license fees and reimbursed patent related fees and costs incurred by MGH and Harvard totaling approximately $0.4 million in the aggregate. We also agreed to pay MGH annual license fees, annual maintenance fees, milestone payments, royalties as a percentage of net sales and a percentage of sublicense income that we receive. Annual license fees are creditable against royalties. Annual maintenance fees are due beginning in the third year of the agreement and are not creditable against royalties. Milestone payments of up to an aggregate of approximately $10.7 million are triggered upon the achievement of specified developmental and commercialization milestones and are not creditable against royalties. Additionally, we paid $1.0 million in connection with our March 2014 offering. The royalty rate is in the low single digits as a percentage of net sales. Net sales do not include amounts billed to patients by clinics and medical practices that use licensed products or perform licensed services for such patients, but do include the amounts paid to us by such clinics and medical practices.

Collaboration with Intrexon

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

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

Technology Access Fee Payable to Intrexon

The technology access fee paid to Intrexon was comprised of (1) the issuance of 273,224 shares, or $2.5 million of common stock issued to Intrexon, upon the execution of the OvaTure Collaboration in December 2013, and (2) a $2.5 million cash payment that was made in December 2014.

The shares issued to Intrexon are subject to "piggy-back" registration rights that entitle Intrexon, unless waived, to have the shares included in any new registration statement filed in connection with an underwritten public offering, subject to underwriter cutback.

Research and Development Funding and Potential Commercial Milestone

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

Termination Rights

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

Royalties

Upon the delivery of laboratory and animal data necessary to support the successful filing of an IND application, we will pay Intrexon a mid-single digit royalty on net sales of potential OvaTure fertility treatments, and the exact royalty will depend upon the timing of the completion of the milestone.

OvaXon Joint Venture

On December 18, 2013, we also entered into a joint venture with Intrexon to leverage Intrexon's synthetic biology technology platform and our technology relating to EggPC cells to focus on developing significant improvements in human and animal health. We and Intrexon formed OvaXon, LLC, or OvaXon, to conduct the joint venture. Each

party contributed $1.5

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million of cash to OvaXon, each has a 50% equity interest and all costs and profits will be split accordingly. Each party will also have 50% control over OvaXon and any disputes between us and Intrexon will be resolved through arbitration, if necessary.

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

As of December 31, 2016, the Company's investment in OvaXon was approximately $0.1 million. As of December 31, 2015, OvaXon incurred expenses of $0.1 million in excess of the investment, which was included within accrued expenses on our consolidated balance sheet as we were committed to provide additional funding in 2016. Each party contributed $1.8 million during 2016. Our maximum exposure to loss with respect to our joint venture is limited to the carrying amount of the investment and any unfunded commitment.

4. Fair value Measurements

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

- Level 1 — quoted prices (unadjusted) in active markets for identical assets.
- Level 2 — quoted prices for similar assets in active markets or inputs that are observable for the asset, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.
- Level 3 — unobservable inputs based on our assumptions used to measure assets at fair value.

For fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. The prices provided by third party pricing services are validated by reviewing their pricing methods and obtaining market values from other pricing sources. After completing these validation procedures, we did not adjust or override any fair value measurements provided by the pricing services as of December 31, 2016 or December 31, 2015.

We review investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. To determine whether an impairment is other-than-temporary, we consider the intent to sell, or whether it is more likely than not that we will be required to sell, the investment before recovery of the investment's amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with our investment policy, the severity and the duration of the impairment and changes in value subsequent to year end.

The following tables provide our assets that are measured at fair value as of December 31, 2016 and 2015 (in thousands):

Description	Balance as of December 31, 2016	Level 1	Level 2	Level 3
Assets:				
Cash and money market funds	$ 43,930	$43,930	$—	$ —
Corporate debt securities (including commercial paper)	70,458	—	70,458	—
Total assets	$ 114,388	$43,930	$70,458	$ —

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Description	Balance as of December 31, 2015	Level 1	Level 2	Level 3
Assets:				
Cash and money market funds	$43,224	$43,224	$—	$ —
Corporate debt securities (including commercial paper)	83,438	—	83,438	—
Total assets	$126,662	$43,224	$83,438	$ —

There have been no changes to the valuation methods during the years ended December 31, 2016 and 2015. There were no transfers of assets between Level 1 and Level 2 during the years ended December 31, 2016 and 2015. Prepaid expenses, accounts payable and accrued expenses are carried at amounts that approximate fair value due to their short-term maturities.

5. Cash, Cash Equivalents and Short-term Investments

The following tables summarize the Company's cash, cash equivalents and short-term investments as of December 31, 2016 and 2015 (in thousands):

December 31, 2016	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$43,930	$ —	$ —	$43,930
Corporate debt securities:				
Due in one year or less	62,505	3	(45)	62,463
Due in two years or less	8,013	—	(18)	7,995
Total	$114,448	$ 3	$ (63)	$114,388
Reported as:				
Cash and cash equivalents	$43,930	$ —	$ —	$43,930
Short-term investments	70,518	3	(63)	70,458
Total	$114,448	$ 3	$ (63)	$114,388

December 31, 2015	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$43,224	$ —	$ —	$43,224
Corporate debt securities:				
Due in one year or less	68,898	—	(107)	68,791
Due in two years or less	14,710	—	(63)	14,647
Total	$126,832	$ —	$ (170)	$126,662
Reported as:				
Cash and cash equivalents	$43,224	$ —	$ —	$43,224
Short-term investments	83,608	—	(170)	83,438
Total	$126,832	$ —	$ (170)	$126,662

At December 31, 2016 and 2015 we held twenty-one and forty-three debt securities that had been in an unrealized loss position for less than 12 months, respectively. The aggregate fair value of these securities was $46.6 million and $81.4 million at December 31, 2016 and 2015, respectively. As of December 31, 2016, we held one security with a fair value of $1.3 million that had been in a continuous unrealized loss position for greater than 12 months. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors, and we considered the decline in market value for the twenty-one debt securities in an unrealized loss for less than 12 months and the one security in an unrealized loss position greater than 12 months as of December 31, 2016 to be primarily attributable to current economic and market conditions. We will likely not be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost bases, which recovery is expected within the next 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of

December 31, 2016 and 2015.

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As of December 31, 2016, we held $11.5 million in financial institution debt securities and other corporate debt securities located in Canada, the United Kingdom, New Zealand, Norway and Sweden. As of December 31, 2015, we held $11.7 million in financial institution debt securities and other corporate debt securities located in Canada, the United Kingdom, and Australia.

We had immaterial realized gains on our short-term investments for the years ended December 31, 2016 and 2015. We had no realized gains or losses on our short-term investments for the year ended December 31, 2014.

6. Property and Equipment

Property and equipment, net as of December 31, 2016 and 2015 follows (in thousands):

	As of December 31,	
	2016	2015
Laboratory equipment	$5,362	$7,270
Furniture	793	712
Computer equipment	208	230
Leasehold improvements	2,829	2,521
Total property and equipment, gross	9,192	10,733
Less: accumulated depreciation	(3,620)	(2,420)
Total property and equipment, net	$5,572	$8,313

We recorded depreciation and amortization expense of $2.2 million, $1.3 million and $0.5 million for the years ended December 31, 2016, 2015, and 2014, respectively. We have $3.7 million of property and equipment, net in the United States and the remaining $1.9 million is located at our clinic accounts in various international regions.

As a result of the restructuring announced in December 2016 (refer to Note 14 for additional details on our restructuring activities), we evaluated our fixed assets for impairment as in December 2016, the time in which the decision was made to execute the restructuring. In performing the recoverability test, we concluded that a substantial portion of the carrying value of our assets were not recoverable. We recorded an impairment charge of $2.0 million related to these assets after comparing the fair value of the fixed assets to their carrying values. We determined the fair value of the assets subject to impairment based on expected future cash flows using Level 3 inputs under ASC 820.

7. Common Stock

In March 2014, we issued and sold in a public offering an aggregate of 5,518,630 shares of our common stock at $10.00 per share, which included 518,630 shares that represented the partial exercise of an overallotment option granted to the underwriters in connection with the offering. The shares included in this offering were registered under the Securities Act of 1933, or the Securities Act, pursuant to a registration statement Form S-3 (File No. 333-190939) that the Securities and Exchange Commission, or SEC, declared effective on September 10, 2013. This public offering resulted in $51.7 million of net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us.

In January 2015, we issued and sold in an underwritten public offering an aggregate of 2,645,000 shares of our common stock at $50.00 per share, which included 345,000 shares that represented the full exercise of an option to purchase additional shares granted to the underwriters in connection with the offering. The shares included in this offering were registered under the Securities Act, pursuant to a registration statement on Form S-3 (File No. 333-200040) that the SEC declared effective on November 21, 2014. The offering resulted in $124.1 million of net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us.

In June 2016, we issued and sold in an underwritten public offering an aggregate of 8,222,500 shares of our common stock at $7.00 per share, which included 1,072,500 shares that represented the full exercise of an option to purchase additional shares granted to the underwriters in connection with the offering. The shares included in this offering were registered under the Securities Act, pursuant to a registration statement on Form S-3 (File No. 333-209778) that the SEC declared effective on May 5, 2016. The offering resulted in $53.9 million of net proceeds, after deducting underwriting discounts and commissions and other offering expenses payable by us.

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

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	December 31, 2016	December 31, 2015
Outstanding stock options	4,611,392	4,650,114
Outstanding restricted stock units	50,000	100,451

8. Stock-Based Compensation

In March 2012, our board of directors and stockholders approved the 2012 Stock Incentive Plan (the "2012 Plan"). The 2012 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock units and other stock-based or cash awards to purchase shares of common stock to eligible employees, officers, directors and consultants. The number of shares of our common stock that are reserved for issuance under the 2012 Plan is equal to the sum of (1) 1,453,253 shares of common stock issuable under the 2012 Plan plus the number of shares of our common stock subject to outstanding awards under the 2011 Stock Incentive Plan (the "2011 Plan"), described below, that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right (up to 679,622 shares) plus (2) an annual increase, to be added on the first day of each year beginning in 2013 and each subsequent anniversary until the expiration of the 2012 Plan, equal to the lowest of 975,000 shares of its common stock, 4.0% of the number of shares of our common stock outstanding on the first day of the year and an amount determined by our board of directors. We began making grants under the 2012 Plan following June 11, 2012, the effective date of our registration of securities on Form 10. Shares issued under the 2012 Plan are funded through the issuance of new shares. We ceased granting options under the 2011 Plan following the effective date of our registration of securities on Form 10.

Founders' stock

For the years ended December 31, 2015 and 2014, 329,021 and 658,060 shares of our Founder's stock vested, respectively. As of December 31, 2015, all shares of Founder's stock were fully vested.

We record stock-based compensation expense for the common stock subject to repurchase based on the grant date intrinsic value for employees and the vesting date intrinsic value for non-employees. All of the restricted shares were issued at fair value. We recognized total stock-based compensation expense of $3.4 million and $7.5 million for the years ended December 31, 2015 and 2014, respectively for the Founders' stock. No stock-based compensation expense for the Founder's shares was recognized for the year ended December 31, 2016 as all shares had vested as of December 31, 2015.

Stock options

A summary of our stock option activity and related information is as follows:

	Shares	Weighted average exercise price per share	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2015	4,650,117	$ 21.49	8.58	$ 2,970
Granted	2,580,600	6.80		
Exercised	(63,986)	3.50		
Forfeited / Canceled	(2,555,339)	19.87		
Outstanding at December 31, 2016	4,611,392	14.42	8.23	45
Exercisable at December 31, 2016	2,201,432	17.71	7.27	45
Vested and expected to vest at December 31, 2016	4,074,825	14.82	8.11	45

The total intrinsic value (the amount by which the fair market value exceeded the exercise price) of stock options exercised was $0.3 million, $6.7 million, and $4.2 million for the years ended December 31, 2016, 2015, and 2014, respectively.

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

We have used the simplified method to calculate the expected term as we do not have sufficient historical exercise and post-vest termination data to provide a reasonable basis upon which to estimate the expected term for the options granted to employees. The remaining contractual term is used for option awards granted to non-employees. Historical data will be incorporated into our assumption as it becomes available.

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The computation of expected volatility is based on a hybrid approach of blending the Company's historical volatility with the historical volatility of a representative group of companies with similar characteristics to ours, including stage of potential fertility treatment development and life science industry focus. The representative group of companies consisted of ANI Pharmaceuticals, Inc., Corcept Therapeutics Inc., Neogenomics Inc., Sangamo Biosciences, Inc., Stem Cells Inc. and Sarepta Therapeutics, Inc. As a result of being an early stage fertility company with limited revenues, the representative group of companies has certain similar, but not all similar, characteristics to ours. We believe the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of ours.

The fair value of each stock option is estimated using the Black-Scholes option pricing model using the following assumptions:

	December 31,		
	2016	2015	2014
Risk-free interest rate	1.3%-2.0%	1.6%-2.3%	1.6% - 2.2%
Dividend yield	—	—	—
Volatility	78%-89%	72%-78%	76% - 84%
Expected term (years)	5.3-9.9	5.3-9.9	5.3 - 10.0

During the year ended December 31, 2016, we granted options to purchase 2,570,600 shares of our common stock with a weighted average exercise price of $6.80 per share at a weighted average grant date fair value of $4.84. During the year ended December 31, 2015, we granted options to purchase 1,744,600 shares of our common stock with a weighted average exercise price of $33.13 per share at a weighted average grant date fair value of $20.87. During the year ended December 31, 2014, we granted options to purchase 2,434,138 shares of our common stock to employees with a weighted average exercise price of $19.19 per share at a weighted average grant date fair value of $13.41.

We recognized total stock-based compensation expense for employee stock option grants of $8.7 million, $14.1 million, and $3.3 million for the years ended December 31, 2016, 2015, and 2014, respectively.

We granted 10,000, 50,500 and 30,000 options to purchase common stock with a weighted average exercise price of $6.96, $36.25 and $13.26 per share to non-employees for the year ended December 31, 2016, 2015 and 2014, respectively. Stock-based awards issued to non-employees are revalued at each reporting date until vested. We recognized total stock-based compensation of $0.1 million, $1.1 million, and $0.8 million for the year ended December 31, 2016, 2015, and 2014, respectively for these non-employee awards.

At December 31, 2016 there was $13.4 million of total unrecognized compensation cost related to non-vested stock options. We expect to recognize these costs over a remaining weighted average period of 2.58 years.

Restricted stock units

A summary of our restricted stock unit activity and related information is as follows:

	Shares	Weighted average grant date fair value
Outstanding at December 31, 2015	112,039	$ 7.44
Granted	300,000	9.04
Vested	(16,250)	9.79
Forfeited	(345,789)	8.76
Outstanding at December 31, 2016	50,000	$ 7.15

We granted restricted stock units (“RSUs”) to Michelle Dipp, M.D., Ph.D., currently our Executive Chair, in December 2014 and 2012. The RSUs issued at each date included a service-based award that vests evenly over eight quarters and a performance-based award that vests in two one-year tranches upon the achievement of certain performance conditions for the respective year, as determined by our board of directors. The grant date fair value of the service-based awards is based on the closing price of our common stock on the award date and the stock-based

compensation expense for these service-based awards are recognized on a straight-line basis over the vesting period. The grant date fair value of the performance-based awards is based on the closing price of our common stock on the date that the performance criteria is established for each

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tranche and communicated to Dr. Dipp and the stock-based compensation for these performance-based awards is recognized over the requisite service period.

The following table summarizes the December 9, 2014 award.

Award Type	Number of RSUs Granted	Grant Date Fair Value	RSUs Vested as of December 31, 2015
Service-based	30,902	$ 32.36	15,450
Performance-based - Year 1	11,588	$ 43.47	4,635
Performance-based - Year 2	11,588	$ —	—

The number of RSUs granted for the 2014 performance award is reflective of the maximum number of RSUs that can be earned, if the board of directors determines the performance criteria were achieved at 150%. On March 29, 2015 our board of directors established the 2015 performance criteria for the first tranche of the performance-based award and communicated the performance criteria to our Chief Executive Officer. The grant date stock price of these performance-based RSUs was $43.47 per share. In December 2015 our board of directors determined that certain of the performance criteria had been met resulting in the partial vesting of the first tranche award.

In January 2016, as part of Dr. Dipp's appointment as our Executive Chair all then outstanding RSUs previously issued to her were canceled, including the second tranche of the performance-based award and the remaining service based RSUs.

For the year ended December 31, 2015, we recognized a total expense of $0.7 million related to the 2014 performance awards of which $0.5 million and $0.2 million were attributable to the service-based and performance-based awards, respectively. For the year ended December 31, 2014, we recognized a total expense of $29,000 related to the 2014 performance awards all attributable to the service-based awards. No expense was recognized for the year ending December 31, 2016 as a result of the cancellation of the awards.

For the December 5, 2012 award, an aggregate of 192,308 RSUs were granted to our Dr. Dipp, 128,205 of which were serviced based and the remaining 64,103 were performance-based. As of December 31, 2014, all RSUs under the December 5, 2012 award were fully vested and expensed. For the year ending December 31, 2014, we recognized a total expense of $0.8 million of which $0.5 million and $0.3 million were attributable to the service-based and performance-based awards, respectively.

On December 3, 2015 we issued a total of 85,000 RSUs to certain senior executives and to a non-employee consultant with a grant date fair value of $9.81. This included 75,000 RSUs with service condition-based vesting as follows: 25% vesting on the first anniversary of the grant date and evenly thereafter until the fourth anniversary of the grant date. The remaining 10,000 RSUs were issued with service condition-based vesting that occurs monthly over 12 months from the grant date until December 3, 2016. During 2016, of the 85,000 RSUs granted, 16,250 vested and the remaining 68,750 service-based RSUs were cancelled. For the year ended December 31, 2016 we recognized $0.3 million in compensation expense related to these awards. We recognized an immaterial amount of total stock-based compensation of for the year ended December 31, 2015 related to these awards.

The total fair value of RSUs that vested during the year was $0.1 million, $0.5 million, and $1.3 million for the year ended December 31, 2016, 2015, and 2014, respectively. As of December 31, 2016, there was $0.2 million of total unrecognized compensation cost related to non-vested service-based RSUs granted under the 2012 Plan. The expense is expected to be recognized over a weighted average period of 3.68 years.

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9. Income Taxes

The expense for income taxes consists of the following (in thousands):

	Year Ended Year ended December 31, 2016	2015	2014
Current:			
Federal	$ —	$ —	$ —
State	18	21	—
Foreign	183	54	—
Total income tax expense	201	75	—

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

	Year Ended Year ended December 31, 2016	2015	2014
Income tax benefit using U.S. federal statutory rate	34.00 %	34.00 %	34.00 %
State income taxes, net of federal benefit	4.86 %	5.23 %	5.28 %
Research and development tax credits	0.90 %	0.83 %	1.75 %
Permanent items - stock based compensation	(2.66)%	(8.15)%	(0.27)%
Foreign differential	(11.03)%	(14.25)%	(1.59)%
Other adjustments	(0.11)%	(0.94)%	(0.31)%
Change in the valuation allowance	(26.21)%	(16.82)%	(38.86)%
	(0.25)%	(0.10)%	— %

The principal components of our deferred tax assets are as follows (in thousands):

	2016	2015
Deferred Tax Assets:		
Net operating loss carryforwards	53,654	36,127
Tax credit carryforwards	3,034	2,296
Accrued expenses	1,737	654
Stock based compensation	7,750	6,472
Intangibles	3,366	3,109
Other	1,181	553
Gross deferred tax assets	70,722	49,211
Valuation allowance	(70,722)	(49,211)
Net deferred tax assets	—	—

We have evaluated the positive and negative evidence bearing upon the realizability of our deferred tax assets. We have considered our history of operating losses and concluded, in accordance with the applicable accounting standards, that it is more likely than not that we will not realize the benefit of our deferred tax assets. Accordingly, our deferred tax assets have been fully reserved at December 31, 2016 and 2015. We reevaluate the positive and negative evidence on a quarterly basis.

The valuation allowance increased approximately $21.5 million during the year ended December 31, 2016, due primarily to the increase in net operating loss carryforwards and tax credits. The valuation allowance increased approximately $12.3 million during the year ended December 31, 2015, due primarily to the increase in the net operating loss carryforwards and tax credits.

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Subject to the limitations described below at December 31, 2016, 2015, and 2014, we had net operating loss carryforwards of approximately $119.8 million, $94.2 million, and $72.1 million, respectively, to offset future federal taxable income, which expire beginning in 2031 continuing through 2036. The federal net operating loss carryforwards include approximately $10.9 million of deductions related to the exercise of stock options. This amount represents an excess tax benefit and has not been included in the gross deferred tax asset reflected for net operating losses. This amount will be recorded as an increase in additional paid in capital on the consolidated balance sheet once the excess benefits are "realized" in accordance with ASC 718. As of December 31, 2016, 2015, and 2014, we had net operating loss carryforwards of approximately $116.9 million, $92.5 million and $71.5 million, respectively, to offset future state taxable income, which expire beginning in 2031 continuing through 2036. The state net operating loss carryforwards include $10.9 million of deductions related to the exercise of stock options. As of December 31, 2016 and 2015, we had net operating loss carryforwards of approximately $59 million and $18.2 million, respectively, to offset future foreign taxable income, which do not expire. As of December 31, 2014, we did not have any net operating loss carryforwards to offset future foreign taxable income. We also had tax credit carryforwards of approximately $3.4 million, $2.6 million, $1.9 million as of December 31, 2016, 2015, and 2014, respectively, to offset future federal and state income taxes, which expire beginning in 2027 continuing through 2036.

The NOL and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on our value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. During 2015, we conducted an IRC Section 382 study. The study resulted in an adjustment to our NOL carryforward of $0.5 million. As a full valuation allowance has been provided against our NOL and tax credit carryforwards, this adjustment was offset by an adjustment to the valuation allowance, and there was no impact to the consolidated balance sheet or consolidated statements of operations. The study was not updated during 2016.

We apply ASC 740, Income Taxes. ASC 740 provides guidance on the accounting for uncertainty in income taxes recognized in financial statements. At December 31, 2016 and 2015, we had no unrecognized tax benefits.

We will recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2016, 2015, and 2014, we had no accrued interest or penalties related to uncertain tax positions and no amounts have been recognized in our consolidated statements of operations.

We file income tax returns in the U.S. Federal, Massachusetts and foreign jurisdictions. The statute of limitations for assessment by the Internal Revenue Service ("IRS") and state tax authorities is open for tax years ended December 31, 2015, 2014 and 2013. Federal and state carryforward attributes that were generated prior to the tax year ended December 31, 2013 may still be adjusted upon examination by the IRS or state tax authorities if they either have been or will be used in a period for which the statute of limitations remains open. The statute of limitations for assessment by the authorities in the various foreign jurisdictions in which we file ranges from one to five years and is open for the tax year ended December 31, 2015 and 2014. There are currently no federal, state or foreign income tax audits in progress.

We have not, as yet, conducted a study of research and development ("R&D") credit carryforwards. Such a study, once undertaken by us, may result in an adjustment to our R&D credit carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against our R&D credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations if an adjustment is required.

10. Commitments and Contingencies

In May 2015, we entered into a lease agreement for approximately 25,200 square feet of office and laboratory space in a building in Waltham, MA. The term of the lease commenced on June 1, 2015 and extends through November 2020, with an optional additional five year term extension. Future non-cancelable minimum annual lease payments under the

lease are expected to be approximately $0.9 million in 2017, $1.0 million for each of the years ending 2018 and 2019, and $0.9 million in 2020. We have provided a security deposit in the form of a letter of credit in the amount of $0.4 million. The letter of credit is cash collateralized, which has been recorded as long-term restricted cash on our consolidated balance sheet.

In connection with this lease, the landlord provided a tenant improvement allowance of up to $1.2 million for the costs associated with the construction of tenant improvements for the leased facility. We account for the allowance received as a lease incentive, which is recorded as a reduction to rent expense over the lease term.

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In December 2016, we entered into a lease agreement for approximately 950 square feet of office space in Oxford, UK that is on a month-to-month basis and cancellable by us or the landlord with one month's written notice.

We maintain office space in Tokyo, Japan under a lease agreement that expires in April 2017. We also maintain lab space in Toronto, Canada under a lease agreement that is cancellable by either us or the landlord with 60 days written notice.

Future minimum lease payments as of December 31, 2016 are as follows (in thousands):

Year	
2017	$986
2018	960
2019	985
2020	924
	$3,855

Rent expense is recorded straight-line over the operating lease term, with deferred rent included on our consolidated balance sheet within other liabilities. Rent expense for the years ended December 31, 2016, 2015, and 2014 amounted to $0.8 million, $0.9 million, and $0.6 million, respectively.

11. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following as of December 31, 2016 and 2015 (in thousands):

	December 31, 2016	December 31, 2015
Compensation and related benefits	$ 5,869	$ 2,237
Development, site costs, and contract manufacturing	524	734
Legal, audit and tax services	1,280	1,540
Consulting	888	813
Other accrued expenses and other current liabilities	2,465	2,567
	$ 11,026	$ 7,891

Other accrued expenses consist of accrued costs related to travel, equipment purchases, lab supplies and other miscellaneous costs.

12. Net Loss Per Share

The following table sets forth the computation of basic and diluted loss per share applicable to common stockholders (in thousands, except per share data):

	Year Ended December 31,		
	2016	2015	2014
Net loss applicable to common stockholders	$(82,260)	$(73,219)	$(49,520)
Weighted average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	32,148	27,085	22,647
Net loss per share applicable to common stockholders—basic and diluted	$(2.56)	$(2.70)	$(2.19)

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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,		
	2016	2015	2014
Outstanding stock options and restricted stock units	4,661	4,751	3,683
Founders' stock	—	—	329
Total	4,661	4,751	4,012

13. Employee Benefit Plan

The Company maintains 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, we may make discretionary contributions as approved by our board of directors. During the years ended December 31, 2016, 2015, and 2014, we made contributions to the 401(k) Plan of $0.4 million, $0.3 million, and $0.2 million, respectively.

14. Restructuring

On December 21, 2016, we announced a reduction in workforce of approximately 30% in connection with our change in corporate strategy, primarily related to the commercialization strategy associated with our AUGMENT treatment. For the year ended December 31, 2016, we recognized restructuring charges totaling $5.4 million related to termination benefits and other related charges, including $1.4 million recorded as a one-time termination benefit, and $1.7 million recorded as a benefit under an ongoing benefit plan. The remaining 2016 restructuring charges relate to a $2.0 million impairment of our fixed assets and $0.4 million of other restructuring related charges. We did not make any cash payments related to this restructuring during the year ending December 31, 2016. As of December 31, 2016, our restructuring accrual was approximately $3.0 million and was recorded in accrued expenses and other current liabilities in our consolidated balance sheet. We expect to incur total costs associated with our restructuring activities of approximately $6.8 million to $8.2 million, with approximately $1.4 million to $2.8 million expected to be recorded in 2017.

The following table outlines our restructuring activities for the year ended December 31, 2016 (in thousands):

Opening balance:	$—
Charges:	
Severance	3,016
Other	390
Payments:	—
Balance at December 31, 2016	$3,406

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Other restructuring costs consist primarily of professional fees including legal fees and contract termination costs.

The $5.4 million of restructuring costs are included in our consolidated statements of operations for the year ended December 31, 2016.

In connection with our restructuring activities but excluded from the $5.4 million of restructuring charges, we identified approximately $0.4 million of excess inventory, which was recorded as costs of revenue in our consolidated statements of operations and comprehensive loss for 2016.

In January 2017, the Compensation Committee of the Board of Directors approved cash and stock option retention incentive awards for certain remaining eligible employees who continue employment with the Company in order to execute the Company’s strategic priorities. Cash awards totaling $0.8 million will be payable to these employees in either July 2017 or January 2018 based on continued employment and services performed during these periods. Stock option awards covering 1,116,000 shares were granted and will vest quarterly over two years from the date of grant.

SUPPLEMENTARY INFORMATION
(Unaudited)

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The following sets forth certain unaudited consolidated quarterly statements of operations data for each of our last eight quarters. In our opinion, this quarterly information reflects all adjustments consistency only of normal recurring adjustments, necessary for a fair statement for the periods presented. Such quarterly results are not necessarily indicative of future results of operations and should be read in conjunction with audited consolidated financial statements and the notes thereto included elsewhere herein.

	Three months Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
	(in thousands, except per share amounts)			
Revenues	$146	$189	$ 197	$ 121
Costs of revenues	1,176	1,233	1,559	1,433
Total operating expenses (excluding restructuring)	20,409	17,197	17,602	15,656
Restructuring charges	—	—	—	5,400
Loss from operations	(21,439)	(18,241)	(18,964)	(22,368)
Net loss	(21,683)	(18,568)	(19,291)	(22,644)
Net loss per share—basic and diluted	$(0.80)	$(0.62)	$ (0.54)	$ (0.64)
Weighted average number of common shares used in net loss per share—basic and diluted	27,301	30,036	35,568	35,612

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	Three months Ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
	(in thousands, except per share amounts)			
Revenues	$15	$30	$ 75	$ 157
Cost of revenues	35	116	940	1,158
Total operating expenses	$16,828	$17,204	$ 17,847	$ 20,397
Loss from operations	(16,813)	(17,174)	(17,772)	(20,240)
Net loss	(17,206)	(17,490)	(17,922)	(20,601)
Net loss per share—basic and diluted	$(0.65)	$(0.64)	$ (0.66)	$ (0.76)
Weighted average number of common shares used in net loss per share—basic and diluted	26,588	27,198	27,267	27,280

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